United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA738-R-98-019
November 1998

Reregistration Eligibility Decision (RED)

IPRODIONE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Iprodione which includes the active ingredients [enter chemical names here]. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998 contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations

will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Frank Rubis at (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Dennis Deziel at (703) 380-8173.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Iprodione

LIST B

CASE 2335

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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2335 REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Alan Halvorson	Economic Analysis Branch
Leo Lasota	Biological Analysis Branch

Environmental Fate and Effects Risk Assessment

Dana Spatz	Environmental Risk Branch 4
Jose Melendez	Environmental Risk Branch 4
Ann Stavola	Environmental Risk Branch 4
Sid Abel	Environmental Fate and Monitoring Branch

Health Effects Risk Assessment

Christina Scheltema	Risk Characterization and Analysis Branch
William Smith	Chemistry and Exposure Branch 1
Kelly O'Rourke	Occupational and Residential Exposure Branch
Linda Taylor	Reregistration Action Branch 2
Jerome Blondell	Chemistry and Exposure Branch 2

Registration Support Risk Assessment

Carl Grable	Fungicide-Herbicide Branch

Risk Management

Dennis Deziel	Reregistration Branch 1

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision (RED) of the pesticide iprodione. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products.

Iprodione is a contact and/or locally systemic fungicide registered for use on a variety of field, fruit, and vegetable crops. These end-use patterns for the current formulations have been classified for outdoor use only, and applications include aircraft (fixed-wing and helicopter), airblast sprayer, chemigation, groundboom, drench, in furrow spray planter, high- and low-pressure handwand, backpack sprayer, tractor-drawn spreader, push-type lawn spreader, and garden hose-end sprayer. It is formulated as a liquid, dry flowable, wettable powder, and granular. Rhone-Poulenc, Inc., is supporting the reregistration of iprodione.

The Agency has concluded that most uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment, subject to conditions imposed in this RED. Based on cancer risk concerns, the Agency has determined that iprodione residential uses on turf, ornamentals and vegetable/small fruit gardens are ineligible for reregistration. The registrant, Rhone-Poulenc, has requested to voluntary cancelation of all residential uses of iprodione. Furthermore, Rhone Poulenc has requested to voluntary cancelation of the application of iprodione using a belly grinder, which posed an unacceptable risk to handlers.

In addition, to reduce acute dietary risk and dietary cancer risk concerns posed by the use of iprodione, Rhone-Poulenc has voluntarily agreed to a number of risk mitigation measures: (1) increase the pre-harvest interval on all stone fruit uses from 7-days to up to but no later than petal fall; (2) increase the pre-harvest interval for strawberry uses from 0-days to up to but no later than first flower; and, (3) reduce the number of applications of iprodione on table grapes (includes grapes for juice and raisins, but *not* wine and sherry grapes) from four applications per season to one application early- to mid-bloom. Also, the tolerance for iprodione on all stone fruit and strawberries will be reduced to the limit of quantitation (0.05 ppm).

With these risk mitigation measures in place, the acute dietary risk from iprodione is within the range the Agency considers acceptable (MOE = 351), as is the aggregate cancer risk (1.8×10^{-6}).

The Agency found that the toxicity data base for iprodione is complete, based on current requirements. The Agency has concluded that iprodione is a B2, or "likely" carcinogen. In reaching the determination of safety for infants and children as mandated by the Food Quality and Protection Act (FQPA), the Agency has concluded that the FQPA safety factor will be applied for: 1) acute dietary risk assessment of females 13+ because the toxicology endpoint is based on an *in utero* effect; 2) for a chronic dietary risk assessment for the general population including infants and children because the endpoint is based on male reproductive toxicity; and, 3) for residential exposure risk assessments for the general

population including infants and children since the use pattern indicate potential exposure by all population subgroups.

In examining aggregate exposure, FQPA directs the Agency to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. Estimated average concentrations of iprodione in ground water are not currently available for comparison against drinking water level of concern values; however, based on iprodione's physical/chemical characteristics and available, but limited, monitoring data, iprodione is not expected to significantly impact ground water, and is expected to be below the Agency's level of concern for surface water. However, iprodione is a B2 carcinogen with both residential and food uses. The aggregate cancer risk estimate, before risk mitigation, exceeds the Agency's threshold target/goal of 10^{-6} for a number of dietary/residential scenarios. In order to be reregistered, all residential uses must be removed from iprodione product labels (see above).

The Agency does not have, at this time, available data to determine whether iprodione has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this reregistration decision, the Agency has not assumed that iprodione has a common mechanism of toxicity with other substances.

Because of potential effect to non-target organisms in ecological systems from iprodione, the Agency is including additional label warnings for iprodione manufacturing and end-use products. These mitigation measures include a 25-foot vegetative buffer strip for application of iprodione adjacent to water bodies, and a limit for the maximum number of applications on turf, lawn, golf course, ornamental trees and plants from an "unlimited" unspecified number of applications to a maximum to 6 per year.

Before reregistering the products containing iprodione, the Agency is requiring that product specific data, revised Confidential Statement of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "EPA" or the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality and Protection Act of 1996 (FQPA) (Public Law 104-170) was signed. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*. The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency will, therefore, continue its ongoing reregistration program while it determines how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of iprodione . The document consists of six sections. Section I is the introduction. Section II describes iprodione, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for iprodione . Section V discusses the reregistration requirements for iprodione. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

!	**Common Name:**	Iprodione
!	**Chemical Name:**	[3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide]
!	**Chemical Family:**	imide
!	**CAS Registry Number:**	36734-19-7
!	**OPP Chemical Code:**	109801
!	**Empirical Formula:**	$C_{13}H_{13}Cl_2N_3O_3$
!	**Trade and Other Names:**	Chipco Rovral Kidan
!	**Basic Manufacturer:**	Rhone-Poulenc

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of iprodione is in Appendix A. Due to the length of Appendix A (over 100 pages), copies are available separately upon request per the instructions in Appendix E.

For iprodione:

Type of Pesticide: fungicide

Use Sites:

- *Agricultural Crops*, including almonds, apricots, cherries, nectarines, peaches, pecans, plums, prunes, beans (dried, lima, and snap), blackberries, blueberries, broccoli, bushberries, caneberries, carrots, garlic, grapes, ginseng,

gooseberries, huckleberries, lettuce (head and leaf), loganberries, mustard cabbage, Chinese cabbage, dry bulb onions, peanuts, potatoes, raspberries, and strawberries.

- *Ornamentals*, including flowering trees and shrubs, woody shrubs and vines, evergreens, flowering and nonflowering plants, ground covers and shade trees.

- *Turfgrass*, including sod farms, golf courses and institutional lawn areas of bentgrass, blue grass, Bermuda grass, St. Augustine grass, rye grass, fine fescue or tall fescue.

- *Fruit/Nut Trees*, including almonds, apricots, cherries, nectarines, peaches, and plums**.**

- *Small Fruit/Vegetable Garden Crops*, including beans (dried, lima, and snap), blackberries, blueberries, broccoli, bushberries, caneberries, carrots, garlic, grapes, ginseng, gooseberries, huckleberries, lettuce (head and leaf), loganberries, mustard cabbage, Chinese cabbage, dry bulb onions, peanuts, potatoes, raspberries, and strawberries.

- *Ornamentals at Residences*, including shade trees, evergreens and flowering and non-flowering shrubs.

- *Turfgrass*, including residential lawn areas.

Target Pests:

Type of fungi that iprodione is used to prevent, treat, and control include (but are not limited to) the following (USEPA 1997c):

- Dollar spot (*Lanzia* spp. and *Moellerodiscus* spp.), Brown patch *(Rhizoctonia solani*), Leaf spot and Melting out (*Drechslera* spp.) , Fusarium blight (*Fusarium* spp.), Gray snow mold (*Typhula* spp.) and Pink snow mold (*Fusarium nivale*), Corticum red thread (*Laetisaria fuciformis*) on turfgrass;

- Aerial web blight (*Rhizoctonia* sp.), Alternaria leaf blight (*Alternaria zinniae*), Botrytis blight (*Botrytis* sp.), Ink spot (*Drechslera iridis*), Ray blight (*Ascochyta chrysanthami*), Tulip fire (*Botrytis tulipae*), and Fusarium corn rot (*Fusarium oxysporum*) on ornamentals;

- Sclerotinia blight (*Sclerotinia minor*) on peanuts;

- Sheath blight (*Rhizoctonia solani*), Brown spot (*Bipolaris oryzai*), Sheath spot (*Rhizoctonia oryzae*) and Narrow brown leaf spot (*Cercospora oryzae*) on rice;

- Brown rot blossom blight (*Monilinia* spp.), Fruit brown rot (*Monilinia* spp.), Shot hole (*Stigmina carpophila*), Scab (*Ventura carpophila*), and Cherry leaf spot (*Blumeriella jaapii*) on stone fruit;

- Bunch rot (*Botrytis cinerea*) on grapes;

- Gray mold (*Botrytis cinerea*), White mold (*Sclerotinia sclerotiorum*) on beans, Black leg (*Leptosphaeria maculans*) on broccoli, Alternaria blight (*Alternaria dauci*) and Black crown rot (*Alternaria radicina*) on carrots, White rot (*Sclerotium cepivorum*) on garlic, Lettuce drop (*Sclerotinia* spp.) and Brown rot (*Rhizoctonia solani*) on lettuce, and Early blight (*Alaternaria solani*) and White mold (*Sclerotinia sclerotiorum*) on potatoes.

Formulation Types Registered:

- TECHNICAL GRADE ACTIVE INGREDIENT: 95 percent;
- Liquid soluble concentrate (14 and 41.6 percent active ingredient);
- Wettable powder (33.3 and 50 percent active ingredient);
- Dry flowable (50 percent active ingredient);
- Flowable concentrate (41.6 percent active ingredient);
- Emulsifiable concentrate (19.65, 23.3, and 50 percent active ingredient);
- Granular (1.02 and 1.3 percent active ingredient).

Method and Rates of Application:

Application Rates:

- *Commercial Agricultural Crops:* The maximum application rate for commercial crops ranges from 0.5 lb ai/acre to 1.0 lb ai/acre for all application methods.

- *Commercial Ornamentals:* The maximum application rate for pre-planting and cold storage dip treatments ranges from 0.005 to 0.01 lb ai/gallon. The maximum application rate for other application methods applicable to greenhouse treatments range from 0.002 to 0.01 lb ai/gallon. The maximum rates for field nursery application range from 1.4 to 4 lb ai/acre.

- *Commercial/Residential Turfgrass:* Using granular, dry flowable and liquid formulations, the maximum application rate applied to sod farms, golf courses and institutional and residential lawns ranged from 1.4 to 5.5 lb ai/acre.

Granular formulations are to be applied using a light rate (1.4 lb ai/acre) to prevent certain fungi such as pink or gray snow mold or leaf spot. A normal (2.7 lb ai/acre) to heavy application rate (4.1 lb ai/acre) is recommended to control fungi such as leaf spot, brown patch and red leaf spot (EPA Reg. No. 538-159).

- *Residential Fruit and Nut Trees:* The maximum application rates range from 0.0013 to 0.0026 lb ai/gallon for foliar spray to fruit/nut trees.

- *Residential Fruit/Vegetable Garden Crops*: The maximum application rate ranges from 0.0052 to 0.104 lb ai/gallon.

- *Ornamentals at Residences:* The maximum application rates vary from 0.002 to 0.01 lb ai/gallon.

Methods and Types of Equipment used for Mixing, Loading, and Application:

- *Commercial Agricultural Crops:* Equipment includes aircraft (fixed-wing and helicopter), airblast sprayer for orchards, chemigation, groundboom, drench, in furrow spray planter, and high pressure handwand. Seeds can be treated in slurry form or in a seed soaker. Additionally, a dip treatment may be used before cold storage or as a pre-planting preventive measure on strawberries.

- *Commercial Ornamentals:* Equipment used on nursery and green house stock includes high pressure handwand, low pressure handwand, backpack sprayer, chemigation systems, groundboom spray, drench and low pressure/high volume handgun. Additionally, a dip treatment may be used before cold storage or as a pre-planting preventive measure on certain ornamental stock, including roses, gladiolus and azaleas.

- *Commercial/Residential Turfgrass:* Granular application to turfgrass areas involves the use of a tractor-drawn spreader, belly grinder, push type lawn spreader, or hand application of granules for spot treatment. Liquid and wettable powder formulations can be applied to turfgrass sod farms, using chemigation systems, aircraft (fixed-wing or helicopter), groundbooms, low pressure/high volume handguns, low pressure handwands, high pressure handwands, and backpack sprayers. These same formulations can be applied to other turf areas such as institutional areas, golf courses and residential lawns.

- *Residential Fruit and Nut Trees:* Equipment for residential application includes backpack sprayers, low pressure handwands, and garden hose-end sprayers.

- *Residential Fruit/Vegetable Garden Crops:* Equipment for residential application includes low pressure handwands, backpack sprayers, garden hose-end sprayers. Other possible application methods include dipping for cold storage or pre planting and seed soaking.

- *Ornamentals at Residences:* Ornamentals may be treated using a low pressure handwand, backpack sprayer, or a garden hose-end sprayer.

Table 1. Main Application Methods for Iprodione

Crop	Application Rate (lbs)	Number of Applications	Application Interval (days)	Main Application Method
Peanuts	1	3	14	Ground
Almonds	0.5	4	14	Air
Grapes	1	4	14	Ground
Peaches	1	4	7	Air
Potatoes	1	4	10	Air
Onions	0.75	5	7	Air
Strawberries	1	4	10	Ground
Cotton	0.15	1	NA	Ground
Turf - South	5.45	26	14	Ground
Turf - North	5.45	13	14	Ground

Timing and Frequency of Applications:

- *Commercial Agricultural Crops:* The maximum number of applications per season applied to commercial agricultural crops ranges from 1 (e.g., dip, in furrow spray at planting, post harvest spray to fruit, and seed soak or treatment) to 10 per season for crops such as carrots, dry bulb onions, and strawberries. Typically, the applications made 10 times per season (e.g., strawberries) are applied using one half the application rate of that for sites where the maximum number of applications is 4 times per year. Application intervals range from 7-21 days.

- *Commercial Ornamentals:* Foliar spray applications to ornamental crops can be sprayed to runoff at 7-14 day intervals for an unspecified maximum number of applications per season. Dip treatments to bare root roses, cuttings prior to planting, and corns prior to storage are applied only once per season. Drench treatments at seeding and/or after transplanting can be made at 14 day intervals.

- *Commercial/Residential Turfgrass:* Iprodione labels state that applications to turfgrass may be made at 7-30 day intervals an unspecified number of times per season, or as stated on some labels "as required"(e.g., EPA Reg. No. 264-562) .

- *Residential Fruit and Nut Trees:* Iprodione labels call for a maximum of 5 applications per season at intervals of 7-14 days for stone fruit trees (e.g. apricots, nectarines, cherries, peaches, plums and prunes). A maximum of 4 applications per year can be made to almond trees at pink bud and if conditions are favorable for disease development, up to 3 subsequent applications can be made at: 1) full bloom, 2) petal fall, and 3) up to 5 weeks after petal fall.

- *Residential Fruit/Vegetable Garden Crops:* A maximum of 10 applications can be made to strawberries and dry bulb onions at 7-14 day intervals. The maximum number of applications per season for other vegetables ranges from 2 (e.g., broccoli and beans) to 4 (e.g., potatoes, carrots and caneberries), all applied at 7-14 day intervals.

- *Ornamentals at Residences:* Residential rate frequency and application intervals are the same as for commercial ornamental applications.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of iprodione. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

An estimated 930,000 to 1,730,000 pounds a.i. of iprodione are applied annually in the U.S., with usage appearing to be fairly stable over the past few years. Much of this usage is in agriculture. Applications include about 75,000 to 205,000 pounds a.i. to almonds, 80,000 to 125,000 pounds a.i. to grapes, 50,000 to 65,000 to peaches, 55,000 to 215,000 pounds a.i. to potatoes and 65,000 to 145,000 pounds a.i. to rice. These five crops account for about 35 to 44 percent of the total pounds a.i. applied. Other sites treated include berries, carrots, golf courses, lawns, lettuce, ornamentals, onions, peanuts, pistachios and other stone fruit.

Crops with the highest percentage of acreage treated are apricots (70-85%), raspberries (45-57%), almonds (30-60%), strawberries (32-50%) and carrots (17-50%).

Table 2. Iprodione Major Use Information

Crop	Pounds Iprodione per Year
Almonds	75,000 to 205,000
Grapes	80,000 to 125,000
Peaches	50,000 to 65,000
Potatoes	55,000 to 215,000
Rice	65,000 to 145,000

D. Data Requirements

Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Iprodione was registered in the United States in 1979 for use as a fungicide. A Data Call-In was issued in September 1991 for iprodione. The iprodione Phase 4 Review dated 3/15/91 required additional generic and product-specific product chemistry data for the Rhone-Poulenc 95% T/TGAI. Data submitted concerning GLNs 63-7 and 63-9 (OPPTS 830.7300 and 830.7950) were found to be adequate for Phase 5 review; Rhone-Poulenc committed to conduct new studies concerning the remaining guideline requirements.

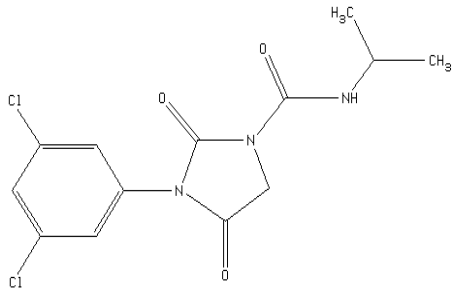
Adequate data concerning the potential for formation of polyhalogenated dibenzo-p-dioxins and/or polyhalogenated dibenzofurans during the manufacture of iprodione have been submitted. The Agency has concluded that reaction conditions are not favorable to dioxin/dibenzofuran formation, and that trichlorophenols (TCDD precursor), tetrachlorophenols, or other highly chlorinated impurities are not probable impurities.

This reregistration eligibility decision reflects a reassessment of all data which were submitted in response to the Data Call-In. Prior to completion of this RED document, Rhone-Poulenc requested changes to its iprodione product registrations to mitigate unacceptable dietary, worker, and ecological risk.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

Iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide] is a contact and/or locally systemic fungicide registered for use on a variety of field, fruit, and vegetable crops.



Empirical Formula:	$C_{13}H_{13}Cl_2N_3O_3$
Molecular Weight:	330.17
CAS Registry No.:	36734-19-7
Shaughnessy No.:	109801

Iprodione is a white odorless crystalline solid with a melting point of ~128 C. Iprodione is soluble in dichloromethane (45 g/100 mL), acetone (34 g/100 mL), ethyl acetate (23 g/100 mL), acetonitrile (17 g/100 mL), and toluene (15 g/100 mL), but is practically insoluble in water (13 mg/L). Iprodione is stable under normal storage conditions.

B. Human Risk Assessment

1. Hazard Assessment

a. Toxicology Database

There are no data gaps for the standard Subdivision F Guideline requirements for a food-use chemical by 40 CFR Part 158. However, the Agency has concluded that an assessment of effects on the male reproductive system following pre and/or postnatal exposure is required and these aspects can be addressed by conducting the study as described in OPPTS 870.3800.

b. Acute Toxicity

Sufficient data are available on the acute toxicity of iprodione. Iprodione is not acutely toxic via the oral, dermal, inhalation, or ocular routes of exposure. Acute toxicity values and categories for technical are summarized in Table 3.

Table 3. Acute Toxicity of Technical Iprodione

Guideline	Study Type	MRID #	Results	Toxicity Category
81-1	Acute Oral - rat	42306301	LD_{50} = 4468 mg/kg	III
81-2	Acute Dermal - rabbit	40567601	LD_{50} > 2000 mg/kg	III
81-3	Acute Inhalation - rat	42946101	LC_{50} = > 5.16 mg/L	IV
81-4	Primary Eye Irritation - rabbit	41867301	mild irritant	III
81-5	Primary Skin Irritation - rabbit	41867302	not an irritant	IV
81-6	Dermal Sensitization - guinea pig	40567602 42524601	not a dermal sensitizer	-

In an acute oral toxicity study with rats, the LD_{50} was 4468 mg/kg, which is toxicity category III [Guideline 81-1; MRID 42306301]. The LD_{50} in an acute dermal toxicity study with rabbits was found to be greater than 2000 mg/kg. This is toxicity category III [Guideline 81-2; MRID 40567601]. In an acute inhalation toxicity study with rats, the LC_{50} was greater than 5.16 mg/L for 4 hours. This is toxicity category IV [Guideline 81-3; MRID 42946101].

In a primary eye irritation study with rabbits, iprodione was a mild ocular irritant. This is toxicity category III [Guideline 81-4; MRID 41867301]. Iprodione did not induce irritation in a primary dermal irritation study in rabbits. This is toxicity category IV [Guideline 81-5; MRID 41867302].

In a dermal sensitization study in guinea pigs, iprodione was not found to be a dermal sensitizer [Guideline 81-6; MRID 40567602, 42524601].

c. Subchronic Toxicity

Sufficient data are available on the subchronic toxicity of iprodione. In a 21-day dermal toxicity study, five New Zealand rabbits/sex/group were administered iprodione [96.2%] via the skin at dose levels of 0, 100, 500, and 1000 mg/kg/day for 21 days. There were no deaths or clinical signs of toxicity, and no adverse effects were observed on body weight, food consumption, the skin, liver, or kidneys. The NOEL is $\geq$ 1000 mg/kg/day, the highest dose tested [Guideline §82-2; MRID 42023201].

In a subchronic feeding study, 10 Crl:CD(SD)BR rats/sex/group were administered iprodione [95.7%] via the diet at dose levels of 0, 1000 ppm [♂♂ 78/♀♀ 89 mg/kg/day], 2000 ppm [♂♂ 151/♀♀ 189 mg/kg/day], 3000 ppm [♂♂ 252/♀♀ 266 mg/kg/day], and 5000 ppm [♂♂ 355/♀♀ 408 mg/kg/day] for 90 days. Signs of toxicity included hunched posture, pilo-erection, pale and/or cold extremities, an emaciated appearance, decreased body weight [♂♂ 75%, 52%, and 39% of control/♀♀ 86%, 70%, and 55% of control at the 2000, 3000, and 5000 ppm dose levels, respectively], decreased body-weight gain [♂♂ 61% and 26% of control/♀♀ 70% and 38% of control at the 2000 and 3000 ppm dose levels, respectively], negative body-weight gain for both sexes at 5000 ppm, decreased food consumption [81% of control for 2000 ppm males; 69%/79% of control for males/females at 3000 ppm], and decreased food efficiency for both sexes at 2000 and 3000 ppm. The 5000 ppm dose group was terminated early [week 8]. The sex organs, pituitary, and adrenals of both sexes appear to be target organs for iprodione. In general, the decreases observed in organ weights and the accompanying increases in relative organ weights may be attributed to the decreased body weight, but in females, decreased relative organ weights were observed in the uterus, ovary, adrenal, and pituitary, mainly at the high [3000 ppm] dose. These latter decreases and the decrease in absolute brain weight in females appear to be treatment-related. Dose-related microscopic lesions were observed in the sex organs and adrenals of both sexes at the 2000, 3000, and 5000 ppm dose levels. The NOEL is 1000 ppm [♂♂ 78/♀♀ 89 mg/kg/day], and the LOEL is 2000 ppm [♂♂ 151/♀♀ 184 mg/kg/day], based on decreased body weight/gain, decreased food consumption/ food utilization, organ weight effects, and microscopic lesions in the sex organs. This study is classified Acceptable, although clinical chemistry and hematology parameters were not monitored. This study was performed to determine appropriate dose levels for the 2-year chronic toxicity/ carcinogenicity study in rats, and these parameters were monitored in the long-term study. Therefore, an additional subchronic feeding study in rats is not required [Guideline §82-1(a); MRID 42960701].

In a subchronic feeding study, 2 Beagle dogs/sex/group were administered iprodione [technical] via the diet at dose levels of 0, 800 ppm [≈60 mg/kg/day], 2400 ppm [≈ 180 mg/kg/day], and 7200 ppm [≈ 270 mg/kg/day] for 90 days [standard conversion of 0.075 used]. There were no deaths. One high-dose dog displayed general fatigue with muscular atony from week 5 to 13. Body weights were comparable among the groups in both sexes. High-dose dogs displayed a slight anemia during the study, as well as increased alkaline phosphatase and transaminase [SGOT, SGPT] values compared to the controls. There were no effects reported in clinical chemistry and urinalysis. At necropsy, both females and one male at the high dose displayed slight liver hypertrophy and the other male displayed a pale liver, in addition to anemia and hypertrophy of the prostate and testes. No treatment-related microscopic lesions were observed. The NOEL is 2400 ppm [≈180 mg/kg/day], and the LOEL is 7200 ppm [≈270 mg/kg/day], based on liver hypertrophy and increased alkaline phosphatase. This subchronic feeding study in dogs is classified Unacceptable, but there is an acceptable chronic toxicity study in dogs; therefore, an additional subchronic study is not required [Guideline §82-1(b); MRID 00157377, MRID 00157378, MRID 00232702].

d. Chronic Toxicity and Carcinogenicity

Sufficient data are available to assess the chronic toxicity and carcinogenic potential of iprodione. Iprodione has been classified as a Group B2 carcinogen, based on evidence of tumors in both sexes of mouse [liver] and in the male rat [Leydig cell]. For the purpose of risk characterization, a low dose extrapolation model was applied to the animal data for quantification of human risk [Q^*_1 = ♂♂ 8.7 x 10^{-3}/♀♀ 5.07 x 10^{-3} combined hepatocellular adenoma/ carcinoma (mouse) and ♂♂ 4.39 x 10^{-2} testicular tumors (rat)].

(1) Combined Chronic Toxicity/Carcinogenicity Study in Rats

In the combined chronic toxicity/carcinogenicity study in rats, iprodione [≈95% a.i.] was administered to 60 Sprague-Dawley rats/ sex/dose via the diet at dose levels of 0, 150, 300, and 1600 ppm [♂♂ 6.1, 12.4, and 69/♀♀ 8.4, 16.5, 95 mg/kg/day, respectively] for 24 months. An additional 10 rats/sex/group were administered iprodione for 52 weeks [interim sacrifice].

There were no adverse effects on survival or clinical signs in either sex. Body-weight gains were decreased in both sexes at the high-dose level compared to the controls and overall, body-weight gains were 86% and 92% of control values in the high-dose males and females, respectively. At week 12, body-weight gain was 83.6% of the control in males and 80.7% of the control in females at the high-dose level. Food consumption was decreased slightly at this dose level in both sexes also. There were no treatment-related clinical pathology findings in either sex. At the interim sacrifice, high-dose males displayed an increase in the incidence of lesions in the adrenals, and there was an increased incidence of centrilobular hepatocyte enlargement in mid- and high-dose males. High-dose females displayed an increase in centrilobular hepatocyte enlargement and an increase in the incidence

of generalized rarefaction and fine vacuolation of the zone fasciculata in the adrenals compared to the control and other dose groups. At the terminal sacrifice, increased liver weight [absolute and relative-to-body] was observed in males at the mid- and high-dose levels [dose-related]. At the high-dose level in males, testes with epididymides and thyroid weights [absolute and relative-to-body] were increased at the terminal sacrifice. At the terminal sacrifice, interstitial cell hyperplasia in the testes, reduced spermatozoa in the epididymides, and absent/empty secretory colloid cells or reduced secretion in the seminal vesicles were observed in the mid- and high-dose males. Atrophy of the seminiferous tubules in the testes, with atrophy of the prostate and absence of spermatozoa in the epididymides were observed at the high-dose level. Centrilobular hepatocyte enlargement was increased in males at the high-dose level. Adrenal lesions were observed in both sexes at the mid- and high-dose levels, although the males displayed more lesions than the females. There was an increased incidence of tubular hyperplasia in the ovaries and increased sciatic nerve fiber degeneration in the high-dose females compared to the controls. Hemosiderosis was increased in females at the mid- and high-dose levels. The NOEL for non-neoplastic changes is 150 ppm [♂♂ 6.1/♀♀ 8.4 mg/kg/day], and the LOEL is 300 ppm [♂♂ 12.4/♀♀ 16.5 mg/kg/day], based on increases in generalized enlargement of the cells of the zona glomerulosa in males and females, in fine vacuolation of the zona fasciculata and in generalized fine vacuolation of the zone reticularis in males in the adrenal cortex, an increased incidence of interstitial cell hyperplasia, reduced spermatozoa in the epididymides, reduced secretion of the seminal vesicles, increased hemosiderosis in the spleen in females, and increased liver weight.

There was an increase in the incidence of both unilateral and bilateral benign interstitial cell tumors in the testes of males at the 1600 ppm dose level. There was a dose-related increasing trend and a significant difference in the pairwise comparison of the 1600 ppm dose group with controls for testicular tumors, which exceeds the historical control incidence [Guideline §83-5; MRID 42637801; MRID 42787001].

In an earlier chronic toxicity/carcinogenicity study in Charles River CD outbred albino rats, no treatment-related tumors were reported, although the incidence of testicular interstitial cell tumors was 2, 2, 4, and 5 out of 60 rats/group at dose levels of 0, 125 ppm [≈6.25 mg/kg/day], 250 ppm [≈12.5 mg/kg/day], and 1000 ppm [≈50 mg/kg/day], respectively [using standard conversion factor of 0.05]. This study is classified Unacceptable, but it was replaced by the study cited above [Guideline §83-5; MRID 00071997; MRID 00128931; MRID 001164249].

(2) Chronic Toxicity Study in Dogs

In a chronic feeding study, 6 Beagle dogs/sex/group were administered iprodione [86.5%] via the diet at dose levels of 0, 100 ppm [♂♂ 4.1/♀♀ 4.3 mg/kg/day], 600 ppm [♂♂ 24.9/♀♀ 28.3 mg/kg/day], and 3600 ppm [♂♂ 145.3/♀♀ 152.5 mg/kg/day] for 12 months. There were no treatment-related deaths, and no adverse effects were observed on body weight, food consumption, or clinical signs in either sex. At the high-dose level, there were increases in absolute and relative liver weight, alkaline phosphatase, SGOT, SGPT and LDH enzyme levels, and increased absolute and relative adrenal weights [both sexes]. At the mid- and high-dose levels, males displayed an increased number of erythrocytes with Heinz bodies

and decreased prostate weights. The NOEL is 100 ppm [♂♂ 4.1/♀♀ 4.3 mg/kg/day], and the LOEL is 600 ppm [♂♂ 24.9/♀♀ 28.3 mg/kg/day], based on decreased prostate weight and an increased incidence of erythrocytes with Heinz bodies [Guideline §83-1(b); MRID 00144391; MRID 41327001].

In a second chronic feeding study designed to complement the study cited above, 6 Beagle dogs/sex/group were administered iprodione [96.1%] via the diet at dose levels of 0, 200 ppm [♂♂ 7.8/♀♀ 9.1 mg/kg/day], 300 ppm [♂♂ 12.4/♀♀ 13.1 mg/kg/day], 400 ppm [♂♂ 17.5/♀♀ 18.4], and 600 ppm [♂♂ 24.6/♀♀ 26.4 mg/kg/day] for 12 months. There were no treatment-related deaths, and no adverse effects were observed on clinical signs, body weight/gain, and food consumption in either sex. At the high-dose level, decreases were observed in the red blood cell parameters [hemoglobin, hematocrit, and red blood cells]. The NOEL for systemic toxicity is 400 ppm [♂♂ 17.5/♀♀ 18.4 mg/kg/day], and the LOEL is 600 ppm [♂♂ 24.6/♀♀ 26.4 mg/kg/day], based on decreased red blood cell values. This nonguideline study is classified Acceptable. When both chronic dog studies are considered together, the NOEL is 400 ppm [≈18 mg/kg/day] [Guideline §83-1(b); MRID 42211101].

(3) Carcinogenicity Study in Mice

In a carcinogenicity study, iprodione [95.7% a.i.] was administered in the diet to 50 Crl: CD-1 (ICR) BR mice/sex/dose for 99 weeks at dose levels of 0, 160 ppm [♂♂ 23/♀♀ 27 mg/kg/day], 800 ppm [♂♂ 115/♀♀ 138 mg/kg/day], and 4000 ppm [♂♂ 604/♀♀ 793 mg/kg/day]. There was an interim sacrifice group of 15 mice/sex/group.

The statistical evaluation of mortality indicated no significant incremental changes with increasing dose in either sex, although the high-dose group displayed the highest mortality rate for both sexes. Food consumption and clinical signs were comparable among the groups for both sexes. Decreased body- weight gains [overall gain ♂♂ 86%/♀♀ 89% of control] were observed in both sexes at the highest dose level. There was an increase in the incidence of liver tumors in both sexes at the high-dose level, which was accompanied by increases in several liver lesions [centrilobular hepatocyte enlargement/ vacuolation, area(s) of enlarged eosinophilic hepatocytes, pigmented macrophages, centrilobular necrosis, and amyloid deposits]. SGOT and SGPT levels were elevated at the high-dose level in both sexes compared to the controls at the interim sacrifice [only time examined for these enzymes]. Liver weight was increased at the high-dose level in both sexes at both the interim and terminal sacrifices. There was an increase in the incidence of benign ovarian tumors [luteoma] in females at the high dose compared to the control incidence, which was accompanied by an increase in luteinization of the interstitial cells, corpora lutea absent, and prominent granulosa cells. There was also an increased incidence of generalized vacuolation/hypertrophy of the interstitial cells of the testes in the mid- and high-dose males compared to the controls. Dosing was considered adequate, based on an overall decrease in body-weight gain [♂♂ 86%/♀♀ 89% of control]. The LOEL is 800 ppm [♂♂ 115/♀♀ 138 mg/kg/day], based on the increased incidence of centrilobular hepatocyte enlargement in females and the increased incidence of generalized vacuolation/hypertrophy of the interstitial cells in the testes of males. The NOEL is 160 ppm [♂♂ 23/♀♀ 27 mg/kg/day] [Guideline §83-2; MRID 42825002].

In a previous chronic toxicity/carcinogenicity study in Carworth CF-1 albino mice, iprodione was negative for carcinogenicity. The dose levels were 200 ppm [≈30 mg/kg/day],

500 ppm [≈75 mg/kg/day], and 1250 ppm [≈187.5 mg/kg/day] (using standard conversion factor of 0.15), and the duration was 18 months. Only one ovarian tumor [malignant] was reported [mid dose], and the incidence of liver tumors was as follows:

Table 4. Liver Tumors (# with Tumor, # mice examined)

Sex	Dose/Tumor Type	Benign	Malignant
Males	0	0/60	2/60
	200	2/59	0/59
	500	0/60	4/60
	1250	2/59	5/59
Females	0	0/60	0/60
	200	0/60	0/60
	500	1/58	2/58
	1250	0/59	1/59

This study is classified unacceptable, but in has been replaced by the study cited above [Guideline §83-2; MRID 00070963].

(4) Studies on Carcinogenicity Mechanism of Action

Several mechanistic studies on iprodione are available. These were submitted in support of the premise that both the liver and testicular tumors are threshold phenomena.

TESTES

In an in vitro study using immature porcine cultured Leydig cells, iprodione [99.7%] and two of its metabolites [RP36112 (99.2%) and RP36115 (96.7%)] inhibited testosterone secretion when Leydig cells were stimulated with (1) the gonadotropin hCG, (2) with drugs that enhance cAMP production [(a) cholera toxin, which stimulates Gs protein; (b) forskolin, which stimulates adenylate cyclase catalytic unit, and (3) with a cAMP analog [8-bromo-cAMP]. Because there were no effects observed on gonadotropin-stimulated cAMP production with iprodione, it is hypothesized that the inhibition of testosterone secretion by iprodione is downstream from cAMP production. At the next step in testosterone biosynthesis, inhibition of testosterone secretion by iprodione was not observed when the substrate 22ROHCT was added to the culture medium, which indicates that the step that is inhibited is located between the cAMP production and the movement/penetration of cholesterol into the mitochondria. Since 22ROHCT is a cholesterol substrate that passes through the mitochondrial membrane without the need of an active transport system, the sensitive site of inhibition of testosterone synthesis by iprodione [or RP 36115] maybe the transport/availability of cholesterol substrate for the cholesterol side chain cleavage enzyme. The RP 36112 metabolite appears to act downstream from the cholesterol step; i.e., at the level of steroidogenic enzyme 17 αhydroxylase/17, 20 lyase. Iprodione and its metabolites appear to modulate Leydig cell steroidogenesis by interfering at the level of cholesterol transport and/or steroidogenic enzyme activity. [Non-Guideline; MRID 44171901].

In another in vitro study, the objective was to determine the effect of in vitro iprodione [99.7%] exposure on basal testosterone secretion and stimulated release from

testicular sections in culture media [in vitro Endocrine Challenge Test (ECT) using human chorionic gonadotropin (hCG)]. The effects of prior in vivo exposure of the male rats via the diet [3000 ppm iprodione for 14 days] was also evaluated. Testicular sections obtained from 12 male CD® Sprague-Dawley rats administered iprodione via the diet for 14 days at dose levels of 0 ppm or 3000 ppm were incubated with 0, 1, 10, or 100 µg/mL iprodione for one hour. Half of these testicular sections from each in vitro treatment group were challenged with human chorionic gonadotrophin and the other half of the sections were monitored for basal testosterone secretion. Media testosterone concentrations were monitored at hourly intervals for 3 hours after challenge. There was a dose-related reduction in testosterone secretion from testicular sections incubated in vitro with iprodione, with and without hCG stimulation. Prior exposure of the rats to iprodione in vivo for 14 days appeared to have little effect on the secretion of testosterone, with and without hCG stimulation, from testicular sections incubated in vitro other than a slight increase initially. At sacrifice following the 14-day exposure period to iprodione in vivo, plasma LH concentrations were significantly increased compared to the control and, although plasma testosterone was not significantly affected, the levels were somewhat increased compared to the control [132% of control]. The significant increase in plasma LH at necropsy suggests a possible stimulation of the homeostatic mechanism. Under the conditions of this 14-day study, iprodione was shown to produce a reduction in testosterone secretion from testicular sections following incubation in vitro with iprodione. Prior exposure of male rats to iprodione in vivo via the diet for 14 days did not alter the reduction in testosterone secretion observed in their testicular sections exposed to iprodione in vitro. Although the in vitro inhibition appeared to be dose-related, it appears that a maximum response may have occurred between the 10 and 100 µg/mL dose levels. The data presented provide pieces to the "puzzle" but not a complete picture of what may be occurring in the testes/rat that ultimately results in testicular tumors. Although it appears that the premise is that iprodione produces testosterone biosynthesis inhibition, resulting ultimately in the increased incidence of Leydig cell tumors, there are inconsistencies in the in vitro and in vivo data, and the in vitro effects observed in the short-term studies to date have not been demonstrated to occur in long-term studies, nor is it clear that the levels at which the in vitro effects were observed are attained in vivo. [Non-Guideline; MRID 44171903].

In an in vivo study, no changes in testicular function, as assessed by measuring testosterone levels in plasma and testicular homogenates from 15 male Sprague-Dawley rats administered iprodione [97.3%] via the diet at doses levels of 0 ppm and 3000 ppm for 2, 7 or 14 days, were observed. Decreased body weight [95% of control after 2 days, 90-91% of control after 7 days, and 87% of control after 14 days], body-weight gain [negative gain after 2 days, 32% of control after 7 days, 44% of control after 14 days], and food consumption were observed following all exposure intervals. Organ-weight effects included decreased absolute liver, kidney, epididymis, and total accessory sex organs [TASO]; increased absolute and relative adrenal; and decreased relative TASO. The objective of this study was to assess the effects of in vivo iprodione exposure on plasma and testicular homogenate testosterone concentrations in the male rat following a human chorionic gonadotrophin [hCG] Endocrine Challenge Test (ECT). There were no significant differences in either peripheral plasma or

testicular homogenate testosterone levels observed in samples collected one hour after human chorionic gonadotrophin [hCG] challenge. Under the conditions of this study, iprodione did not produce alterations in testicular function following dietary exposure at 3000 ppm for up to 14 days [Non-Guideline; MRID 44171904].

In a mechanistic study in male rats designed to (a) assess the competitive binding affinity of iprodione to the androgen receptor; (b) establish an effective dose and dosing regimen and quantify testosterone, luteinizing hormone [LH], follicle-stimulating hormone [FSH], and estradiol concentrations in a single plasma sample; and (c) describe testosterone, LH, and FSH profiles during a 4-hour baseline occurring after 30 days of iprodione exposure, iprodione was shown to have poor binding affinity to the androgen receptor following exposure at very high dose levels. LH and FSH concentrations were increased after 15 days exposure but not after 30 days of exposure to iprodione. At necropsy, testosterone concentrations were comparable between the iprodione and the pair-fed rats, and estradiol concentrations were increased at necropsy following 30 days of exposure. A marked increase in adrenal weights, accompanied by histopathological lesions [vacuolation] indicative of an alteration of steroidogenesis, was observed following the 30-day exposure period. Although there was some evidence to suggest that iprodione interferes with sex/steroid hormone regulation, the differences in the spectrum of effects observed between iprodione and flutamide in this study indicate that the two compounds share only certain parts of a mechanism of toxicity/carcinogenicity. [Non-Guideline; MRID 43535002; MRID 44203401].

In an in vitro study using porcine cultured Leydig cells, iprodione [99.7%] and two of its metabolites were shown to inhibit gonadotropin-stimulated testosterone secretion in a concentration range of 1-10 µg/mL. Inhibition by iprodione was observed after short-term exposure [3 hours], and the inhibitory effects were similar to those observed with the fungicide ketoconazole. The inhibitory effects do not appear to be related to Leydig cell damage because the removal of iprodione from the culture medium for 72 hours resulted in the recovery of the cells ability to secrete testosterone following hCG stimulation. There was no discussion as to how the concentrations of iprodione used in this study relate to the levels attained within the testicular cells following oral dosing in the rat carcinogenic study where testicular tumors were observed. [Non-Guideline; MRID 43830601].

LIVER

In a 3-day and 14-day oral exposure study, groups of CD1 male mice [15/dose/group/chemical; 7 weeks old on arrival] were administered (1) iprodione via the diet at dose levels of 4000 ppm [696 mg/kg/day] or 12000 ppm [2138 mg/kg/day]; (2) ketoconazole via the diet at a dose of 2000 ppm [341 mg/kg/day]; (3) phenobarbital via gavage at a dose level of 75 mg/kg/day; and (4) cyproterone acetate via gavage at a dose level of 40 mg/kg/day. The control for the dietary studies was basal diet, and 0.5% methylcellulose was the control of the gavage studies. The objective of the study was to examine the potential liver effects of iprodione in mice and to compare these effects with those produced by well characterized liver enzyme inducers and/or rodent liver carcinogens. Ketoconazole was

selected as a positive control for its potential to inhibit testosterone secretion; phenobarbital and cyproterone acetate were selected for their potential to induce early liver changes and subsequent liver tumor formation in rodents. All of the liver effects produced by ketoconazole, phenobarbital, and/or cyproterone acetate [increases in liver weight, alanine aminotransferase, aspartate aminotransferase, # hepatocytic mitoses, total cytochrome P-450 content, staining for isoforms CYP 2B and CYP 3A, benzoxyresorufin [BROD], ethoxyresorufin [EROD], pentoxyresorufin [PROD] enzyme activities, and hepatocyte proliferation, in addition to increases in the incidence of liver enlargement, centrilobular hypertrophy, diffuse hypertrophy, centrilobular/midzonal fine vacuolation] were exhibited by iprodione at 12000 ppm. An effect observed following iprodione exposure that was not observed following any of the other test material exposures was an increase in lauric acid hydroxylation. Although several of the effects observed in the liver following iprodione exposure are analogous to those observed following the positive controls, especially phenobarbital [centrilobular hypertrophy, liver weight, increased BROD, PROD, and EROD activities, cell proliferation after 3 days], in several cases the liver effect observed was most pronounced in the iprodione mice compared to the positive controls [centrilobular/midzonal fine vacuolation, increased number of mitoses, cell proliferation at day 15].

This study demonstrates that iprodione, at dose levels that are 5- and 15- fold greater than the LOEL for liver effects observed in the mouse carcinogenicity study, induces (1) liver cell proliferation, (2) increased microsomal enzyme activities, (3) an increase in total cytochrome P-450 content, and (4) centrilobular hypertrophy. These observations most closely resemble the pattern of liver effects observed following phenobarbital exposure. Hepatocytic hypertrophy was observed at the high-dose level of iprodione following both the 3- and 14-day exposure periods but only following the 14-day exposure period at the low dose. Liver cell proliferation was observed after both the 3-day and 14-day exposure periods at both dose levels of iprodione. Increased cytochrome P-450 content and increased microsomal enzyme activities were observed at both dose levels of iprodione following the 14-day exposure period, but neither analysis was performed following the 3-day exposure period. The dose level where liver tumors were observed in the mouse carcinogenicity study [604 mg/kg/day] is comparable to the low dose used in the current study. The findings in this study support the Registrant's arguments that the liver tumors observed in the iprodione mouse carcinogenicity study may be secondary to liver toxicity. However, several pieces of data are lacking. The current study does not address whether cytochrome P-450 content and the microsomal enzyme activities are increased initially [after the 3-day exposure period]; therefore, one cannot determine whether the cell proliferation and hepatocytic hypertrophy observed after 3-days exposure to iprodione is due to a direct effect of iprodione on the liver or the result of adaptive processes. Additionally, the current study does not identify a NOEL for the liver effects monitored over a 14-day exposure period or address the question of whether these liver effects occur initially at the lower doses utilized in the mouse carcinogenicity study. Another outstanding question is whether the liver effects [hepatocytic hypertrophy, increased total cytochrome P-450 content, increased microsomal activities, cell proliferation] observed in the current study persist throughout a long-term exposure. It is to be noted that phenobarbital produces a short-term increase in hepatocyte proliferation that

is not sustained. In a paper on proliferation and liver tumor development [CIIT Activities, vol. 15 (8), August, 1995], it is stated that the proliferative response seen after acute exposure does not always reflect the proliferative response observed after chronic exposure [Non-Guideline; MRID # 44171902]].

Based on these mechanistic studies, the Agency's Cancer Assessment Review Committee (CARC) concluded that the data available do not provide a definitive mode of action with respect to either the Leydig cell tumors or the liver tumors.

e. Reproduction and Developmental Toxicity Studies

(1) Two-Generation Reproduction Study in Rats

In a 2-generation reproduction study, 28 Crl:CD®BR/VAF/PLUS rats/sex/group were administered iprodione [96.2%] via the diet at dose levels of 0, 300 ppm [♂♂ 18.5/♀♀ 22.5 mg/kg/day], 1000 ppm [♂♂ 61.4/♀♀ 76.2 mg/kg/day], and 3000/2000 ppm [♂♂ 154.8/♀♀ 201.2 mg/kg/day] for two generations [2 litters per generation]. The systemic maternal/parental NOEL was 300 ppm [♂♂ 18.5/♀♀ 22.5 mg/kg/day], and the LOEL was 1000 ppm [♂♂ 61.4/♀♀ 76.2 mg/kg/day], based on decreased body weight, body-weight gain, and food consumption in both sexes and both generations. The reproductive [offspring] NOEL was 1000 ppm [76.2 mg/kg/day], and the reproductive [offspring] LOEL was 2000 ppm [201.2 mg/kg/day], based on decreased pup viability [as evidenced by an increased number of stillborn pups and decreased survival during postnatal days 0-4], decreased pup body weight throughout lactation, and an increased incidence in clinical signs in pups during the lactation period [smallness, reduced mobility, unkempt appearance, hunching, and/or tremors] [Guideline §83-4; MRID 00162983; MRID 41871601].

(2) Developmental Toxicity Study in Rats

In a developmental toxicity study, 20 pregnant Sprague-Dawley CD rats [mated 1:1] were administered iprodione [94.2%] at dose levels of 0 [0.5% methylcellulose], 40, 90, and 200 mg/kg/day via gavage from day 6 through 15 of gestation. On day 20 of gestation, the dams were sacrificed via CO_2 inhalation. There were no deaths. Body weights were comparable among the groups. There were no significant differences observed in the mean number of viable fetuses, implantations, corpora lutea, resorptions, and pre- and postimplantation losses were comparable among the groups. There was no evidence of maternal toxicity at any dose level [maternal NOEL $\geq$ 200 mg/kg/day. The developmental NOEL was 90 mg/kg/day, and the developmental toxicity LOEL was 200 mg/kg/day, based on delayed fetal development [slightly reduced fetal body weight and increased incidences of space between the body wall and organs in the fetuses]. [Guideline §83-3(a); MRID 00162984; MRID 40514901].

In a 1976 prenatal developmental toxicity study, groups of pregnant Sprague-Dawley rats (25-30/dose) received iprodione (100%) in 1% carboxymethylcellulose via gavage at

doses of 0, 100, 200, or 400 mg/kg/day during gestation days 5 through 15. For maternal toxicity, the NOEL was 200 mg/kg/day and the LOEL was 400 mg/kg/day based on slightly decreased body weight gain and significantly decreased food consumption. For developmental toxicity, the NOEL was 200 mg/kg/day and the LOEL was 400 mg/kg/day based on decreased implantation sites. This study does not appear to provide a robust evaluation of fetal effects following *in utero* exposure of iprodione (MRID 0071324).

In a 1997 special prenatal developmental toxicity study, pregnant Sprague-Dawley rats (25/dose) received iprodione (97.1%) in methylcellulose via gavage at dose levels of 0, 20, 120, or 250 mg/kg/day during gestation days 6 through 19. For maternal toxicity, the NOEL was 20 mg/kg/day, the LOEL was 120 mg/kg/day, based on decreased body-weight gain and decreased food efficiency. At 250 mg/kg/day, deaths occurred [9 out of 25] in addition to decreased body-weight gain and food consumption/ efficiency. For developmental toxicity, the NOEL was 20 mg/kg/day and the LOEL was 120 mg/kg/day, based on decreased anogenital distance (AGD) in the male pups (MRID No. 44365001).

(3) Developmental Toxicity Study in Rabbits

In a developmental toxicity study, 18 artificially inseminated New Zealand female rabbits were administered iprodione [95.0-99.3%] at dose levels of 0 [0.5% aqueous methylcellulose], 20, 60, and 200 mg/kg/day via gavage from day 6 through 18 of gestation. On day 29 of gestation, the does were sacrificed. Seven high-dose does aborted between days 17 and 23 of gestation, and prior to aborting all had displayed decreased urination and defecation. One mid-dose doe [day 28] and one control doe [day 20] also aborted. All other does survived until study termination, and nine of the high-dose does that did not abort displayed decreased urination and defecation. During the dosing period, the mid-dose does gained less weight than the control, and the high-dose does lost weight. A negative net body-weight gain was observed at the mid- and high-dose levels. The high-dose does displayed decreased food consumption during the dosing period. Gravid uterine weight was decreased at the high-dose level [90% of control] compared to the control. The maternal NOEL is 20 mg/kg/day, and the maternal LOEL is 60 mg/kg/day, based on decreased body-weight gain. At the highest dose tested [200 mg/kg/day], maternal toxicity was demonstrated by an increased rate of abortions [7 does], body-weight loss, decreased food consumption, and decreased defecation and urination in females that aborted. The developmental toxicity NOEL was 60 mg/kg/day, and the developmental toxicity LOEL was 200 mg/kg/day, based on an increased incidence of skeletal variations [13^{th} full rib, malaligned sternebrae, and/or 27 presacral vertebrae, with or without delayed ossification]. [Guideline §83-3(b); MRID 00155469].

Due to the structural similarity of iprodione to procymidone and vinclozolin and to the observed effects on the reproductive system in males in the long-term feeding study in rats, a pre-and postnatal developmental toxicity study is required to assess the effects of iprodione on the male reproductive system for iprodione. This concern for postnatal exposure was highlighted previously by the RfD Committee (2/10/94). These effects can be addressed

by adhering to the new guidelines for reproductive toxicity, OPPTS 870.3800. This study is required.

(4) Mutagenicity Studies

Sufficient data are available to satisfy data requirements for mutagenicity testing [§84-2].

f. Gene Mutation

Iprodione was negative for induction of reverse gene mutations at the histidine locus in *Salmonella typhimurium* strains TA 98, TA 100, TA1535, TA 1537, and TA 1538, both in the presence and absence of S9 activation. There was sufficient cytotoxicity, as evidenced by reductions in mean numbers of revertants and background lawn, at the highest dose in the absence of S9, and a slight to moderate precipitate was observed at doses ≥ 250 µg/plate in the presence and absence of S9. In the presence of S9, iprodione was assayed to the limit dose [Guideline §84-2; MRID 41604106].

Iprodione did not induce mutation with or without metabolic activation in the in vitro forward gene mutation [CHO/HGPRT] assay at adequate dose levels [Guideline §84-2; MRID 00148206].

g. Chromosomal Aberration Assay

Iprodione was negative in an in vitro chromosomal aberration assay in Chinese hamster ovary [CHO] cells both in the presence and absence of metabolic activation at adequately high dose levels [doses of 40, 150, 400 µg/mL with; doses of 15, 75, 150 µg/mL without S9]. There was precipitation at exposure levels ≥150 µg/mL both with and without S9. [Guideline §84-2; MRID 00148207].

In an in vivo mouse micronucleus assay, 5 CD-1 mice/sex/group were administered iprodione [96.1%] suspensions [1% aqueous methylcellulose] via oral gavage once at dose levels of 750, 1500, and 3000 mg/kg. Bone marrow cells were collected for micronucleated polychromatic erythrocytes [MPEs]. One male and eight females died at the high dose, and signs of toxicity at this dose level included piloerection, hunched posture, ptosis, lethargy, and coma. Dose-related cytotoxic effects on the target tissue were also seen at 48 hours postdose; the response was significant at the high dose. The positive control induced the expected high yield of MPEs in both sexes. There was no evidence of a clastogenic or aneugenic effect at any dose or harvest time [Guideline §84-2; MRID 43535001].

h. Other Genotoxic Effects

Iprodione was negative in a sister chromatid exchange assay in Chinese hamster ovary cells both with and without metabolic activation [Guideline §84-2; MRID 00148209].

Iprodione was tested against 19 strains [including 2 wild type] of Bacillus subtilis both with and without metabolic activation at dose levels of 20.6-1670 µg/disc. Iprodione was positive both with and without metabolic activation [Guideline §84-2; MRID 00148208].

i. Metabolism

Sufficient data are available on the metabolism of Iprodione in the rat. ^{14}C-Iprodione was absorbed readily from the gastrointestinal tract, metabolized, and excreted by rats of both sexes following single low [50 mg/kg] and high [900 mg/kg] oral doses and 14 repeated low [50 mg/kg/day] doses. Peak blood levels were observed at 4 and 2 hours, respectively, in the low-dose males and females and at 6 hours in the high-dose rats of both sexes. The elimination of ^{14}C from the blood was slower in males than in females. There were both dose- and sex-related differences noted in absorption; males absorbed a greater percentage of the low and repeated doses than females. Although levels of ^{14}C were found in most tissues monitored, the levels were ≤ 0.5% of the total amount administered. It is to be noted that the testes of the low-dose males [both single and repeat] showed no detectable amount of ^{14}C; the high dose in the rat chronic toxicity/ carcinogenicity study where testicular tumors were observed was 69 mg/kg/day. The primary route of elimination of ^{14}C following single and repeat low dose exposure was the urine, and the feces was the primary route following high-dose exposure. Dealkylation and cleavage of the hydantoin ring were the two primary steps in the metabolism of Iprodione. Hydroxylation of the phenyl ring and oxidation of the alkyl chain also occurred. The primary metabolites recovered from the urine [both sexes] included a dealyklated derivative of Iprodione and 2 polar but unidentified compounds. Males produced larger amounts of a hydantoin ring-opened metabolite than females, and the urine of the females contained a higher proportion of unchanged parent than that of the males. Several urinary metabolites were not identified. The feces contained much larger amounts of unchanged parent than the urine, which the authors suggested was unabsorbed iprodione and metabolites or hydrolyzed conjugates of absorbed material.

In another single oral administration study in rats using 50 mg/kg, no sex differences were apparent in the excretion profile, and both urinary elimination [♂♂ 37%/♀♀ 28%] and fecal excretion [♂♂ 56%/♀♀ 50%] were major routes of excretion, and the majority of the radiolabel was excreted within the first 24 hours post dose in both sexes. Approximately 80% of the 24-hour urine sample radiolabel [≈24% of the dose] and ≈91% of the 24-hour fecal radiolabel [≈49% of the dose] were characterized. Overall, ≈72% of the dose was identified, which accounted for nearly 90% of the total radiolabel found in the samples. The metabolism of iprodione was extensive and characterized by the large number of metabolites formed. In the urine, RP 36115, RP 32490, RP 36112, RP 36119, and RP 30228 were either confirmed or indicated. The feces contained a large proportion of parent; the major fecal metabolites were RP 36115, RP 36114, RP 32490, and RP 30228.

A general metabolic pathway for iprodione in the rat indicates that biotransformation results in hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain, and rearrangement followed by cleavage of the hydantoin moiety. Additionally, structural

isomers of iprodione resulting from molecular rearrangement, as well as intermediates in the pathway, were detected [Guideline §85-1; MRID 41346701; MRID 42984101; MRID 43484901].

j. Dermal Penetration Study

In a dermal penetration study, 4 male Crl: CD®BR rats/group/time point were exposed dermally to a single dose of iprodione at dose levels of 0.4, 4.0, and 40 mg/rat for 0.5, 1, 2, 4, 10, and 24 hours. Skin residues increased with the duration of exposure to 5-10% of the applied dose, although there was no apparent dose response. The portion of the test material absorbed increased with the duration of exposure to 7.41%, 3.16%, and 0.19% of the applied dose at 0.4, 4.0, and 40 mg/rat, respectively. Absorption appears to be saturated at the two highest dose levels. Following a 10-hour exposure period, ≈5% iprodione is absorbed [Guideline §85-2; MRID 43535003].

k. Inhalation Toxicity

The only inhalation study available for iprodione is an acute inhalation toxicity study, with an acute LD_{50} = 5.16 mg/L [MRID 42946101]. These results place iprodione in Toxicity Category IV. No other studies are available via this route.

2. Dose - Response Assessment

The dose-response assessment for iprodione was conducted by OPP's toxicology peer review committees, who selected risk assessment endpoints after reviewing the entire toxicology database for iprodione. A brief history of the findings of OPP's peer review committees is presented below.

On February 10, 1994 EPA's RfD/Peer Review Committee established a Reference Dose (RfD) of 0.06 mg/kg/day based on a NOEL of 6.1 mg/kg/day established in a combined chronic toxicity/carcinogenicity study in rats and an Uncertainty Factor of 100 for inter-species extrapolation and intra-species variability.

On October 16, 1997, the EPA's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data to assess the potential enhanced sensitivity of infants and children from exposure to iprodione as required by the Food Quality Protection Act (FQPA) of 1996. On February 25, 1998, the HIARC met again to re-evaluate the toxicological endpoints for acute and chronic dietary as well as occupational and residential (dermal and inhalation) exposure risk assessments in light of a recently submitted special prenatal developmental toxicity sexual differentiation study in rats (MRID No. 44365001). The HIARC determined that the application of the FQPA safety factor for the protection of infants and children from exposure to iprodione, as required by FQPA, would be determined during risk characterization.

a. Determination of Susceptibility to Infants and Children

(1) Neurotoxicity Data

Neurotoxicity studies are not required since iprodione is neither an organophosphate nor structurally related to compounds that are known to induce neurotoxicity.

(2) Developmental Toxicity Data

In a 1986 prenatal developmental toxicity study, groups of pregnant Sprague-Dawley rats (25-30/dose) received iprodione (100%) in 1% carboxymethylcellulose via gavage at doses of 0, 100, 200, or 400 mg/kg/day during gestation days 5 through 15. For maternal toxicity, the NOEL was 200 mg/kg/day and the LOEL was 400 mg/kg/day based on slightly decreased body weight gain and significantly decreased food consumption. For developmental toxicity, the NOEL was 200 mg/kg/day and the LOEL was 400 mg/kg/day based on decreased implantation sites. This study does not appear to provide a robust evaluation of fetal effects following *in utero* exposure of iprodione (MRID 0071324).

In a 1986 prenatal developmental toxicity study, groups of pregnant Sprague-Dawley rats were given oral (gavage) administrations of iprodione (94.2%) in 0.5% methylcellulose at doses of 0, 40, 90, or 200 mg/kg/day during gestation days 6 through 15. No maternal toxicity was observed (maternal NOEL $\geq$200 mg/kg/day). For developmental toxicity, the NOEL was 90 mg/kg/day and the LOEL was 200 mg/kg/day, based upon delayed fetal development, as evidenced by slightly reduced fetal weights and an increased incidence of space between the body wall and organs in fetuses(MRID 00162984).

In a 1997 special prenatal developmental toxicity study, pregnant Sprague-Dawley rats (25/dose) received iprodione (97.1%) in methylcellulose via gavage at dose levels of 0, 20, 120, or 250 mg/kg/day during gestation days 6 through 19. For maternal toxicity, the NOEL was 20 mg/kg/day, the LOEL was 120 mg/kg/day, based on decreased body-weight gain and decreased food efficiency. At 250 mg/kg/day, deaths occurred [9 out of 25] in addition to decreased body-weight gain and food consumption/ efficiency. For developmental toxicity, the NOEL was 20 mg/kg/day and the LOEL was 120 mg/kg/day, based on decreased anogenital distance in the male pups (MRID No. 44365001).

In a prenatal developmental toxicity study, pregnant New Zealand white rabbits (18/group), were given oral (gavage) administration of iprodione (95% or 99.3%, from two different lots) in 0.5% Methocel at doses of 0, 20, 60, or 200 mg/kg/day during gestation days 6 through 18. For maternal toxicity, the NOEL was 20 mg/kg/day and the LOEL was 60 mg/kg/day based on decreased body weight gain. Also at 200 mg/kg/day, the following were observed: increased numbers of abortions, body weight loss, decreased food consumption and decreased defecation and urination. For developmental toxicity, the NOEL was 60 mg/kg/day and the LOEL was 200 mg/kg/day based upon increased skeletal variations (13th full rib, malaligned sternebrae, and 27 presacral vertebrae, occurring alone or in combination with each other or accompanied by delayed ossification) (MRID No. 00155469).

(3) Reproductive Toxicity Data

In a two-generation reproduction study, male and female Sprague-Dawley received diets containing iprodione (96.2%) at 0, 300, 1000, or 2000/3000 ppm (0, 18.5, 61.4, or 154.8 mg/kg/day for males and 22.49, 76.2, or 201.2 mg/kg/day for females) For parental systemic toxicity, the NOEL was 300 ppm (21 mg/kg/day) and the LOEL was 1000 ppm (69 mg/kg/day), based on decreased body weight, body weight gain, and food consumption in both sexes and generations. For offspring toxicity, the NOEL was 1000 ppm (69 mg/kg/day) and the LOEL was 2000/3000 ppm (178 mg/kg/day), based on decreased pup viability (as evidenced by an increased number of stillborn pups and decreased survival during postnatal days 0-4), decreased pup body weight throughout lactation, and an increased incidence in clinical signs (smallness, reduced mobility, unkempt appearance, hunching, and/or tremors) in pups during the lactation period. (MRID No. 41871601).

(4) Determination of Susceptibility

The prenatal developmental toxicity study in rabbits, the special prenatal study in rats, and the two-generation reproduction study in rats demonstrated no indication of increased susceptibility to *in utero* and/or postnatal exposure to iprodione.

In the 1986 prenatal developmental toxicity study in rats, however, developmental effects in the fetuses (a slight dose-related decrease in fetal weight and increased incidence of fetuses with a space between the body wall and the internal organs) were noted in the absence of maternal toxicity. It is noted that the fetal findings were suggestive but not conclusive of fetal toxicity. Fetal weights were not altered in a statistically significant manner and were well within historical values. The incidence of space between the body wall and organs was also not apparently statistically significant. This finding may have been supportive (as were the c-section observations of "small fetus") of weight decrements in fetuses at the LOEL, but it could also be an artifact of preservative techniques. Also, the fetal findings were marginal and not statistically significant, within ranges of historical control values, and were not supported by data from other studies. Therefore, due to the lack of confidence in these data, the findings of this study were not judged to be an appropriate measure of potential sensitivity following *in utero* exposure to iprodione. Based on the weight-of-the-evidence of all available studies, the Committee concluded that there was no increased susceptibility to rat and rabbit fetuses following *in utero* and/or post natal exposure to iprodione.

(5) Recommendation for a Developmental Neurotoxicity Study

Based on the following weight-of-the-evidence considerations, the Hazard Identification Assessment Committee (HIARC) determined that a developmental neurotoxicity study in rats is not required for iprodione.

(i) Evidence that support not requiring a developmental neurotoxicity study:

- Overall, iprodione does not appear to be a frankly neurotoxic chemical. There were no effects on brain weight or histopathology (nonperfused) of the nervous system in the chronic studies in rats, mice, and dogs. Findings that were suggestive of neurotoxicity (see below) were often equivocal, unsupported by data from other studies, and/or observed only at doses which compromised the survival of the animals.

- No evidence of developmental anomalies of the fetal nervous system was observed in the prenatal developmental toxicity studies in either rats or rabbits, at developmentally and/or maternally toxic oral doses up to 200 mg/kg/day.

- Evaluation of the special postnatal developmental toxicity study did not reveal any endpoints of concern that would trigger a developmental neurotoxicity study.

(ii) Evidence that would suggest the need for a developmental neurotoxicity study:

- In the chronic toxicity study in rats, degeneration of the sciatic nerve was observed after 2 years of dietary exposure to iprodione. This finding was also observed at a relatively high incidence in control animals, although the incidence doubled for females at the highest dose tested (1600 ppm).

- In the carcinogenicity study in mice, absolute brain weight was slightly decreased and adjusted brain weight was significantly decreased at the HDT (4000 ppm).

- In the 90-day subchronic study in rats, absolute brain weight was significantly decreased for females only at the HDT (3000 ppm). Clinical signs of toxicity in this study included piloerection and hunched posture at 3000 and 5000 ppm (the 5000 ppm treatment group was terminated early due to severe toxicity).

- In the two-generation reproduction study in rats, clinical observations in pups included reduced mobility, unkempt appearance, hunching, and/or tremors at the HDT (2000/3000 ppm = 178 mg/kg/day). At this treatment level, severe toxicity was observed in the parental animals, pup body weight was reduced, and pup survival was compromised.

- Iprodione causes endocrine disruption, affecting the reproductive system, pituitary, adrenals, and/or thyroid in various studies.

(iii) Other Unknown Factors:

Because of the lack of acute and subchronic neurotoxicity studies in rats, there was no evaluation of the nervous system following perfusion. Findings in other studies that were suggestive of neurotoxicity could not be confirmed or refuted.

(6) Determination of the FQPA Safety Factor

The decision to evaluate the need for an additional safety factor to ensure the protection of infants and children from exposure to iprodione, as required by FQPA, was elevated to the OPP Division Directors, who met to discuss the iprodione FQPA Safety Factor on April 7, 1997. The Division Directors decision and decision logic is summarized below.

It was determined that the additional 10x Safety Factor for the protection of infants and children (as required) by FQPA should be reduced to 3x and the rationale for reducing the 10x factor to 3x are as follows:

- No enhanced susceptibility was seen in rat and rabbit developmental and the two generation reproduction study in rats.

- The critical endpoint for acute dietary risk assessment (decreased AGD) was seen at a high dose (120 mg/kg/day) and there were only marginal differences in the degree of decreased AGD between the doses 20 mg/kg/day (2.44), 120 mg/kg/day (2.32) and 250 mg/kg/day (2.10) thus indicating the "true" NOEL could be higher than the one established at 20 mg/kg/day.

- The proposed mode of action of iprodione is disruption of testosterone biosynthesis.

- The use of a realistic dietary exposure data (refined using monitoring data and percent crop treated).

- The endpoints selected for both the acute (AGD) and the chronic (histopathology of male reproductive system) risk assessments are based on developmental/reproductive effects.

- The uncertainty with regard to the pre/post natal exposure study requested by the HIARC which may confirm the effects seen in the standard developmental and/or reproductive studies.

Of note, Rhone-Poulenc Ag Co., the current manufacturer of iprodione, disputes the appropriateness of retaining the 3X FQPA uncertainty factor since: (1) the Agency concluded that there was not increased susceptibility to rat and rabbit fetuses following *in utero* and/or post natal exposure to iprodione; (2) marginal differences on AGD were only observed in the

presence of substantial maternal toxicity; (3) Rhone-Poulenc considers that no data gap exists with regards to the pre/post natal effects of iprodione; an acceptable two-generation reproduction study in rats having been completed as recently as 1991; and, (4) Rhone-Poulenc believes that it is especially not appropriate to justify retaining a FQPA safety factor on the acute RfD for a perceived data gap relating to a multi-generation reproduction study.

(7) Application of the FQPA Safety Factor

(i). Acute Dietary Risk Assessment. The FQPA Safety Factor will be applied for acute dietary risk assessment for Females 13 + only because the endpoint (decreased AGD) is an *in utero* effect occurring during prenatal exposure. An appropriate endpoint attributable to a single dose was not identified for the General Population including Infants and Children for this risk assessment. Since the decreased AGD occurs during *in utero* exposure, it is not an appropriate endpoint for acute dietary risk assessment of Infants and Children (i.e., the anogenital distance can not be altered after birth in Infants and Children).

ii. Chronic Dietary Risk Assessment. The FQPA Safety Factor will be applied for chronic dietary risk assessment for the General Population including Infants and Children since the endpoint is based on reproductive effects (histopathological lesions in the male reproductive organs).

iii. Occupational Exposure. The FQPA Safety Factor will not be applied to any occupational scenarios, as per Agency policy.

iv. Residential Exposure. The FQPA Safety Factor will be applied to residential exposure risk assessments for Female 13 + as well as the General Population including Infants and Children due to the potential exposure by these subpopulations based on the use pattern (ornamental lawn and turf) and the inhalation endpoint is based on reproductive effects in a chronic rat study (NOEL of 6.1 mg/kg/day).

b. Toxicological Endpoints for Risk Assessment

(1) Acute Dietary

The HIARC on February 25, 1998 determined that the developmental NOEL of 20 mg/kg/day based on decreased anogenital distance (AGD) in male fetuses at 120 mg/kg/day should be used for acute dietary risk assessment. This NOEL is from a special rat developmental study (MRID 44365001) which was designed to determine the impact of iprodione on sexual differentiation. This endpoint applies only to females 13+ because the endpoint (decreased AGD) is an *in utero* effect occurring during prenatal exposure. An appropriate endpoint attributable to a single dose was not identified for the General

Population including Infants and Children for this risk assessment. The target acute dietary MOE for iprodione is 300, based on uncertainty factors of 10X for interspecies variability, 10X for intraspecies variability, and 3X for FQPA for the protection of infants and children.

The HIARC selected the dose of 20 mg/kg/day from the special rat study as a conservative estimate for risk assessment, however, doubted if this dose represented a "true" NOEL for the following reasons: 1) effects at the next higher dose (120 mg/kg/day, the LOEL), consisted of only marginal decreases; 2) although the decrease in AGD at the LOEL showed statistical significance, the biological significance is questionable because of the extent of the decreases seen between the NOEL (2.44±0.14) and the LOEL (2.32±0.12) which indicate that the "actual" no effect level could be higher, some where in between these levels (i.e, 20 and 120 mg/kg/day); 3) lack of evaluation of another critical endpoint (i.e., nipple development, characterized as areolas/nipple anlagen in two strains of rats) which was observed along with the decrease in AGD with Vinclozolin, a structurally related compound; and 4) although AGD was not measured, another developmental toxicity study in rats demonstrated a developmental NOEL of 90 mg/kg/day based on delayed fetal development (MRID 00162984).

The HIARC noted that the Toxicological Endpoint Selection (TES) Committee previously selected the NOEL of 90 mg/kg/day established in the 1986 study along with an additional Uncertainty Factor of 3 due to the lack of data on the androgen deprivation effect. This yielded a dose (90÷3=30 mg/kg/day) which is comparable to the 20 mg/kg/day dose selected for this risk assessment. The HIARC considered the earlier developmental toxicity study as co-critical in the choice of the toxicological endpoint for acute dietary risk assessment.

An MOE approach is being used for the iprodione acute dietary risk assessment for consistency with the acute dietary risk assessments done from 1995 to 1997 for this chemical for Special Review. Also, an MOE approach is used for ease of comparison with the Novigen Acute Monte Carlo Dietary Risk Assessment conducted in 1997.

At present the Agency uses an acute RfD approach for acute dietary risk assessments. The percentage of the acute RfD is a measure of how close the high-end exposure comes to the Reference Dose, and is calculated as the ratio of exposure (mg/kg/day) to the RfD (mg/kg/day). If this approach is taken, for iprodione, the FQPA Safety Factor of 3x will be incorporated into the acute RfD for the subpopulation Females 13+ only because the endpoint (decreased AGD) in an *in utero* effect. The acute RfD is calculated as follows:

$$\textbf{Acute RfD} = \frac{\text{20 mg/kg/day (NOEL)}}{\text{300 (UF)}} = 0.06 \text{ mg/kg/day}$$

The 300 UF includes inter-species variation (10x), intra-species extrapolation (10x), and the FQPA Safety Factor (3x).

However, as stated earlier, for iprodione, to ensure consistency with earlier risk assessments, the present acute dietary risk assessment is based on the MOE and as a percentage of the acute RfD. The acute RfD is presented here only as a reference value.

(2) Chronic Reference Dose (RfD)

The February 28, 1998 HIARC re-affirmed the dose and endpoints selected for establishing the chronic RfD in 1994. The chronic RfD was based on a NOEL of 6.1 mg/kg/day from a rat combined chronic toxicity/carcinogenicity study (MRID 42637801; MRID 42787001]) based on histopathological lesions in the male reproductive system and effects on the adrenal glands in males at 12.4 and in females at 16.5 mg/kg/day (LOEL). The NOEL was adjusted with an uncertainty factor of 300 (10 x for inter-species extrapolation and 10 x for intra-species variability and 3X for FQPA considerations). The chronic RfD was determined to be 0.02 mg/kg/day.

$$\text{Chronic RfD} = \frac{\text{6.1 mg/kg/day (NOEL)}}{\text{300 (UF)}} = \text{0.02 mg/kg/day}$$

Iprodione has been reviewed by the FAO/WHO Joint Committee Meeting on Pesticide Residues [JMPR]. The World Health Organization (WHO) established an acceptable daily intake (ADI) of 0.3 mg/kg/day in 1977. This ADI was revised to 0.2 mg/kg/day in 1992.

(3) Carcinogenic Risk Assessment

On November 19, 1997, EPA's Cancer Assessment Review Committee (CARC) in accordance with the EPA *Proposed Guidelines for Carcinogen Risk Assessment* (April 10, 1996), classified iprodione as a "likely" human carcinogen based on the combined hepatocellular adenomas/ carcinomas in mice and testicular tumors in male rats with a linear low-dose extrapolation approach and a 3/4s interspecies scaling factor for human risk characterization. For the combined hepatocellular adenomas/ carcinomas, the Q_1*s are 8.7 x 10^{-3} for the male mouse and 5.07 x 10^{-3} for the female mouse. For the Leydig cell tumors in male rats, the Q_1* is 4.39 x 10^{-2}. The CARC determined that of these, the most potent Q_1* of 4.39 x 10^{-2} should be used for cancer risk assessments. Therefore, the Q_1* of 4.39 x 10^{-2} should be used for estimating carcinogenic risk.

Of note, Rhone-poulenc Ag Co. contends that cancer risk assessments for iprodione should be conducted using a margin of exposure (MOE) approach rather than a linear low dose extrapolation model. This contention is based on the mechanistic data described in this document and recently submitted data which may demonstrate that iprodione suppresses plasma testosterone levels with corresponding increases in plasma LH levels *in vivo* at a dose equivalent to that which induced benign Leydig cell tumors in the chronic rat study. According to Rhone-Poulenc, this data further substantiates the view that iprodione provokes hormonal imbalances in the rat which predisposes this highly sensitive species to the development of an increased incidence of benign Leydig cell tumors. The dose-response for this type of hormonally-mediated effect would be expected to be non-linear.

c. Occupational/Residential Exposure

(1) Short- and Intermediate-Term Dermal - (1 day to several months)

The HIARC determined that short- and intermediate-term dermal risk assessments are not required since no dermal or systemic toxicity was seen. No dermal or systemic toxicity was seen following repeated dermal application of iprodione at 0, 100, 500 or 1000 mg/kg/day, 6 hours/day, 5 days/week over a three week period to male and female New Zealand rabbits (MRID No. 42032301). The HIARC concurred with the TES Committee's conclusions that there is no potential hazard via the dermal route because of the lack of systemic toxicity at the Limit-Dose (1000 mg/kg/day) and the demonstration of low (5%) absorption via the dermal route.

(2) Long-Term Dermal (Several Months to Life-Time)

(A). Non-Cancer (Chronic) Effects. A NOEL of 6.1 mg/kg/day from a combined rat chronic toxicity/carcinogenicity study (MRID Nos. 43308201 & 43000501) was chosen for chronic dermal risk assessment. The NOEL of 6.1 mg/kg/day was based on histopathological lesions in the male reproductive system and effects on the adrenal glands in males at 12.4 and in females at 16.5 mg/kg/day (LOEL). This dose was selected since the current use pattern (6 days/week for up to 180 days) indicates potential for Long-Term dermal exposures. This oral NOEL with a dermal absorption factor of 5% should be used only for non-cancer dermal risk assessments. Dermal exposure should not be combined with inhalation exposure since a Long-Term inhalation risk assessment is not required.

(B). Carcinogenic Effects. The Q_1* of 4.39 x 10^{-2} should be used for estimating carcinogenic risk from occupational exposure. The dermal and inhalation exposures should be combined and appropriate dermal (5%) and inhalation (100%) absorption factors should be used in carcinogenic risk assessments. This risk assessment is required.

(3) Dermal Absorption

The HIARC determined the dermal absorption factor for iprodione to be 5% at 10 hours. This factor is necessary ONLY for Long-Term chronic and carcinogenic dermal risk assessments since Short-and Intermediate-Term risk assessments are not required. This dermal absorption factor is based on MRID No. 43535003.

(4) Inhalation Exposure (Short and Intermediate-Term only)

Except for an acute inhalation toxicity study, the results of which place iprodione in Toxicity Category IV (LC_{50} = 5.16 mg/L), no other studies are available via this route. The current use pattern (4 days/week up to several weeks) indicates a concern only for Short and

Intermediate-Term but not for Long-Term exposures via this route. Therefore, the HIARC selected the doses only for Short and Intermediate-Term inhalation exposure risk assessments.

(a) Short-Term Inhalation Exposure

The Developmental NOEL of 20 mg/kg/day from the special rat developmental toxicity study (MRID No.44365001) was selected for short term inhalation risk assessment. This NOEL is based on decreased AGD in male fetuses at 120 mg/kg/day (LOEL). The inhalation exposure component (i.e., µg a.i/lb/day) using a 100% absorption rate (default value) should be *converted to* an *equivalent oral dose* (mg/kg/day). This converted oral dose should then be compared to the NOEL identified above. Inhalation exposure should not be combined with dermal exposure since a dermal risk assessment is not required. This risk assessment is required.

(b) Intermediate-Term Inhalation Exposure

The NOEL of 6.1 mg/kg/day from the rat combined Chronic Toxicity/Carcinogenicity Study (MRID Nos.43308201 & 43000501). This NOEL is based on histopathological lesions in the male reproductive system and effects on the adrenal glands in males at 12.4 and in females at 16.5 mg/kg/day (LOEL).

The inhalation unit exposure (in µg a.i/lb/day) should be *converted to* an *equivalent oral dose* (mg/kg/day) using a 100% absorption rate (default value). This converted oral dose should then be compared to the NOEL identified above. Inhalation exposure should not be combined with dermal exposure since a dermal risk assessment is not required.

(c) Long-Term Exposure

The current use pattern does not indicate a concern for Long-Term exposure or risk. This risk assessment is not required.

d. Target Margin of Exposure for Occupational/Residential Exposures

A Margin of Exposure (MOE) of 100 is adequate for occupational exposure risk assessments. However, because of the FQPA Safety Factor, a MOE of 300 is required for residential exposure risk assessments for the general population including infants and children.

e. Recommendation for Aggregate Exposure Risk Assessments

For acute aggregate exposure risk assessment, combine the high end exposure values from food + water and compare it to the oral NOEL to calculate the MOE or percent acute RfD.

For short and intermediate aggregate exposure risk assessment, combine the average exposure values from food + water together with the exposure from inhalation route (100% absorption) only and compare it to the oral NOELs to calculate the MOE (dermal risk assessments are not required for these exposure periods).

For chronic aggregate exposure risk assessment, combine the average exposure values from food + water together. There are no chronic residential use scenarios to include in this risk assessment. The doses and toxicological endpoints selected for various exposure scenarios are summarized in Table 5.

Table 5. Summary of Toxicological Endpoints to be used for Iprodione Risk Assessment

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	Developmental NOEL=20	Decreased anogenital distance in male pups.	Developmental- Rat
	UF=100 and 3X for FQPA	Acute FQPA RfD = 0.06 mg/kg/day	
Chronic Dietary	NOEL=6.1	Histopathological lesions in the male reproductive system and the adrenal glands in both sexes.	Combined Chronic Toxicity/ Carcinogenicity -Rat
	UF=100 and 3x for FQPA	Chronic FQPA RfD = 0.02 mg/kg/day	
Carcinogenicity (Dietary)	Q_1*= 4.39×10^{-2}	Iprodione is classified as a "Likely" human carcinogen with a low-dose extrapolation approach for human risk assessment.	
Short-Term (Dermal)	Not Applicable	No dermal or systemic toxicity seen at the Limit-Dose in a 21-day dermal toxicity study in rabbits. This risk assessment is not required.	
Intermediate-Term (Dermal)	Not Applicable	No dermal or systemic toxicity seen at the Limit-Dose in a 21-day dermal toxicity study in rabbits. This risk assessment is not required.	
Long-Term (Dermal) [a,b] Non-Cancer	Oral NOEL=6.1	Histopathological lesions in the male reproductive system and the adrenal glands in both sexes.	Combined Chronic Toxicity/ Carcinogenicity-Rat
Long-Term (Dermal) [a] Cancer	Q_1*= 4.39×10^{-2}	Iprodione is classified as a "Likely" human carcinogen with a low-dose extrapolation approach for human risk assessment.	
Short-Term (Inhalation)[a,b]	Oral Developmental NOEL=20 UF=100 and 3x for FQPA	Decreased anogenital distance in male pups.	Developmental-Rat
Intermediate-Term (Inhalation)[a,b]	Oral NOEL=6.1 UF=100 and 3x for FQPA	Histopathological lesions in the male reproductive system and the adrenal glands in both sexes.	Combined Chronic Toxicity/ Carcinogenicity-Rat
Long-Term (Inhalation)	Not Applicable	Based on the use pattern, there is no concern for exposure or risk. This risk assessment is not required.	

a = Appropriate route-to-route extrapolation should be performed (i.e., a dermal absorption factor of 5% and an inhalation absorption factor of 100% used for conversion to oral equivalent doses and then compared to the oral NOELs).
b = MOE=100 for occupational exposure.

3. Occupational and Residential Exposure and Risk Assessment

a. Occupational-use sites

Iprodione has been registered for occupational-use on commercial/industrial lawns, golf course turf, ornamentals and shade trees, ornamental herbaceous plants, ornamental woody shrubs and vines, and food crops. The occupational crops use sites have been grouped as follows:

- *Agricultural Crops*:, including almonds, apricots, cherries, nectarines, peaches, pecans, plums, prunes, beans (dried, lima, and snap), blackberries, blueberries, broccoli, bushberries, caneberries, carrots, garlic, grapes, ginseng, gooseberries, huckleberries, lettuce (head and leaf), loganberries, mustard cabbage, Chinese cabbage, dry bulb onions, peanuts, potatoes, raspberries, and strawberries.

- *Ornamentals:* including flowering trees and shrubs, woody shrubs and vines, evergreens, flowering and nonflowering plants, ground covers and shade trees.

- *Turfgrass:* including sod farms, golf courses and institutional lawn areas of bentgrass, blue grass, Bermuda grass, St. Augustine grass, rye grass, fine fescue or tall fescue.

b. Residential-use sites

Potential residential and non-occupational use sites may include residential sites (e.g., exposure to fungicide use on fruit and vegetable gardens, ornamentals, and turfgrass), professional uses at residential sites (e.g., fungicide use on trees, shrubs, and other ornamentals, application to lawns), and other sites where non-occupational exposure may occur (e.g., turfgrass in golf courses, parks, residential and recreational areas). The non-occupational crops use sites have been grouped as follows:

- *Fruit/Nut Trees:* including almonds, apricots, cherries, nectarines, peaches, and plums**.**

- *Small Fruit/Vegetable Garden Crops:* including beans (dried, lima, and snap), blackberries, blueberries, broccoli, bushberries, caneberries, carrots, garlic, grapes, ginseng, gooseberries, huckleberries, lettuce (head and leaf), loganberries, mustard cabbage, Chinese cabbage, dry bulb onions, peanuts, potatoes, raspberries, and strawberries.

- *Ornamentals at Residences:* including shade trees, evergreens and flowering and non-flowering shrubs.

- *Turfgrass:* including residential lawn areas.

c. Occupational Exposures & Risks

EPA has determined, based on current use patterns, that there are potential exposures to workers handling iprodione products, as well as to workers who come into contact with treated surfaces following applications of iprodione products.

(1) Handler Exposures & Risks

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with iprodione.

(2) Handler Exposure Scenarios

Based on the use patterns, 19 major handler exposure scenarios were identified for iprodione: (1a) mixing, loading liquids for aerial/chemigation application; (1b) mixing, loading liquids for groundboom application; (1c) mixing, loading liquids for orchard airblast sprayer application; (1d) mixing, loading liquids for professional application to turfgrass/ornamentals using a low pressure/high volume handgun; (2a) mixing, loading wettable powder for aerial/chemigation application; (2b) mixing, loading wettable powder for groundboom application; (2c) mixing, loading wettable powder for orchard airblast sprayer application; (2d) mixing, loading wettable powder for professional applicator to turfgrass/ornamentals using a low pressure/high volume handgun; (3a) mixing, loading dry flowables for chemigation application; (3b) mixing, loading dry flowables for groundboom application; (4) loading granulars for tractor-drawn spreader application;(5) applying sprays with fixed-wing aircraft; (6) applying sprays with a helicopter; (7) applying sprays using a groundboom sprayer; (8) applying to orchards with an airblast sprayer; (9) applying with a low pressure/high volume handgun to turfgrass/ornamentals; (10) applying granulars with a tractor-drawn spreader; (11) mixing, loading, applying sprays using a low pressure hand wand; (12) mixing, loading, applying sprays using a high pressure hand wand (13) mixing, loading, applying sprays using a backpack sprayer; (14) loading/ applying granulars using a belly grinder; (15) loading/ applying granulars with a push-type granular spreader; (16) mixing, loading, applying as a seed soak treatment; (17) mixing, loading, applying as a commercial seed treatment in slurry form; (18) mixing, loading, applying solutions as a dip treatment; and (19) flagging during aerial spray application.

(3) Handler Exposure Scenarios -- Data and Assumptions

No chemical-specific handler exposure data were submitted in support of the reregistration of iprodione. Therefore, an exposure assessment was developed for scenarios where appropriate surrogate data are available, using the *Pesticide Handlers Exposure Database (PHED) Version 1.1* (USEPA 1997d). Table 6 summarizes the caveats and parameters specific to the surrogate data used for each scenario and corresponding exposure/risk assessment. These caveats include the source of the data and an assessment of the overall quality of the data. The assessment of data quality is based on the number of observations and the available quality control data. The quality control data are based on a grading criteria established by the PHED task force.

The following assumptions and factors were used in order to complete this exposure assessment:

- Average body weight of an adult handler is 70 kg. This body weight is used in the intermediate-term inhalation and cancer assessments. A body weight of 60 kg is used in the short-term inhalation assessment because the NOEL is based on a developmental effect.

- Average work day interval represents an 8 hour workday (e.g., the acres treated or volume of spray solution prepared in a typical day).
- Daily acres and volumes (as appropriate) to be treated in each scenario. These are based on the ORE Science Advisory Council estimates of areas treated per day for the broad categories of application methods and equipment considered. They include:
  - -- 350 acres for aerial and chemigation applications in agricultural settings and to turfgrass (including flaggers supporting aerial applications)
  - -- 80 acres for groundboom spraying of agricultural areas, sod farms, and ornamental field stock
  - -- 80 acres for tractor-drawn spreader application to turfgrass
  - -- 40 acres for orchard airblast application
  - -- 5 acres for application to turfgrass using a low pressure/high volume handgun and to turf and ornamentals with a low pressure handwand and to turf with a high pressure handwand
  - -- 5 acres for application of granular formulations to turfgrass using a push-type spreader or belly grinder (e.g., golf courses)
  - -- 40 gallons of spray to turf and ornamentals using a low pressure handwand or backpack sprayer
  - -- 1,000 gallons of spray to ornamentals using a high pressure handwand

- For drench treatments no PHED data were available; thus, as a surrogate, the PHED unit exposure data for groundboom spray was used to calculate dermal and inhalation exposure.

- Calculations are completed at the maximum application rates for specific crops recommended by the available iprodione labels to bracket risk levels associated with the various use patterns. No data were provided concerning the "typical" application rates used for iprodione.

- Due to a lack of scenario-specific data, EPA often must calculate unit exposure values using generic protection factors (PF) to represent various risk mitigation options (i.e., the use of personal protective equipment (PPE) and engineering controls). PPE protection factors include those representing a double layer of clothing (50 percent PF for body exposure), chemical resistant gloves (90 percent PF for hand exposure), and respiratory protection (80 percent PF for use of dust/mist mask). Engineering controls are generally assigned a PF of 80 percent.

(4) Handler Exposure and Non-Cancer Risk Estimates

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an acceptable margin of exposure (assumed to be MOE 100 or greater) or cancer risk (1.0E-4 to 1.0E-6 for workers). The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, and no chemical-resistant gloves. The following

tables present exposure and risk estimates for the handling of iprodione. Table 7 presents the short-term and intermediate-term inhalation risks at baseline. Table 8 presents the PPE-level risks for those scenarios where MOEs are less than 100 at baseline. Table 9 presents the short-term and intermediate-term inhalation risks for water soluble bag formulations and applications employing closed cockpit aircraft.

In calculations of short-term and intermediate-term inhalation risks, potential daily exposures were calculated using the following formula:

$$Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure\left(\frac{\mu g\ ai}{lb\ ai}\right) x\ Conversion\ Factor\left(\frac{1mg}{1{,}000\ \mu g}\right) x\ Use\ Rate\left(\frac{lb\ ai}{A}\right) x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

The potential baseline short-term and intermediate-term inhalation doses were calculated using the following formulas:

$$Short\text{-}term\ Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Short\text{-}term\ Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

For iprodione, the short-term inhalation dose was calculated using a 60 kg body weight, while the intermediate-term inhalation dose uses a 70 kg body weight in the calculations. An inhalation absorption rate of 100 percent was used in the calculations.

$$Intermediate\text{-}term\ Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Intermediate\text{-}term\ Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

For iprodione, the short-term inhalation MOE was calculated using a NOEL of 20 mg/kg/day, and the intermediate-term inhalation MOE was calculated using a NOEL of 6.1 mg/kg/day. The baseline short-term and intermediate-term inhalation MOEs were calculated using the following formulas:

$$Short\text{-}term\ Inhalation\ MOE = \frac{Short\text{-}term\ NOEL\left(\frac{mg}{kg/day}\right)}{Short\text{-}term\ Inhalation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

$$Intermediate\text{-}term\ Inhalation\ MOE = \frac{Intermediate\text{-}term\ NOEL\left(\frac{mg}{kg/day}\right)}{Intermediate\text{-}term\ Inhalation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Table 6. Exposure Scenario Descriptions for the Use of Iprodione

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations (1a/1b/1c/1d)	PHED V1.1	350 acres for aerial, 350 acres for chemigation of sod farms and agriculture, 100 acres for chemigation of ornamental nurseries, 80 acres for groundboom in agriculture, ornamental nurseries and turfgrass. 40 acres for orchard airblast applications and 5 acres for treatment of ornamentals and turf when using a low pressure/high volume handgun	**Baseline:** Hand, dermal, and inhalation = AB grades. Hand = 53 replicates; Dermal = 72 to 122 replicates; and Inhalation = 85 replicates. High confidence in hand, dermal and inhalation data. No protection factor was needed to define the unit exposure value.
			PPE: The same dermal data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hands = AB grades. Hands = 59 replicates. High confidence in hands, dermal data.
			Engineering Controls: Mechanical transfer method. Hands, dermal and inhalation unit exposures = AB grades. Hands = 31 replicates; dermal = 16 to 22 replicates, and inhalation = 27 replicates. High confidence in dermal, hand and inhalation data. Gloves were worn during the use of the engineering controls.
Mixing/Loading Wettable Powders(2a/2b/2c/2d)	PHED V1.1	350 acres for aerial and chemigation of agriculture, 80 acres for groundboom in agriculture, 40 acres for orchard airblast applications	**Baseline:** Hands, dermal and inhalation = ABC grades. Hands = 7 replicates, dermal = 22-45 replicates and inhalation = 44 replicates. Low confidence in dermal, hands data due to the low number of hand replicates. Medium confidence in inhalation data.
			PPE: Gloved data for hands = ABC grades. Hands = 24 replicates. Medium confidence in hands data. Dermal values calculated by applying a 50% protection factor to baseline values to account for an additional layer of clothing. A 5-fold PF (e.g. 80% PF was applied to the baseline inhalation data).
			Engineering Controls: Water soluble bags. Dermal and hand data = AB grades. Inhalation = All grade. Inhalation = 15 replicates, dermal = 6-15 replicates and hands = 5 replicates. Low confidence in the dermal, hands and inhalation data.
Mixing/Loading Dry Flowable Formulations (3a and 3b)	PHED V1.1	350 acres for chemigation of turfgrass, 80 acres for groundboom application to ornamentals, turfgrass and tractor-drawn spreader application to turfgrass	**Baseline**: Hands, dermal and inhalation = AB grades. Low confidence in hands, dermal data. High confidence in inhalation data. Hand = 7 replicates, dermal = 16-26 replicates and inhalation = 23 replicates.
			PPE: Gloved data for hands = AB grade. High confidence in hands data. Hands = 21 replicates. Dermal values calculated by applying a 50% protection factor to baseline values to account for an additional layer of clothing. A 5-fold PF (e.g. 80% PF was applied to the baseline inhalation data.
			Engineering Controls: Based on scenario for wettable powders (water soluble bags). See above scenario.
Loading Granular Formulations (4)	PHED V1.1	80 acres for tractor drawn spreaders for turfgrass	**Baseline:** Hands = All grade, dermal = ABC grade, and inhalation = AB grade. Hands = 10 replicates; dermal = 33 to 78 replicates; and inhalation = 58 replicates. Low confidence in dermal/ hand data. High confidence in inhalation data.
			PPE: Baseline assessment sufficient
			Engineering Controls: Baseline assessment sufficient
Applicator Descriptors			
Applying Sprays with a Fixed-Wing Aircraft (5)	PHED V1.1	350 acres for aerial	**Baseline:** No data
			PPE: No data
			Engineering Controls: Hands = AB grade, dermal and inhalation = ABC grade. Medium confidence in hands/dermal and inhalation data. Hands = 34 replicates, dermal = 24-48 replicates, and inhalation = 23 replicates.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Applying Sprays with a Helicopter (6)	PHED V1.1	350 acres for aerial	**Baseline:** No data
			PPE: No data
			Engineering Controls: Hands and inhalation = A grade, dermal = C grade. Low confidence in inhalation data, and extremely low confidence in hands and dermal data due to very low number of replicates. Hands = 2 replicates, dermal = 3 replicates, and inhalation = 3 replicates.
Applying Sprays with a Groundboom Sprayer (7)	PHED V1.1	80 acres in agricultural, ornamental and turfgrass settings	**Baseline:** Hand, dermal, and inhalation = AB grades. Hands = 29 replicates, dermal = 23 to 42 replicates, and inhalation = 22 replicates. High confidence in hand, dermal, and inhalation data.
			PPE: Baseline assessment sufficient
			Engineering Controls: Baseline assessment sufficient
Applying to Orchards with an Airblast Sprayer (8)	PHED V1.1	40 acres for orchard spraying	**Baseline**: Hand, dermal and inhalation are AB grade. Hands 22 replicates, dermal = 32 to 49 replicates, and inhalation = 47 replicates. High confidence in hand, dermal and inhalation data.
			PPE: Baseline assessment sufficient
			Engineering Controls: Baseline assessment sufficient
Applying with a Low Pressure/High Volume Handgun to Turfgrass (9)	PHED V1.1	5 acres for turfgrass	**Baseline:** No hand data. See PPE. Inhalation data are AB grades with 14 replicates and low to medium confidence.
			PPE: Dermal and inhalation data are C grade with low confidence. Hands = 14 replicates; dermal = 0-14 replicates.
			Engineering Controls: Not feasible.
Applying Granulars with a Tractor-Drawn Spreader (10)	PHED V1.1	80 acres for turfgrass	**Baseline:** Hands, dermal and inhalation = AB grades. Low confidence in hands, dermal and inhalation data. Hands = 5 replicates, dermal = 1-5 replicates and inhalation = 5 replicates.
			PPE: Baseline assessment sufficient
			Engineering Controls: Baseline assessment sufficient
Mixer/Loader/Applicator Descriptors			
Mixing/Loading/Applying with a Low Pressure Handwand (11)	PHED V1.1	5 acres for turfgrass application and 40 gallons for turf and ornamental use	**Baseline:** Dermal and inhalation = ABC grade, hands = All grades. Low confidence in hands/dermal data. Medium confidence in inhalation data. Hands =70 replicates, dermal =9-80 replicates and inhalation =80 replicates.
			PPE: Hands = ABC grade with 10 replicates. Low confidence in dermal/hand data. The same dermal data are used as for the baseline.
			Engineering Controls: Not feasible
Mixing/Loading/Applying with a High Pressure Handwand (12)	PHED V1.1	1,000 gallons for ornamentals and 5 acres for agricultural settings.	**Baseline:** Dermal = AB grades, inhalation = A grade. Dermal = 7-13 replicates; inhalation = 13 replicates. Gloved data was used to calculate the no gloved hand data, assuming gloves provide 90% protection. Hands = C grade with 13 replicates. Low confidence in hand, dermal, and inhalation data. Baseline data includes use of chemical-resistant gloves.
			PPE: The same dermal data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hands data = C grade with 13 replicates. Low confidence in hand and dermal data. A 5-fold PF (e.g. 80% PF) was applied to the baseline inhalation data.
			Engineering Controls: Not feasible

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixing/Loading/Applying with a Backpack Sprayer (13)	PHED V1.1	5 acres for turf use, and 40 gallons for turf and ornamental use	**Baseline:** No hands data. See PPE. Inhalation = A grade, with 11 replicates and low confidence.
			PPE: Dermal = AB grades. Hands = C grade. Dermal = 9-11 replicates, hands = 11 replicates. 80% PF was applied to baseline inhalation data to account for use of dust mist respirator.
			Engineering Controls: Not feasible.
Loading/Applying Granulars Using a Belly Grinder (14)	PHED V1.1	5 acres for turfgrass application	**Baseline:** Hands and dermal = ABC grades and inhalation = AB grade. Medium confidence in hands/dermal data and high confidence in inhalation data. Hands = 23 replicates, dermal = 29-45 replicates and inhalation = 40 replicates.
			PPE: = Gloved data for hands = All grades with 20 replicates. Low confidence in hand data. The dermal data are taken from the baseline coupled with a 50% protection factor to account for an additional layer of clothing. A 5-fold protection factor (80% PF) was applied to baseline inhalation data to account for use of dust mist respirator.
			Engineering Controls: Not feasible
Loading/Applying Using a Push-Type Granular Spreader (15)	PHED V1.1	5 acres for turfgrass application	**Baseline:** Hand and dermal = C grades, and inhalation = B grade. Hand = 15 replicates, dermal = 0-15 replicates, and inhalation = 15 replicates. Low confidence in hand and dermal data, and high confidence in inhalation data.
			PPE: The same dermal and hand data are used as for the baseline coupled with a 90% protection factor to account for the use of chemical resistant gloves.
			Engineering Controls: Not feasible.
Flagging Spray Applications (19)	PHED V1.1	350 acres	**Baseline:** Hands, dermal and inhalation data = AB grades. High confidence in dermal, hands and inhalation. Hands = 30 replicates, Inhalation = 28 replicates, and dermal = 18-28 replicates.
			PPE: Baseline assessment sufficient
			Engineering Controls: Baseline assessment sufficient

[a] All *Standard Assumptions* are based on an 8-hour work day as estimated by EPA.

[b] All handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:
High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = any run that included D or E grade data or has less than 15 replicates per body part.

Table 7. Occupational Short-term and Intermediate-term Inhalation Risks from Iprodione at Baseline

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (μg/lb ai)	Range of Application Rates[b] (lb ai/A)	Crop Type or Target[c]	Amount Handled per Day[d]	Baseline Daily Inhalation Exposure[e] (mg/day)	Short-term Baseline Daily Inhalation Dose[f] (mg/kg/day)	Int.-term Baseline Daily Inhalation Dose[g] (mg/kg/day)	Baseline Short-term Inhalation MOE[h] (mg/day)	Baseline Int.-term Inhalation MOE[i] (mg/day)
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	1.2	0.5 lb ai/A	Ag	350 acres	0.21	0.0035	0.0030	5,700	2,000
		1 lb ai/A			0.42	0.0070	0.0060	2,900	1,000
		5.5 lb ai/A	Turf		2.3	0.038	0.033	530	180
		1.4 lb ai/A	Ornamentals	100 acres	0.17	0.0028	0.0024	7,100	2,500
Mixing/Loading Liquids for Groundboom Application (1b)	1.2	0.27 lb ai/A	Ag	80 acres	0.026	0.00043	0.00037	47,000	16,000
		0.5 lb ai/A			0.048	0.00080	0.00069	25,000	8,800
		1 lb ai/A			0.096	0.0016	0.0014	13,000	4,400
		1.4 lb ai/A	Ornamentals	80 acres	0.13	0.0022	0.0019	9,100	3,200
		4 lb ai/A			0.38	0.0063	0.0054	3,200	1,100
		5.5 lb ai/A	Turf		0.53	0.0088	0.0076	2,300	800
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	1.2	0.5 lb ai/A	Ag	40 acres	0.024	0.00040	0.00034	50,000	18,000
		1 lb ai/A			0.048	0.00080	0.00069	25,000	8,800
Mixing/Loading Liquids for Professional Application to Turf Using a Low Pressure/High Volume Handgun (1d)	1.2	1.4 lb ai/A	Ornamentals	5 acres	0.0084	0.00014	0.00012	140,000	51,000
		5.5 lb ai/A	Turf		0.033	0.00055	0.00047	36,000	13,000
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	43	0.5 lb ai/A	Ag	350 acres	7.5	0.13	0.11	150	55
		1 lb ai/A			15.0	0.25	0.21	80	29
Mixing/Loading Wettable Powder for Groundboom Application (2b)	43	0.5 lb ai/A	Ag	80 acres	1.7	0.028	0.024	710	250
		1 lb ai/A			3.4	0.057	0.049	350	120
Mixing/Loading Wettable Powder for Orchard Airblast Sprayer Application (2c)	43	0.5 lb ai/A	Ag	40 acres	0.86	0.014	0.012	1,400	510
		1 lb ai/A			1.7	0.028	0.024	710	250
Mixing/Loading Wettable Powder for Professional Application to Turf using a Low pressure/High Volume Handgun (2d)	43	1.4 lb ai/A	Ornamental	5 acres	0.30	0.0050	0.0043	4,000	1,400
		5.5 lb ai/A	Turf		1.2	0.020	0.017	1,000	360
Mixing/Loading Dry Flowable for Chemigation Application (3a)	0.77	5.5 lb ai/A	Turf	350 acres	1.5	0.025	0.021	800	290
Mixing/Loading Dry Flowable Groundboom Application (3b)	0.77	1 lb ai/A	Ornamentals	80 acres	0.062	0.0010	0.00089	20,000	6,900
		5.5 lb ai/A	Turf	80 acres	0.34	0.0057	0.0049	3,500	1,200
Loading Granulars for Tractor-Drawn Spreader Application (4)	1.7	0.68 lb ai/A	Turf	80 acres	0.092	0.0015	0.0013	13,000	4,700
		1.4 lb ai/A			0.19	0.0032	0.0027	6,300	2,300
		4.1 lb ai/A			0.56	0.0093	0.0080	2,200	760
Applicator Exposure									
Applying Sprays with a Fixed-Wing Aircraft (5)	No Data See Eng. Con.	0.5 lb ai/A	Ag	350 acres	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
		1 lb ai/A			See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (μg/lb ai)	Range of Application Rates[b] (lb ai/A)	Crop Type or Target[c]	Amount Handled per Day[d]	Baseline Daily Inhalation Exposure[e] (mg/day)	Short-term Baseline Daily Inhalation Dose[f] (mg/kg/day)	Int.-term Baseline Daily Inhalation Dose[g] (mg/kg/day)	Baseline Short-term Inhalation MOE[h] (mg/day)	Baseline Int.-term Inhalation MOE[i] (mg/day)
Applying Sprays with a Helicopter (6)	No Data See Eng. Con.	0.5 lb ai/A	Ag	350 acres	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
		1 lb ai/A			See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
Applying Sprays with a Groundboom Sprayer (7)	0.74	0.27 lb ai/A	Ag	80 acres	0.016	0.00027	0.00023	74,000	27,000
		0.5 lb ai/A			0.030	0.00050	0.00043	40,000	14,000
		1 lb ai/A			0.059	0.00098	0.00084	20,000	7,300
		1.4 lb ai/A	Ornamentals	80 acres	0.083	0.0014	0.0012	14,000	5,100
		4 lb ai/A			0.24	0.0040	0.0034	5,000	1,800
		5.5 lb ai/A	Turf	80 acres	0.33	0.0055	0.0047	3,600	1,300
Applying to Orchards with an Airblast Sprayer (8)	4.5	0.5 lb ai/A	Ag	40 acres	0.090	0.0015	0.0013	13,000	4,700
		1 lb ai/A			0.18	0.0030	0.0026	6,700	2,300
Applying with a Low Pressure/High Volume Handgun to Turfgrass (9)	1.4	1.4 lb ai/A	Ornamentals	5 acres	0.0098	0.00016	0.00014	120,000	44,000
		5.5 lb ai/A	Turf		0.039	0.00064	0.00055	31,000	11,000
Applying Granulars with a Tractor-Drawn Spreader (10)	1.2	0.68 lb ai/A	Turf	80 acres	0.065	0.0011	0.00093	18,000	6,600
		1.4 lb ai/A			0.13	0.0022	0.0019	9,100	3,200
		4.1 lb ai/A			0.39	0.0065	0.0056	3,100	1,100
Mixer/Loader/Applicator Exposure									
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (11)	30	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	0.0024	0.000040	0.000034	500,000	180,000
		0.01 lb ai/gal			0.012	0.00020	0.00017	100,000	36,000
		5.5 lb ai/A	Turf	5 acres	0.83	0.014	0.012	1,400	510
Mixing/Loading/Applying Sprays with a High Pressure Handwand (12)	120	0.5 lb ai/A	Ag	5 acres	0.30	0.0050	0.0043	4,000	1,400
		1 lb ai/A			0.60	0.010	0.0086	2,000	710
		0.002 lb ai/gal	Ornamentals	1,000 gallons	0.24	0.0040	0.0034	5,000	1,800
		0.01 lb ai/gal			1.2	0.020	0.017	1,000	360
Mixing/Loading/Applying Using a Backpack Sprayer (13)	30	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	0.0024	0.000040	0.000034	500,000	180,000
		0.01 lb ai/gal			0.012	0.00020	0.00017	100,000	36,000
		5.5 lb ai/A	Turf	5 acres	0.83	0.014	0.012	1,400	510
Loading/Applying Granulars Using a Belly Grinder (14)	62	0.68 lb ai/A	Turf	5 acres	0.21	0.0035	0.0030	5,700	2,000
		1.4 lb ai/A			0.43	0.0072	0.0061	2,800	1,000
		4.1 lb ai/A			1.3	0.022	0.019	910	320
Loading/Applying Using a Push-Type Granular Spreader (15)	6.3	0.68 lb ai/A	Turf	5 acres	0.0021	0.000035	0.000030	57,000	20,000
		1.4 lb ai/A			0.044	0.00073	0.00063	27,000	9,700
		4.1 lb ai/A			0.13	0.0022	0.0019	9,100	3,200
Mixing/Loading/Applying as a Seed Soak Treatment (16)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (μg/lb ai)	Range of Application Rates[b] (lb ai/A)	Crop Type or Target[c]	Amount Handled per Day[d]	Baseline Daily Inhalation Exposure[e] (mg/day)	Short-term Baseline Daily Inhalation Dose[f] (mg/kg/day)	Int.-term Baseline Daily Inhalation Dose[g] (mg/kg/day)	Baseline Short-term Inhalation MOE[h] (mg/day)	Baseline Int.-term Inhalation MOE[i] (mg/day)
Mixing/Loading/Applying as a Commercial Seed Treatment in Slurry Form (17)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading/Applying Solution as a Dip Treatment (18)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Exposure									
Flagging Spray Applications (19)	0.35	0.5 lb ai/A	Ag	350 acres	0.061	0.0010	0.00087	20,000	7,000
		1 lb ai/A			0.12	0.0020	0.0017	10,000	3,600

Footnotes:

a Baseline inhalation unit exposure reflects no respiratory protection.

b Application rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops. For example:
(1) 0.27 lb ai/A applies to the in-furrow spray treatment of cotton during planting [EPA Reg. No. 264-482, 264-453].
(2) 0.5 lb ai/A applies to almonds, rice (aerial), Chinese mustard and dry bulb onions [EPA Reg. No. 264-482, 264-520].
(3) 1 lb ai/A applies to stone fruits, potatoes, peanuts, broccoli, lettuce and carrots [EPA Reg. 264-482].

c Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated. *Ag* = agricultural crops and *Turf* = turfgrass including sod-farms, institutional areas and golf courses. *Ornamentals* = includes greenhouse, field, landscape, and conifer nurseries.

d Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

e Baseline Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

f Short-term Baseline Daily Inhalation Dose (mg/kg/day) = Baseline Daily Inhalation Exposure (mg/day) / 60 (Body Weight).

g Intermediate-term Baseline Daily Inhalation Dose (mg/kg/day) = Baseline Daily Inhalation Exposure (mg/day) / 70 (Body Weight).

h Baseline Short-term Inhalation MOE (mg/day) = NOEL (20 mg/kg/day) / Short-term Baseline Inhalation Dose (mg/kg/day).

I Baseline Intermediate-term Inhalation MOE (mg/day) = NOEL (6.1 mg/kg/day) / Intermediate-term Baseline Inhalation Dose (mg/kg/day).

Table 8. Occupational Short-term and Intermediate-term Inhalation Risks from Iprodione with PPE(For Scenarios with MOE's <100 at Baseline)

Exposure Scenario (Scen. #)	PPE Inhalation Unit Exposure[a] (μg/lb ai)	Range of Application Rates[b] (lb ai/A)	Crop Type or Target[c]	Amount Handled per Day[d]	PPE Daily Inhalation Exposure[e] (mg/day)	Short-term PPE Daily Inhalation Dose[f] (mg/kg/day)	Int.-term PPE Daily Inhalation Dose[g] (mg/kg/day)	PPE Short-term Inhalation MOE[h] (mg/day)	PPE Int.-term Inhalation MOE[i] (mg/day)
Mixer/Loader Risk									
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	8.6	0.5 lb ai/A	Ag	350 acres	1.5	--	0.021	--	290
		1 lb ai/A			3.0	0.050	0.043	400	140

Footnotes:

a PPE Inhalation Unit Exposure values were calculated with a 5-fold protection factor (80% PF) applied to baseline PHED values. This reflects use of a dust mist respirator.

b Application Rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops. For example:
(1) 0.27 lb ai/A applies to the in furrow spray treatment of cotton during planting [EPA Reg. No. 264-482, 264-453].
(2) 0.5 lb ai/A applies to almonds, rice (aerial), Chinese mustard and dry bulb onions [EPA Reg. No. 264-482, 264-520].
(3) 1 lb ai/A applies to stone fruits, potatoes, peanuts, broccoli, lettuce and carrots [EPA Reg. 264-482].

c Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated. *Ag* = agricultural crops and *Turf* = turfgrass including sod-farms, institutional areas and golf courses. *Ornamentals* = includes greenhouse, field, landscape, and conifer nurseries.

d Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

e PPE Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

f Short-term PPE Daily Inhalation Dose (mg/kg/day) = PPE Daily Inhalation Exposure (mg/day) / 60 (Body Weight).

g Intermediate-term PPE Daily Inhalation Dose (mg/kg/day) = PPE Daily Inhalation Exposure (mg/day) / 70 (Body Weight).

h PPE Short-term Inhalation MOE (mg/day) = NOEL (20 mg/kg/day) / Short-term PPE Inhalation Dose (mg/kg/day).

I PPE Intermediate-term Inhalation MOE (mg/day) = NOEL (6.1 mg/kg/day) / Intermediate-term PPE Inhalation Dose (mg/kg/day).

Table 9. Occupational Short-term and Intermediate-term Inhalation Risks from Iprodione with Engineering Controls - Water Soluble-Packets and Enclosed Cab Aerial Application[k]

Exposure Scenario (Scen. #)	Range of Application Rates[a] (lb ai/A)	Crop Type or Target[b]	Amount Handled per Day[c]	Engineering Controls[i]				
				Inhalation Unit Exposure[d] (μg/lb ai)	Short-term Daily Inhalation Dose[e] (mg/kg/day)	Short-term MOE[f] (mg/day)	Int.-term Daily Inhalation Dose[g] (mg/kg/day)	Int.-term MOE[h] (mg/day)
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	0.5 lb ai/A	Ag	350 acres	0.24	0.00070	29,000	0.00060	10,000
	1 lb ai/A				0.0014	14,000	0.0012	5,100
Mixing/Loading Wettable Powder for Groundboom Application (2b)	0.5 lb ai/A	Ag	80 acres	0.24	0.00016	130,000	0.00014	44,000
	1 lb ai/A				0.00032	63,000	0.00027	23,000
Mixing/Loading Wettable Powder for Orchard Airblast Sprayer Application (2c)	0.5 lb ai/A	Ag	40 acres	0.24	0.000080	250,000	0.000069	88,000
	1 lb ai/A				0.00016	130,000	0.00014	44,000
Mixing/Loading Wettable Powder for Professional Application to Turfgrass using a Low Pressure/ High Volume Handgun (2d)	1.4 lb ai/A	ornamentals	5 acres	0.24	0.000028	710,000	0.000024	250,000
	5.5 lb ai/A	turf			0.00011	180,000	0.000094	65,000
Applicator Risk								
Applying Sprays with a Fixed-wing Aircraft (5)	0.5 lb ai/A	Ag	350 acres	0.068	0.00020	100,000	0.00017	36,000
	1 lb ai/A				0.00040	50,000	0.00034	18,000
Applying Sprays with a Helicopter (6)	0.5 lb ai/A	Ag	350 acres	0.0018	0.0000053	3,800,000	0.0000045	1,400,000
	1 lb ai/A				0.000011	1,800,000	0.0000090	680,000

Footnotes:

a Application rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops. For example:
(1) 0.27 lb ai/A applies to the in furrow spray treatment of cotton during planting [EPA Reg. No. 264-482, 264-453].
(2) 0.5 lb ai/A applies to almonds, rice (aerial), Chinese mustard and dry bulb onions [EPA Reg. No. 264-482, 264-520].
(3) 1 lb ai/A applies to stone fruits, potatoes, peanuts, broccoli, lettuce and carrots [EPA Reg. 264-482].

b Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated.

c Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

d Unit Exposure values are taken from PHED V1.1

e Short-term Daily Inhalation Dose = Inhalation Unit Exposure (ug/lb ai) * Application Rate (lb ai/A) * Amount Handled per Day (acres/day)/Body Weight (60 kg).

f Short-term MOE = NOEL (20 mg/kg/day)/Short-term Daily Inhalation Dose (mg/kg/day).

g Intermediate-term Daily Inhalation Dose = Inhalation Unit Exposure (ug/lb ai) * Application Rate (lb ai/A) * Amount Handled per Day (acres/day)/Body Weight (70 kg).

h Intermediate-term MOE = NOEL (6.1 mg/kg/day)/Intermediate-term Daily Inhalation Dose (mg/kg/day).

I Engineering Controls = 2a, 2b, 2c water soluble bags; 5,6 enclosed cockpit.

j This assessment includes assessments for those scenarios which are currently packaged or applied with engineering controls.

d. Handler Exposure and Risk Estimates for Cancer

Handler exposure assessments were completed by EPA using a baseline exposure scenario and, as needed, increasing levels of risk mitigation (PPE and engineering controls) to achieve acceptable cancer risks. Tables 10, 11, and 12 present total cancer risk calculations at baseline, with PPE and with engineering controls, respectively, for each exposure scenario.

The calculations of daily dermal and inhalation exposure to iprodione by handlers were used to calculate the daily dose, and hence the risks, to those handlers. Potential daily dermal exposure was calculated using the following formula:

$$Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure\left(\frac{mg\ ai}{lb\ ai}\right) x\ Use\ Rate\left(\frac{lb\ ai}{A}\right) x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

Potential daily inhalation exposure was calculated using the following formula:

$$Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) =$$
$$Unit\ Exposure\left(\frac{\mu g\ ai}{lb\ ai}\right) x\ Conversion\ Factor\left(\frac{1mg}{1{,}000\ \mu g}\right) x\ Use\ Rate\left(\frac{lb\ ai}{A}\right) x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

The daily dermal and inhalation doses were calculated using a 70 kg body weight using the following formulas:

$$Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

$$Daily\ Dermal\ Dose\left(\frac{mg\ ai}{Kg/Day}\right) = Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{Day}\right) x\left(\frac{1}{Body\ Weight\ (Kg)}\right) x\ 0.05\ Dermal\ Absorption\ Factor$$

$$Total\ Daily\ Dose = Daily\ Dermal\ Dose\left(\frac{mg}{kg/day}\right) + Daily\ Inhalation\ Dose\left(\frac{mg}{kg/day}\right)$$

The lifetime average daily dose (LADD) was calculated using the following formula:

$$LADD\left(\frac{mg}{kg/day}\right) = Daily\ Total\ Dose\left(\frac{mg}{kg/day}\right) x\left(\frac{days\ worked}{365\ days\ per\ year}\right) x\left(\frac{35\ years\ worked}{70\ year\ lifetime}\right)$$

Total cancer risk was calculated using the following formula:

$$Total\ Cancer\ Risk = LADD \times Q1^{*}$$

where Q_1^{*} = 4.39 E-02

The following assumptions and factors were used in order to complete this cancer risk assessment:

- The average body weight of 70 kg is used, representing a typical adult.
- Exposure time is assumed to be 8 hours per day. This represents a typical work day.
- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years (USEPA 1997, Exposure Factors Handbook).
- Dermal absorption is assumed to be 5 percent, and inhalation absorption is assumed to be 100 percent (UISEPA 1997a, USEPA 1998). The doses were added together to represent total daily dose.
- The $Q1^{*}$ used in the cancer assessment was 4.39×10^{-2}.
- Two exposure frequencies were used in the calculations, the first represented the maximum number of applications per site per season to represent private use, and the second frequency applied a factor of 10 to the first frequency to represent commercial handlers making multiple applications per site per season. These are high-end values.

Table 10. Occupational Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione at Baseline

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Daily Dermal Exposure[f] (mg/day)	Daily Inhalation Exposure[g] (mg/day)	Baseline Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	Baseline LADD[j] (mg/kg/day)	Baseline Total Cancer Risk[k]
Mixer/Loader Risk											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	2.9	1.2	0.5 lb ai/A	Ag	350 acres	510	0.21	0.37	10 / 100	5.1E-3 / 5.1E-2	2.2E-4 / 2.2E-3
			1 lb ai/A			1,000	0.42	0.73	4 / 40	4.0E-3 /4.0E-2	1.8E-4 / 1.8E-3
			5.5 lb ai/A	Turf		5,600	2.3	4.0	6 / 60	3.3E-2 / 3.3E-1	1.4E-3 / 1.4E-2
			1.4 lb ai/A	Ornamentals	100 acres	410	0.17	0.29	8 / 80	3.3E-3 / 3.3E-2	1.4E-4 / 1.4E-3
Mixing/Loading Liquids for Groundboom Application (1b)	2.9	1.2	0.27 lb ai/A	Ag	80 acres	63	0.026	0.045	1 / 10	6.2E-5 / 6.2E-4	2.7E-6 / 2.7E-5
			0.5 lb ai/A			120	0.048	0.084	10 / 100	1.2E-3 / 1.2E-2	5.3E-5 / 5.3E-4
			1 lb ai/A			230	0.096	0.17	10 / 100	2.3E-3 / 2.3E-2	1.0E-4 / 1.0E-3
			1.4 lb ai/A	Ornamentals	80 acres	320	0.13	0.23	8 / 80	2.5E-3 / 2.5E-2	1.1E-4 / 1.1E-3
			4 lb ai/A			930	0.38	0.67	8 / 80	7.3E-3 / 7.3E-2	3.2 E-4 / 3.2E-3
			5.5 lb ai/A	Turf		1,300	0.53	0.92	8 / 80	1.0E-2 / 1.0E-1	4.4E-4 / 4.4E-3
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	2.9	1.2	0.5 lb ai/A	Ag	40 acres	58	0.024	0.042	4 / 40	2.3E-4 / 2.3E-3	1.0E-5 / 1.0E-4
			1 lb ai/A			120	0.048	0.084	4 / 40	4.6E-4 / 4.6E-3	2.0E-5 / 2.0E-4
Mixing/Loading Liquids for Professional Application to Turf Using a Low Pressure/High Volume Handgun (1d)	2.9	1.2	1.4 lb ai/A	Ornamentals	5 acres	20	0.0084	0.015	8 / 80	1.6E-4 / 1.6E-3	7.0E-6 / 7.0E-5
			5.5 lb ai/A	Turf		80	0.033	0.057	6 / 60	4.8E-4 / 4.8E-3	2.1E-5 / 2.1E-4
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	3.7	43	0.5 lb ai/A	Ag	350 acres	650	7.5	0.57	10 / 100	7.8E-3 / 7.8E-2	3.4E-4 / 3.4E-3
			1 lb ai/A			1,300	15	1.1	4 / 40	6.0E-3 / 6.0E-2	2.6E-4 / 2.6E-3
Mixing/Loading Wettable Powder for Groundboomt Application (2b)	3.7	43	0.5 lb ai/A	Ag	80 acres	150	1.7	0.13	10 / 100	1.8E-3 / 1.8E-2	7.9E-5 / 7.9E-4
			1 lb ai/A			300	3.4	0.26	5 / 50	1.8E-3 / 1.8E-2	7.9E-5 / 7.-9E4
Mixing/Loading Wettable Powder for Orchard Airblast Sprayer Application (2c)	3.7	43	0.5 lb ai/A	Ag	40 acres	74	0.86	0.065	4 / 40	3.6E-4 / 3.6E-3	1.6E-5 / 1.6E-4
			1 lb ai/A			150	1.7	0.13	4 / 40	7.1E-4 / 7.1E-3	3.1E-5 / 3.1E-4
Mixing/Loading Wettable Powder for Professional Application to Turf using a Low Pressure/High Volume Handgun (2d)	3.7	43	1.4 lb ai/A	Ornamentals	5 acres	26	0.30	0.023	8 / 80	2.5 E-4 / 2.5 E-3	1.1 E-5 / 1.1 E-4
			5.5 lb ai/A	Turf		100	1.2	0.90	6 / 60	7.4 E-4 / 7.4 E-3	3.2 E-5 / 3.2 E-4
Mixing/Loading Dry Flowable for Chemigation Application (3a)	0.066	0.77	5.5 lb ai/A	Turf	350 acres	130	1.5	0.11	6 / 60	9.0E-4 / 9.0E-3	4.0E-5 / 4.0 E-4
Mixing/Loading Dry Flowable Groundboom Application (3b)	0.066	0.77	1 lb ai/A	Ornamentals	80 acres	5.3	0.062	0.0047	8 / 80	5.2E-5 /5.2E-4	2.3E-6 / 2.3E-5
			5.5 lb ai/A	Turf	80 acres	29	0.34	0.026	8 / 80	2.9E-4 / 2.9E-3	1.3E-5 / 1.3E-4
Loading Granulars for Tractor-Drawn Spreader Application (4)	0.0084	1.7	0.68 lb ai/A	Turf	80 acres	0.46	0.093	0.0016	8 / 80	1.8E-5 / 1.8E-4	7.9E-7 / 7.9E-6
			1.4 lb ai/A			0.94	0.19	0.0034	8 / 80	3.7E-5 / 3.7E-4	1.6E-6 / 1.6E-5
			4.1 lb ai/A			2.8	0.56	0.0099	8 / 80	1.1E-4 / 1.1E-3	4.8E-6 / 4.8E-5
Applicator Risk											
Applying Sprays with a Fixed-Wing Aircraft (5)	No Data See EC	No Data See EC	0.5 lb ai/A	Ag	350 acres	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
			1 lb ai/A			See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
Applying Sprays with a Helicopter (6)	No Data See EC	No Data See EC	0.5 lb ai/A	Ag	350 acres	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
			1 lb ai/A			See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Daily Dermal Exposure[f] (mg/day)	Daily Inhalation Exposure[g] (mg/day)	Baseline Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	Baseline LADD[j] (mg/kg/day)	Baseline Total Cancer Risk[k]
Applying Sprays with a Groundboom Sprayer (7)	014	0.74	0.27 lb ai/A	Ag	80 acres	0.30	0.016	4.4E-4	1 / 10	6.0E-7 / 6.0E-6	2.6E-8 / 2.6E-7
			0.5 lb ai/A			0.56	0.030	8.2E-4	10 / 100	1.1E-5 / 1.1E-4	4.8E-7 / 4.8E-6
			1 lb ai/A			1.1	0.059	0.0016	10 / 100	2.2E-5 / 2.2E-4	9.7E-7 / 9.7E-6
			1.4 lb ai/A	Ornamentals	80 acres	1.6	0.083	0.0023	8 / 80	2.5E-5 / 2.5E-4	1.1E-6 / 1.1E-5
			4 lb ai/A			4.5	0.24	0.0066	8 / 80	7.2E-5 / 7.2E-4	3.2E-6 / 3.2E-5
			5.5 lb ai/A	Turf	80 acres	6.2	0.33	0.0091	8 / 80	1.0E-4 / 1.0E-3	4.4E-6 / 4.4E-5
Applying to Orchards with an Airblast Sprayer (8)	0.36	4.5	0.5 lb ai/A	Ag	40 acres	7.2	0.090	0.0064	4 / 40	3.5E-5 / 3.5E-4	1.5E-6 / 1.5E-5
			1 lb ai/A			14	0.18	0.013	4 / 40	7.1E-5 / 7.1E-4	3.1E-6 / 3.1E-5
Applying with a Low Pressure/High Volume Handgun to Turfgrass (9)l	No Data (See PPE)	1.4	1.4 lb ai/A	Ornamentals	5 acres	NA	0.098	NA	8 / 80	NA	NA
			5.5 lb ai/A	Turf		NA	0.038	NA	8 / 80	NA	NA
Applying Granulars with a Tractor-Drawn Spreader (10)	0.0099	1.2	0.68 lb ai/A	Turf	80 acres	0.54	0.065	0.0013	8 / 80	1.4E-5 / 1.4E-4	6.1E-7 / 6.1E-6
			1.4 lb ai/A			1.1	0.13	0.0027	8 / 80	3.0E-5 / 3.0E-4	1.3E-6 / 1.3E-5
			4.1 lb ai/A			3.2	0.39	0.0079	8 / 80	8.7E-5 / 8.7E-4	3.8E-6 / 3.8E-5
Mixer/Loader/Applicator Exposure											
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (11)	100	30	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	8.0	0.0024	0.0057	8 / 80	6.3E-5 / 6.3E-4	2.8E-6 / 2.8E-5
			0.01 lb ai/gal			40	0.012	0.029	8 / 80	3.2E-4 / 3.2E-3	1.4E-5 / 1.4E-4
			5.5 lb ai/A	Turf	5 acres	2,800	0.83	2.0	8 / 80	2.2E-2 / 2.2E-1	9.7E-4 / 9.7E-3
Mixing/Loading/Applying Sprays with a High Pressure Handwand (12)	3.5	120	0.5 lb ai/A	Ag	5 acres	8.8	0.30	0.011	10 / 100	1.5E-4 / 1.5E-3	6.6E-6 / 6.6E-5
			1 lb ai/A			18	0.60	0.021	10 / 100	2.9E-4 / 2.9E-3	1.3E-5 / 1.3E-4
			0.002 lb ai/gal	Ornamentals	1,000 gallons	7.0	0.24	0.0084	8 / 80	9.2E-5 / 9.2E-4	4.0E-6 / 4.0E-5
			0.01 lb ai/gal			35	1.2	0.042	8 / 80	4.6E-4 / 4.6E-3	2.0E-5 / 2.0E-4
Mixing/Loading/Applying Using a Backpack Sprayer (13)	No Data See PPE	30	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	See PPE	0.0024	See PPE	8 / 80	See PPE	See PPE
			0.01 lb ai/gal				0.012		8 / 80		
			5.5 lb ai/A	Turf	5 acres	See PPE	See PPE	See PPE	8 / 80	See PPE	See PPE
Loading/Applying Granulars Using a Belly Grinder (14)	10	62	0.68 lb ai/A	Turf	5 acres	34	0.21	0.027	8 / 80	3.0E-4 / 3.0E-3	1.3E-5 / 1.3E-4
			1.4 lb ai/A			70	0.43	0.056	8 / 80	6.1E-4 / 6.1E-3	2.7E-5 / 2.7E-4
			4.1 lb ai/A			210	1.3	0.16	8 / 80	1.8E-3 / 1.8E-2	7.9E-5 / 7.9E-4
Loading/Applying Using a Push-Type Granular Spreader (15)	2.9	6.3	0.68 lb ai/A	Turf	5 acres	9.9	0.021	0.0073	8 / 80	8.0E-5 / 8.0E-4	3.5E-6 / 3.5E-5
			1.4 lb ai/A			20	0.044	0.015	8 / 80	1.6E-4 / 1.6E-5	7.2E-6 / 7.2E-5
			4.1 lb ai/A			59	0.13	0.044	8 / 80	4.8E-4 / 4.8E-3	2..1E-5 / 2.1E-4
Flagger Risk											
Flagging Spray Applications (19)	0.011	0.35	0.5 lb ai/A	Ag	350 acres	1.8	0.061	0.0021	10 / 100	2.9E-5 / 2.9E-4	1.3E-6 / 1.3E-5
			1 lb ai/A			3.5	0.12	0.0042	4 / 40	2.3E-5 / 2.3E-4	1.0E-6 / 1.0E-5

Footnotes:

a Baseline Dermal Unit Exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractors as appropriate.

b Baseline Inhalation Unit Exposure reflects no respiratory protection.

c Application rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops. For example:
(1) 0.27 lb ai/A applies to the in furrow spray treatment of cotton during planting [EPA Reg. No. 264-482, 264-453].

(2) 0.5 lb ai/A applies to almonds, rice (aerial), Chinese mustard and dry bulb onions [EPA Reg. No. 264-482, 264-520].
(3) 1 lb ai/A applies to stone fruits, potatoes, peanuts, broccoli, lettuce and carrots [EPA Reg. 264-482].

d Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated. *Ag* = agricultural crops and *Turf* = turfgrass including sod-farms, institutional areas and golf courses. *Ornamentals* = includes greenhouse, field, landscape, and conifer nurseries.

e Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

f Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

g Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

h Baseline Total Daily Dose = [Baseline Daily Dermal Exposure (mg/day) * 0.05 (Dermal Absorption Factor) + Baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

I Number of Exposures Per Year is based on maximum number of applications which represent private use. A factor of 10 was used to estimate commercial use.

j Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

k Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = 4.39E-2 (mg/kg/day).

l Baseline dermal data not available. See PPE for dermal and combined exposures, doses, and risks.

Table 11. Occupational Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione with PPE

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Mixer/Loader Risk											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	0.017	1.2	0.5 lb ai/A	Ag	350 acres	3.0	0.21	0.0051	10 / 100	7.0E-5 / 7.0E-4	3.1E-6 / 3.1E-5
			1 lb ai/A			6.0	0.42	0.010	4 / 40	5.6E-5 / 5.6E-4	2.5E-6 / 2.5E-5
			5.5 lb ai/A	Turf		33	2.3	0.056	6 / 60	4.6E-4 / 4.6E-3	2.0E-5 / 2.0E-4
			1.4 lb ai/A	Ornamentals	100 acres	2.4	0.17	0.0041	8 / 80	4.5E-5 / 4.5E-4	2.0E-6 / 2.0E-5
Mixing/Loading Liquids for Groundboom Application (1b)	0.023	1.2	0.27 lb ai/A	Ag	80 acres	0.50	0.026	0.00073	1 / 10	9.9E-7 / 9.9E-6	4.4E-8 / 4.4E-7
			0.5 lb ai/A			0.92	0.048	0.0013	10 / 100	1.8E-5/ 1.8E-4	8.1E-7 / 8.1E-6
			1 lb ai/A			1.8	0.096	0.0027	10 / 100	3.7E-5 / 3.7E-4	1.6E-6 / 1.6E-5
			1.4 lb ai/A	Ornamentals	80 acres	2.6	0.13	0.0038	8 / 80	4.1E-5 / 4.1E-4	1.8E-6 / 1.8E-5
			4 lb ai/A			7.4	0.38	0.011	8 / 80	1.2E-4 / 1.2E-3	5.2E-6 / 5.2E-5
			5.5 lb ai/A	Turf		10	0.53	0.015	8 / 80	1.6E-4 / 1.6E-3	7.1E-6 / 7.1E-5
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	0.023	1.2	0.5 lb ai/A	Ag	40 acres	0.46	0.024	0.00067	4 / 40	3.7E-6 / 3.7E-5	1.6E-7 / 1.6E-6
			1 lb ai/A			0.92	0.048	0.0013	4 / 40	7.4E-6 / 7.4E-5	3.2E-7 / 3.2E-6
Mixing/Loading Liquids for Professional Application to Turf Using a Low Pressure/High Volume Handgun (1d)	0.023	1.2	1.4 lb ai/A	Ornamentals	5 acres	0.16	0.0084	0.00024	8 / 80	2.6E-6 / 2.6E-5	1.1E-7 / 1.1E-6
			5.5 lb ai/A	Turf		0.63	0.033	0.00094	6 / 60	7.6E-6 / 7.6E-5	3.3E-7 / 3.3E-6
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	0.13	8.6	0.5 lb ai/A	Ag	350 acres	23	1.5	0.038	10 / 100	5.2E-4 / 5.2E-3	2.3E-5 / 2.3E-4
			1 lb ai/A			46	3.0	0.076	4 / 40	4.2E-4 / 4.2E-3	1.8E-5 / 1.8E-4
Mixing/Loading Wettable Powder for Groundboom Application (2b)	0.13	8.6	0.5 lb ai/A	Ag	80 acres	5.2	0.34	0.0086	10 / 100	1.2E-4 / 1.2E-3	5.3E-6 / 5.3E-5
			1 lb ai/A			10	0.69	0.017	5 / 50	1.2E-4 / 1.2E-3	5.3E-6 / 5.3E-5
Mixing/Loading Wettable Powder for Orchard Airblast Sprayer Application (2c)	0.17	43	0.5 lb ai/A	Ag	40 acres	3.4	0.86	0.015	4 / 40	8.1E-5 / 8.1E-4	3.5E-6 / 3.5E-5
			1 lb ai/A			6.8	1.7	0.029	4 / 40	1.6E-4 / 1.6E-3	7.1E-6 / 7.1E-5
Mixing/Loading Wettable Powder for Professional Application to Turf using a Low Pressure/High Volume Handgun (2d)	0.17	43	1.4 lb ai/A	Ornamentals	5 acres	1.2	0.30	0.0052	8 / 80	5.6 E-5 / 5.6 E-4	2.5 E-6 / 2.5 E-5
			5.5 lb ai/A	turf		4.7	1.2	0.020	6 / 60	1.7 E-4 / 1.7 E-3	7.3 E-6 / 7.3 E-5
Mixing/Loading Dry Flowable for Chemigation Application (3a)	0.047	0.15	5.5 lb ai/A	Turf	350 acres	90	0.29	0.068	6 / 60	5.6E-4 / 5.6E-3	2.5E-5 / 2.5E-4
Mixing/Loading Dry Flowable Groundboom Application (3b)	0.047	0.77	1 lb ai/A	Ornamentals	80 acres	3.8	0.062	0.0036	8 / 80	3.9E-5 / 3.9-4	1.7E-6 / 1.7E-5
			5.5 lb ai/A	Turf	80 acres	21	0.34	0.020	8 / 80	2.1E-4 / 2.1E-3	9.4E-6 / 9.4E-5

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Loading Granulars for Tractor-Drawn Spreader Application (4)	0.0084	1.7	0.68 lb ai/A	Turf	80 acres	0.46	0.093	0.0016	8 / 80	1.8E-5 / 1.8E-4	7.9E-7 / 7.9E-6
			1.4 lb ai/A			0.94	0.19	0.0034	8 / 80	3.7E-5 / 3.7E-4	1.6E-6 / 1.6E-5
			4.1 lb ai/A			2.8	0.56	0.0099	8 / 80	1.1E-4 / 1.1E-3	4.8E-6 / 4.8E-5
Applicator Risk											
Applying Sprays with a Fixed-Wing Aircraft (5)	No Data SeeEng. Con.	No Data SeeEng. Con.	0.5 lb ai/A	Ag	350 acres	SeeEng. Con.	SeeEng. Con.	SeeEng. Con.	See Eng. Con.	See Eng. Con.	SeeEng. Con.
			1 lb ai/A								
Applying Sprays with a Helicopter (6)	No Data See Eng. Con.	No Data See Eng. Con.	0.5 lb ai/A	Ag	350 acres	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.	See Eng. Con.
			1 lb ai/A								
Applying Sprays with a Groundboom Sprayer (7)	0.014	0.74	0.27 lb ai/A	Ag	80 acres	0.30	0.016	4.4E-4	1 / 10	6.0E-7 / 6.0E-6	2.6E-8 / 2.6E-7
			0.5 lb ai/A			0.56	0.030	8.2E-4	10 / 100	1.1E-5 / 1.1E-4	4.8E-7 / 4.8E-6
			1 lb ai/A			1.1	0.059	0.0016	10 / 100	2.2E-5 / 2.2E-4	9.7E-7 / 9.7E-6
			1.4 lb ai/A	Ornamentals	80 acres	1.6	0.083	0.0023	8 / 80	2.5E-5 / 2.5E-4	1.1E-6 / 1.1E-5
			4 lb ai/A			4.5	0.24	0.0066	8 / 80	7.2E-5 / 7.2E-4	3.2E-6 / 3.2E-5
			5.5 lb ai/A	Turf	80 acres	6.2	0.33	0.0091	8 / 80	1.0E-4 / 1.0E-3	4.4E-6 / 4.4E-5
Applying to Orchards with an Airblast Sprayer (8)	0.36	4.5	0.5 lb ai/A	Ag	40 acres	7.2	0.090	0.0064	4 / 40	3.5E-5 / 3.5E-4	1.5E-6 / 1.5E-5
			1 lb ai/A			14	0.18	0.013	4 / 40	7.1E-5 / 7.1E-4	3.1E-6 / 3.1E-5
Applying with a Low Pressure/High Volume Handgun to Turfgrass (9)	0.34	1.4	1.4 lb ai/A	Ornamentals	5 acres	2.4	0.0098	0.0018	8 / 80	2.0E-5 / 2.0E-4	8.9E-7 / 8.9E-6
			5.5 lb ai/A	Turf		9.4	0.039	0.0072	8 / 80	7.9E-5 / 7.9E-4	3.5E-6 / 3.5E-5
Applying Granulars with a Tractor-Drawn Spreader (10)	0.0099	1.2	0.68 lb ai/A	Turf	80 acres	0.54	0.065	0.0013	8 / 80	1.4E-5 / 1.4E-4	6.1E-7 / 6.1E-6
			1.4 lb ai/A			1.1	0.13	0.0027	8 / 80	3.0E-5 / 3.0E-4	1.3E-6 / 1.3E-5
			4.1 lb ai/A			3.2	0.39	0.0079	8 / 80	8.7E-5 / 8.7E-4	3.8E-6 / 3.8E-5
Mixer/Loader/Applicator Risk											
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (11)	0.43	30	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	0.034	0.0024	5.9E-5	8 / 80	6.5E-7 / 6.5E-6	2.8E-8 / 2.8E-7
			0.01 lb ai/gal			0.17	0.012	2.9E-4	8 / 80	3.2E-6 / 3.2E-5	1.4E-8 / 1.4E-7
			5.5 lb ai/A	Turf	5 acres	12	0.83	0.020	8 / 80	2.2E-4 / 2.2E-3	9.7E-6 / 9.7E-5
Mixing/Loading/Applying Sprays with a High Pressure Handwand (12)	1.6	24	0.5 lb ai/A	Ag	5 acres	4.0	0.060	0.0037	10 / 100	5.1E-5 / 5.1E-4	2.2E-6 / 2.2E-5
			1 lb ai/A			8.0	0.12	0.0074	10 / 100	1.0E-4 / 1.0E-3	4.4E-6 / 4.4E-5
			0.002 lb ai/gal	Ornamentals	1,000 gallons	3.2	0.048	0.0030	8 / 80	3.3E-5 / 3.3E-4	1.4E-6 / 1.4E-5
			0.01 lb ai/gal			16	0.24	0.015	8 / 80	1.6E-4 / 1.6E-3	7.0E-6 / 7.0E-5
Mixing/Loading/Applying Using a Backpack Sprayer (13)	1.6	6	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	0.13	0.00048	0.00010	8 / 80	1.1E-6 / 1.1E-5	4.8E-8 / 4.8E-7
			0.01 lb ai/gal			0.64	0.0024	0.00049	8 / 80	5.4E-6 / 5.4E-5	2.4E-7 / 2.4E-6
			5.5 lb ai/A	Turf	5 acres	44	0.17	0.034	8 / 80	3.7E-4 / 3.7E-3	1.6E-5 / 1.6E-4
Loading/Applying Granulars Using a Belly Grinder (14)	9.3	12	0.68 lb ai/A	Turf	5 acres	28	0.041	0.021	8 / 80	2.2E-4 / 2.2E-3	9.9E-6 / 9.9E-5
			1.4 lb ai/A			57	0.084	0.042	8 / 80	4.6E-4 / 4.6E-3	2.0E-5 / 2.0E-4
			4.1 lb ai/A			170	0.25	0.12	8 / 80	1.4E-3 / 1.4E-2	5.9E-5 / 5.9E-4

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Loading/Applying Using a Push-Type Granular Spreader (15)	1.3	6.3	0.68 lb ai/A	Turf	5 acres	4.4	0.021	0.0035	8 / 80	3.8E-5 / 3.8E-4	1.7E-6 / 1.7E-5
			1.4 lb ai/A			9.1	0.044	0.0071	8 / 80	7.8E-5 / 7.8E-4	3.4E-6 / 3.4E-5
			4.1 lb ai/A			27	0.13	0.021	8 / 80	2.3E-4 / 2.3E-3	1.0E-5 / 1.0E-4
Mixing/Loading/Applying as a Seed Soak Treatment (16)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading/Applying as a Commercial Seed Treatment in Slurry Form (17)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading/Applying Solution as a Dip Treatment (18)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Risk											
Flagging Spray Applications (19)	0.011	0.35	0.5 lb ai/A	Ag	350 acres	1.8	0.061	0.0021	10 / 100	2.9E-5 / 2.9E-4	1.3E-6 / 1.3E-5
			1 lb ai/A			3.5	0.12	0.0042	4 / 40	2.3E-5 / 2.3E-4	1.0E-6 / 1.0E-5

Footnotes:

a PPE Dermal Unit Exposure represents:
- double layer of clothes and chemical resistant gloves for scenarios 1a, 2a, 2b, 3a, 3b, 12, 13, and 14.
- chemical resistant gloves for scenarios 1b, 1c, 1d, 2c, 2d, 9, 11, and 15.

b PPE Inhalation Unit Exposure reflects use of dust/mist respirator (5-fold PF) for scenarios 2a, 2b, 3a, 12, 13, and 14.

c Application rates come from values found in the LUIS report and on Iprodione labels. See Table 7 for particular examples.

d Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated. *Ag* = agricultural crops and *Turf* = turfgrass including sod-farms, institutional areas and golf courses. *Ornamentals* = includes greenhouse, field, landscape, and conifer nurseries.

e Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

f PPE Daily Dermal Exposure (mg/day) = PPE Unit Exposure (mg/lb ai) * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

g PPE Daily Inhalation Exposure (mg/day) = PPE Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

h PPE Total Daily Dose = [PPE Daily Dermal Exposure (mg/day) * 0.05 (Dermal Absorption Factor) + PPE Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

I Number of Exposures Per Year is based on maximum number of applications which represent private use. A factor of 10 was used to estimate commercial use.

j PPE LADD (mg/kg/day) = PPE Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

k PPE Total Cancer Risk = PPE LADD (mg/kg/day) * (Q_1*), where Q_1* = 4.39E-2 (mg/kg/day).

Table 12. Occupational Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione with Engineering Controls

Exposure Scenario (Scen. #)	Eng. Cont. Dermal Unit Exposure[a] (mg/lb ai)	Eng. Cont. Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Eng. Con. Daily Dermal Exposure[f] (mg/day)	Eng. Con. Daily Inhalation Exposure[g] (mg/day)	Eng. Cont. Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	Eng. Cont. LADD[j] (mg/kg/day)	Eng. Cont. Total Cancer Risk[k]
Mixer/Loader Risk											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	0.0086	0.083	0.5 lb ai/A	Ag	350 acres	1.5	0.015	0.0013	10 / 100	1.8E-5 /1.8E-4	7.9E-7 / 7.9E-6
			1 lb ai/A			3	0.029	0.0026	4 / 40	1.4E-5 / 1.4E-4	6.1E-7 / 6.1E-6
			5.5 lb ai/A	Turf		17	0.16	0.014	6 / 60	1.2E-4 / 1.2E-3	5.3E-6 / 5.3E-5
			1.4 lb ai/A	Ornamentals	100 acres	1.2	0.012	0.0010	8 / 80	1.1E-5 / 1.1E-4	4.8E-7 / 4.8E-6
Mixing/Loading Liquids for Groundboom Application (1b)	0.0086	0.083	0.27 lb ai/A	Ag	80 acres	0.19	0.0018	0.00016	1 / 10	2.2E-7 / 1.1E-6	9.7E-9 / 9.7E-8
			0.5 lb ai/A			0.34	0.0033	0.00029	10 / 100	4.0E-6 / 4.0E-5	1.8E-7 / 1.8E-6
			1 lb ai/A			0.69	0.0066	0.00059	10 / 100	8.1E-6 / 8.1E-5	3.6E-7 / 3.6E-6
			1.4 lb ai/A	Ornamentals	80 acres	0.96	0.0093	0.00082	8 / 80	9.0E-6 / 9.0E-5	4.0E-7 / 4.0E-6
			4 lb ai/A			2.8	0.027	0.0024	8 / 80	2.6E-5 / 2.6E-4	1.1E-6 / 1.1E-5
			5.5 lb ai/A	Turf		3.8	0.037	0.0032	8 / 80	3.5E-5 / 3.5E-4	1.5E-6 / 1.5E-5
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	0.0086	0.083	0.5 lb ai/A	Ag	40 acres	0.17	0.0017	0.00015	4 / 40	8.2E-7 / 8.2E-6	3.6E-8 / 3.6E-7
			1 lb ai/A			0.34	0.0033	0.00029	4 / 40	1.6E-6 / 1.6E-5	7.0E-8 / 7.0E-7
Mixing/Loading Liquids for Professional Application to Turf Using a Low Pressure/High Volume Handgun (1d)	0.0086	0.083	1.4 lb ai/A	Ornamentals	5 acres	0.060	0.00058	0.000051	8 / 80	5.6E-7 / 5.6E-6	2.5E-8 / 2.5E-7
			5.5 lb ai/A	Turf		0.24	0.0023	0.00020	6 / 60	1.6E-6 / 1.6E-5	7.0E-8 / 7.0E-7
Mixing/Loading Wettable Powder for Aerial/Chemigation Application (2a)	0.021	0.24	0.5 lb ai/A	Ag	350 acres	3.7	0.042	0.0032	10 / 100	4.4E-5 / 4.4E-4	1.9E-6 / 1.9E-5
			1 lb ai/A			7.4	0.084	0.0065	4 / 40	3.5E-5 / 3.5E-4	1.6E-6 / 1.6E-5
Mixing/Loading Wettable Powder for Groundboomt Application (2b)	0.021	0.24	0.5 lb ai/A	Ag	80 acres	0.84	0.0096	0.00074	10 / 100	1.0E-5 / 1.0E-4	4.4E-7 / 4.4E-6
			1 lb ai/A			1.7	0.019	0.0015	5 / 50	1.0E-5 / 1.0E-4	4.4E-7 / 4.4E-6
Mixing/Loading Wettable Powder for Orchard Airblast Sprayer Application (2c)	0.021	0.24	0.5 lb ai/A	Ag	40 acres	0.42	0.0048	0.00037	4 / 40	2.0E-6 / 2.0E-5	8.9E-8 / 8.9E-7
			1 lb ai/A			0.84	0.0096	0.00074	4 / 40	4.0E-6 / 4.0E-5	1.8E-7 / 1.8E-6
Mixing/Loading Wettable Powder for Professional Application with Low Pressure/High Volume Handgun (2d)	0.021	0.24	1.4 lb ai/A	Ornamentals	5 acres	0.15	0.0017	0.00013	8 / 80	1.4E-6 / 1.4E-5	6.2E-8 / 6.2E-7
			5.5 lb ai/A	Turf		0.58	0.0066	0.00051	6 / 60	4.2E -6 / 4.2E-5	1.8E-7 / 1.8E-6
Mixing/Loading Dry Flowable for Chemigation Application (3a)	0.021	0.24	5.5 lb ai/A	Turf	350 acres	40	0.46	0.035	6 / 60	2.9E-4 / 2.9E-3	1.3E-5 / 1.3E-4
Mixing/Loading Dry Flowable Groundboom Application (3b)	0.021	0.24	1 lb ai/A	Ornamentals	80 acres	1.7	0.019	0.0015	8 / 80	1.6E-5 / 1.6E-4	7.1E-7 / 7.1E-6
			5.5 lb ai/A	Turf	80 acres	9.2	0.11	0.0081	8 / 80	8.9E-5 / 8.9E-4	3.9E-6 / 3.9E-5

Table 12. Occupational Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione with Engineering Controls (Continued)

Exposure Scenario (Scen. #)	Eng. Cont. Dermal Unit Exposure[a] (mg/lb ai)	Eng. Cont. Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Eng. Con. Daily Dermal Exposure[f] (mg/day)	Eng. Con. Daily Inhalation Exposure[g] (mg/day)	Eng. Cont. Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	Eng. Cont. LADD[j] (mg/kg/day)	Eng. Cont. Total Cancer Risk[k]
Loading Granulars for Tractor-Drawn Spreader Application (4)	0.00017	0.034	0.68 lb ai/A	Turf	80 acres	0.0092	0.0018	0.000032	8 / 80	3.5E-7 / 3.5E-6	1.5E-8 / 1.5E-7
			1.4 lb ai/A			0.019	0.0038	0.000068	8 / 80	7.5E-7 / 7.5E-6	3.3E-8 / 3.3E-7
			4.1 lb ai/A			0.056	0.011	0.00020	8 / 80	2.2E-6 / 2.2E-5	9.7E-8 / 9.7E-7
Applicator Risk											
Applying Sprays with a Fixed-Wing Aircraft (5)	0.0050	0.068	0.5 lb ai/A	Ag	350 acres	0.88	0.012	0.00080	10 / 100	1.1E-5 / 1.1E-4	4.8E-7 / 4.8E-6
			1 lb ai/A			1.8	0.024	0.0016	4 / 40	8.8E-6 / 8.8E-5	3.9E-7 / 3.9E-6
Applying Sprays with a Helicopter (6)	0.0019	0.0018	0.5 lb ai/A	Ag	350 acres	0.33	0.00032	0.00024	10 / 100	3.3E-6 / 3.3E-5	1.4E-7 / 1.4E-6
			1 lb ai/A			0.67	0.00063	0.00049	4 / 40	2.7E-6 / 2.7E-5	1.2E-7 / 1.2E-6
Applying Sprays with a Groundboom Sprayer (7)	0.005	0.043	0.27 lb ai/A	Ag	80 acres	0.11	0.00093	0.000092	1 / 10	1.3E-7 / 1.3E-6	5.7E-9 / 5.7E-8
			0.5 lb ai/A			0.20	0.0017	0.00017	10 / 100	2.3E-6 / 2.3E-5	1.0E-7 / 1.0E-6
			1 lb ai/A			0.40	0.0034	0.00033	10 / 100	4.5E-6 / 4.5E-5	2.0E-7 / 2.0E-6
			1.4 lb ai/A	Ornamentals	80 acres	0.56	0.0048	0.00047	8 / 80	5.2E-6 / 5.2E-5	2.3E-7 / 2.3E-6
			4 lb ai/A			1.6	0.014	0.0013	8 / 80	1.4E-5 / 1.4E-4	6.1E-7 / 6.1E-6
			5.5 lb ai/A	Turf	80 acres	2.2	0.019	0.0018	8 / 80	2.0E-5 / 2.0E-4	8.8E-7 / 8.8E-6
Applying to Orchards with an Airblast Sprayer (8)	0.019	0.45	0.5 lb ai/A	Ag	40 acres	0.38	0.0090	0.00040	4 / 40	2.2E-6 / 2.2E-5	9.6E-8 / 9.6E-7
			1 lb ai/A			0.76	0.018	0.00080	4 / 40	4.4E-6 / 4.4E-5	1.9E-7 / 1.9E-6
Applying with a Low Pressure/High Volume Handgun to Turfgrass (9)	NA	NA	1.4 lb ai/A	Ornamentals	5 acres	NA	NA	NA	8 / 80	NA	NA
			5.5 lb ai/A	Turf		NA	NA	NA	8 / 80	NA	NA
Applying Granulars with a Tractor-Drawn Spreader (10)	0.0021	0.22	0.68 lb ai/A	Turf	80 acres	0.11	0.012	0.00025	8 / 80	2.7E-6 / 2.7E-5	1.2E-7 / 1.2E-6
			1.4 lb ai/A			0.24	0.025	0.00053	8 / 80	5.8E-6 / 5.8E-5	2.5E-7 / 2.5E-6
			4.1 lb ai/A			0.69	0.072	0.0015	8 / 80	1.6E-5 / 1.6E-4	7.0E-7 / 7.0E-6
Mixer/Loader/Applicator Exposure											
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (11)	NA	NA	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	NA	NA	NA	8 / 80	NA	NA
			0.01 lb ai/gal						8 / 80		
			5.5 lb ai/A	Turf	5 acres	NA	NA	NA	8 / 80	NA	NA
Mixing/Loading/Applying Sprays with a High Pressure Handwand (12)	NA	NA	0.5 lb ai/A	Ag	5 acres	NA	NA	NA	10 / 100	NA	NA
			1 lb ai/A						10 / 100		
			0.002 lb ai/gal	Ornamentals	1,000 gallons	NA	NA	NA	8 / 80	NA	NA
			0.01 lb ai/gal						8 / 80		

Table 12. Occupational Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione with Engineering Controls (Continued)

Exposure Scenario (Scen. #)	Eng. Cont. Dermal Unit Exposure[a] (mg/lb ai)	Eng. Cont. Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Eng. Con. Daily Dermal Exposure[f] (mg/day)	Eng. Con. Daily Inhalation Exposure[g] (mg/day)	Eng. Cont. Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	Eng. Cont. LADD[j] (mg/kg/day)	Eng. Cont. Total Cancer Risk[k]
Mixing/Loading/Applying Using a Backpack Sprayer (13)	NA	NA	0.002 lb ai/gal	Turf & Ornamentals	40 gallons	NA	NA	NA	8 / 80	NA	NA
			0.01 lb ai/gal						8 / 80		
			5.5 lb ai/A	Turf	5 acres	NA	NA	NA	8 / 80	NA	NA
Loading/Applying Granulars Using a Belly Grinder (14)	NA	NA	0.68 lb ai/A	Turf	5 acres	NA	NA	NA	8 / 80	NA	NA
			1.4 lb ai/A						8 / 80		
			4.1 lb ai/A						8 / 80		
Loading/Applying Using a Push-Type Granular Spreader (15)	NA	NA	0.68 lb ai/A	Turf	5 acres	NA	NA	NA	8 / 80	NA	NA
			1.4 lb ai/A						8 / 80		
			4.1 lb ai/A						8 / 80		
Mixing/Loading/Applying as a Seed Soak Treatment (16)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading/Applying as a Commercial Seed Treatment in Slurry Form (17)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading/Applying Solution as a Dip Treatment (18)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Risk											
Flagging Spray Applications (19)	0.00022	0.007	0.5 lb ai/A	Ag	350 acres	0.039	0.0012	4.5 E-5	10 / 100	6.2E-7 / 6.2E-6	2.7E-8 / 2.7E-7
			1 lb ai/A			0.077	0.0025	9.0 E-5	4 / 40	4.9E-7 / 4.9E-6	2.2E-8 / 2.2E-7

Footnotes:

a Engineering Control Unit Exposure values represent : 1a,1b,1c,1d, 3a, 3b, closed mixing and loading; 2a, 2b, 2c water soluble bags; 4,5,6,7,10, 19 enclosed cab or cockpit

b Engineering Control Inhalation Unit Exposure reflects values taken from PHED V1.1 surrogate exposure tables (May 1997) .

c Application rates come from values found in the LUIS report and on Iprodione labels. See Table 7 for particular examples.

d Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated. *Ag* = agricultural crops and *Turf* = turfgrass including sod-farms, institutional areas and golf courses. *Ornamentals* = includes greenhouse, field, landscape, and conifer nurseries.

e Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

f Eng. Con. Daily Dermal Exposure (mg/day) =Eng. Con. Unit Exposure (mg/lb ai) * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

g Eng. Con. Daily Inhalation Exposure (mg/day) = Eng. Con. Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A or lb ai/gallon) * Amount Handled Per Day (acres/day or gallons/day).

h Eng Con. Total Daily Dose = [Eng. Con Daily Dermal Exposure (mg/day) * 0.05 (Dermal Absorption Factor) + Eng. Con Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

I Number of Exposures Per Year is based on maximum number of applications which represent private use. A factor of 10 was used to estimate commercial use.

j LADD (mg/kg/day) = Eng. Con. Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

k Total Cancer Risk = LADD (mg/kg/day) * (Q_1*), where Q_1* = 4.39E-2 (mg/kg/day).

NA = Not Applicable. For scenarios 9 and 11 - 15 engineering controls are not available.

(1) Summary of Risk Concerns for Handlers, Data Gaps, and Confidence in Risk Estimates

Handler Scenarios with Risk Concerns. The calculations of short-term and intermediate-term inhalation risk indicate that inhalation MOEs are more than 100 at baseline for the all the assessed exposure scenarios except the following:

- (2a) mixing/loading wettable powder for aerial/chemigation application (at an application rate of 0.5 lb ai/acre, the short-term inhalation MOE was acceptable, but not at an application rate of 1.0 lb ai/acre).

The calculations of short-term and intermediate-term inhalation risks for scenario 2a indicates that with the additional PPE, inhalation MOEs are greater than 100.

As noted below in the data gaps discussion, several of the exposure scenarios could not be assessed due to lack of PHED surrogate data.

An engineering control assessment was carried out for enclosed cab aerial spray applications, and for wettable powders formulated in water soluble bags. The calculations of short-term and intermediate-term inhalation risks for these scenarios (Table 6) indicate that when engineering controls are employed (i.e., water soluble bags and enclosed cab), the MOEs are more than 100 for all assessed scenarios which include:

- (2a) mixing/loading wettable powder for aerial/chemigation application,
- (2b) mixing/loading wettable powder for groundboom application,
- (2c) mixing/loading wettable powder for orchard airblast application,
- (2d) mixing/loading wettable powder for professional application to turf with low pressure/high volume handgun,
- (5) applying sprays with a fixed-wing aircraft, and
- (6) applying sprays with a helicopter.

The calculations indicate that cancer risks at baseline are greater than the 1.0E-4 for the following scenarios (refer to tables for specific scenarios-- for some scenarios the risks are below 1.0E-4 for private handlers or at lower application rates) :

- (1a) mixing/loading liquids for aerial/chemigation application,
- (1b) mixing/loading liquids for groundboom application (at application rates of 0.5 and greater than or equal to 1 lb ai/acre),
- (1c) mixing/loading liquids for orchard airblast sprayer application (commercial handlers only),
- (1d) mixing/loading liquids for professional application to turf grass using a low pressure/high volume handgun (to turf at an application rate of 5.5 lb ai/acre--commercial handlers only),
- (2a) mixing/loading wettable powder for aerial/chemigation application,

- (2b) mixing/loading wettable powder for groundboom application (commercial handlers only),
- (2c) mixing/loading wettable powder for orchard airblast sprayer application (commercial handlers only),
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun (commercial handlers only)
- (3a) mixing/loading dry flowables for chemigation application (commercial handlers only),
- (3b) mixing/loading dry flowables for groundboom application (to turf at an application rate of 5.5 lb ai/acre) (commercial handlers only),
- (11) mixing/loading/applying sprays using a low pressure hand wand (at an application rate of 0.01 lb ai/gallon for turf and ornamentals, and 5.5 lb ai/acre for turf) (commercial handlers only),
- (12) mixing/loading/applying sprays using a high pressure hand wand (at an application rate of 1 lb ai/acre for agriculture and 0.01 lb ai/gallon for ornamentals) (commercial handlers only),
- (14) mixing/loading/applying granulars using a belly grinder (commercial handlers only), and
- (15) mixing/loading/applying granulars with a push-type granular spreader at the 4.1 lb rate and higher (commercial handlers only).

The calculations indicate that cancer risks at baseline are in the range of 1.0E-4 to 1.0E-6 for the following scenarios (refer to tables for specific scenarios-- for some scenarios the risks are greater than 1.0E-4 for commercial handlers or at higher application rates, and for others they are less than 1.0E-6 for private handlers or at lower application rates) :

- (1b) mixing/loading liquids for groundboom application,
- (1c) mixing/loading liquids for orchard airblast sprayer application (private handlers only),
- (1d) mixing/loading liquids for professional application to turf grass using a low pressure/high volume handgun,
- (2b) mixing/loading wettable powder for groundboom application,
- (2c) mixing/loading wettable powder for orchard airblast sprayer application,
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun (private handlers only),
- (3a) mixing/loading dry flowables for chemigation application,
- (3b) mixing/loading dry flowables for groundboom application,
- (4) loading granulars for tractor-drawn spreader applications,
- (7) applying sprays with a groundboom sprayer,
- (8) applying to orchards with an airblast sprayer,
- (10) applying granulars with a tractor-drawn spreader,
- (11) mixing/loading/applying sprays using a low pressure hand wand,
- (12) mixing/loading/applying sprays using a high pressure hand wand,
- (14) mixing/loading/applying granulars using a belly grinder,
- (15) mixing/loading/applying granulars with a push-type granular spreader, and
- (19) flagging spray applications.

The calculations indicate that cancer risks at baseline are less than 1.0E-6 for the following scenarios:

- (4) loading granulars for tractor-drawn spreader applications (at the 0.68 rate for private handlers only),
- (7) applying sprays with a groundboom sprayer (all handlers at the 0.27 rate and less, and private handlers only at the 1.0 rate and less),
- (10) applying granulars with a tractor-drawn spreader (private handlers only at the 0.68 rate or less), and
- (15) mixing/loading/applying granulars with a push-type granular spreader (private handlers only at the 0.68 rate or less).

The calculations indicate that cancer risks with additional PPE are greater than 1.0E-4 for the following scenarios (refer to tables for specific scenarios-- for some scenarios the risks are below 1.0E-4 for private handlers or at lower application rates) :

- (1a) mixing/loading liquids for aerial/chemigation application,
- (2a) mixing/loading wettable powder for aerial/chemigation application,
- (3a) mixing/loading dry flowables for chemigation application, and
- (13) mixing/loading/applying sprays using a backpack sprayer (at an application rate of 5.5 lb ai/acre to turf).
- (14) mixing/loading/applying granulars using a belly grinder.

The calculations indicate that cancer risks with additional PPE are in the range of 1.0E-4 to 1.0E-6 for the following scenarios (refer to tables for specific scenarios-- for some scenarios the risks are greater than 1.0E-4 for commercial handlers or at higher application rates, and for others they are less than 1.0E-6 for private handlers or at lower application rates):

- (1a) mixing/loading liquids for aerial/chemigation application,
- (1b) mixing/loading liquids for groundboom application,
- (1c) mixing/loading liquids for orchard airblast sprayer application,
- (1d) mixing/loading liquids for professional application to turf grass using a low pressure/high volume handgun,
- (2a) mixing/loading wettable powders for aerial/chemigation application,
- (2b) mixing/loading wettable powder for groundboom application,
- (2c) mixing/loading wettable powder for orchard airblast sprayer application,
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun,
- (3a) mixing/loading dry flowables for chemigation application,
- (3b) mixing/loading dry flowables for groundboom application,
- (4) loading granulars for tractor-drawn spreader applications,
- (7) applying sprays with a groundboom sprayer,
- (8) applying to orchards with an airblast sprayer,

- (9) applying with a low pressure/high volume handgun to turfgrass,
- (10) applying granulars with a tractor-drawn spreader,
- (11) mixing/loading/applying sprays using a low pressure hand wand,
- (12) mixing/loading/applying sprays using a high pressure hand wand,
- (13) mixing/loading/applying using a backpack sprayer,
- (14) mixing/loading/applying granulars using a belly grinder
- (15) mixing/loading/applying granulars with a push-type granular spreader, and
- (19) flagging spray applications.

The calculations indicate that cancer risks with additional PPE are less than 1.0E-6 for the following scenarios:

- (1b) mixing/loading liquids for groundboom application (at the 0.27 rate for all handlers, and for private handlers only at the 1.4 rate and less),
- (1c) mixing/loading liquids for orchard airblast sprayer application (at the 0.5 rate for all handlers and at the 1 lb rate and less for private handlers only),
- (1d) mixing/loading liquids for professional application to turf grass using a low pressure/high volume handgun (at the 1.4 rate for all handlers, and for private handlers only at the 5.5 rate),
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun (at the 1.4 rate for private handlers only),
- (4) loading granulars for tractor-drawn spreader applications (at the 1.4 rate and less for private handlers only),
- (7) applying sprays with a groundboom sprayer (all handlers at the 0.27 rate and less, and private handlers only at the 1.4 rate and less),
- (8) applying to orchards with an airblast sprayer (private handlers only at the 0.5 rate or less),
- (10) applying granulars with a tractor-drawn spreader (private handlers only at the 1.4 rate or less), and
- (11) mixing/loading/applying sprays using a low pressure hand wand (all handlers at rates of 0.01 lb ai/gallon or less),
- (13) mixing/loading/applying using a backpack sprayer (all handlers at the 0.002 lb ai/gallon rate or less, and private handlers only at rates of 0.01 lb ai/gallon or less),
- (15) mixing/loading/applying granulars with a push-type granular spreader (private handlers only at the 0.68 rate or less), and
- (19) flagging spray applications (private flaggers only).

The calculations indicate that cancer risks with engineering controls are greater than 1.0E-4 for none of the exposure scenarios.

The calculations indicate that cancer risks with Engineering Controls (closed mixing/loading, water soluble bags, enclosed cab or airplane cockpit) are in the range of 1.0E-4 to 1.0E-6 for the following scenarios (refer to tables for specific scenarios-- for some scenarios the risks are less than 1.0E-6 for private handlers or at lower application rates) :

- (1a) mixing/loading liquids for aerial/chemigation application,
- (1b) mixing/loading liquids for groundboom application,
- (2a) mixing/loading wettable powders for aerial/chemigation application,
- (2b) mixing/loading wettable powder for groundboom application,
- (2c) mixing/loading wettable powder for orchard airblast sprayer application,
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun,
- (3a) mixing/loading dry flowables for chemigation application,
- (3b) mixing/loading dry flowables for groundboom application,
- (5) applying sprays with fixed wing aircraft,
- (6) applying sprays with a helicopter,
- (7) applying sprays with a groundboom sprayer,
- (8) applying to orchards with an airblast sprayer,
- (10) applying granulars with a tractor-drawn spreader,
- (19) flagging spray applications.

The calculations indicate that cancer risks with Engineering Controls are less than 1.0E-6 for the following scenarios:

- (1b) mixing/loading liquids for groundboom application (all applications at the rate of 0.27 lbs ai/A only)
- (1c) mixing/loading liquids for orchard airblast sprayer application,
- (1d) mixing/loading liquids for professional application to turf grass using a low pressure/high volume handgun,
- (2b) mixing/loading wettable powder for groundboom application (private handlers only),
- (2c) mixing/loading wettable powder for orchard airblast sprayer application (all handlers at the 0.5 rate, and private handlers only at the 1.0 rate),
- (2d) mixing/loading wettable powder for professional application to turf with a low pressure/high volume handgun (all handlers at the rate of 1.4 lb ai/A and private handlers only at the rate of 5.5 lb ai/A),
- (3b) mixing/loading dry flowables for groundboom application (private handlers only at the 1.0 rate or less),
- (4) loading granulars for tractor-drawn spreader applications,
- (5) applying sprays with fixed wing aircraft (private applicators only),
- (6) applying sprays with a helicopter (private applicators only),
- (7) applying sprays with a groundboom sprayer (all applicators at the 0.27 rate, and private applicators only at all other rates),
- (8) applying to orchards with an airblast sprayer (all applicators at the 0.5 lb ai/A rate and private applicators only at the 1.0 rate),
- (10) applying granulars with a tractor-drawn spreader (private applicators only all rates),
- (19) flagging spray applications (flaggers supporting private applications only).

Data Gaps. Data gaps exist for the following scenarios:

- (9) - no chemical specific or PHED baseline dermal data exist for applying with a low pressure/high volume handgun to turfgrass.
- (18) - no chemical specific or PHED data exist for mixing/loading/applying solution as a dip treatment.

Data Quality and Confidence in Assessment. Several issues must be considered when interpreting the occupational exposure risk assessment. These include:

- No chemical specific data were provided; therefore, surrogate PHED data were used to assess exposure.

- Several handler assessments were completed using "low quality" PHED data due to the lack of a more acceptable data set (see Table 3 for the specific scenarios where only "low quality" data were available).

- Several generic protection factors were used to calculate handler exposures. These protection factors are general estimates and variability may be significant.

- Factors used to calculate daily exposures to handlers (including acres treated per day and gallons of liquid applied) are based on label directions and professional judgement for the broad range of sites, equipment, and methods that are possible for each scenario.

- Estimates of risk range from average or "typical" for private handlers, to high end for commercial handlers (i.e., it is possible but not likely that the actual risks to some commercial handlers could exceed those estimated here).

e. Occupational Post-Application Exposures and Risks

(1) Postapplication Exposure Scenarios

The Agency has determined that there are potential Postapplication exposures to individuals entering treated areas for the purpose of:

- Harvesting tree fruits and nuts, low-growing fruits, vegetables, and grapes;

- Pruning and propping fruit and nut trees;

- Harvesting and mowing of sod farm turf;

- Pruning, transplanting, and bundling flowers, ornamental shrubs, and vines; and

- Transplanting trees and other ornamentals.

The specific crop group/activity combinations likely to result in Postapplication exposures from iprodione are listed below. These crop groups/activities were grouped based on assumed exposure level, preharvest interval (PHI), maximum number of applications per season and expected frequency of exposure. These crop groups/activities include the following:

- Grape harvesting, pruning, and staking: assumed to result in higher exposures than other activities such as propping or staking which would have a longer PHI and lower number of days of exposure;

- Stone fruit harvesting: assumed to result in higher exposures than other activities that have lower days of exposure;

- Almond harvesting: assumed to result in high exposure levels, but with lower PHI and lower application rates than stone fruit harvesting;

- Harvesting of small vegetables and fruits, including strawberries: assumed to result in higher exposures than activities such as scouting, thinning, or weeding , which have lower exposure frequencies;

- Harvesting dry bulb onions: assumed to have lower exposure frequencies than the harvesting of small fruits and vegetables group above;

- Non-harvesting activities such as weeding and scouting for crops such as beans, rice, lettuce, potatoes, and peanuts: assumed to have lower exposure levels and lower exposure frequencies than the harvesting scenarios;

- Ornamental shrub, vine and herbaceous plant harvesting, transplanting, pruning, and bundling of flowers: assumed to have high exposure levels and high exposure frequencies, and with greater application rates than fruits and vegetables;

- Sod farm harvesting and mowing: harvesting assumed to have high levels of exposure, but with low frequency; combined with low level more frequent exposures on days of mowing;

- Golf course mowing and maintenance: assumed to have low exposure levels, and high exposure frequency combined with high application rates and the potential for high number of applications per season; and

- Ginseng harvesting, scouting and weeding: assumed to be a discrete crop/activity set that would result in different exposures than those listed above.

One of these crop group/activities has been identified as a scenario yielding potential chronic exposure (i.e., $\geq$ 180 days of exposure/year) concern. These risks are summarized in Table 13. The potential chronic exposure reentry activities include:

- Transplanting, pruning, and bundling of ornamentals: assumed to be a high-exposure level (T_c = 7,000 cm^2/hr) activity. Over a lifetime, the average exposure level is likely to be lower (i.e., see cancer assessment, T_c = 2,400 cm^2/hr) due to variability in use over many years compared to variability in use over one year. Iprodione may be used more frequently in a particular year, such as to control disease potential, or a long duration in a rotational program.

All the crop groups and activities likely to result in Postapplication exposure from iprodione have been assessed for cancer risk.

(2) Data Sources and Assumptions for Scenarios Considered

No chemical-specific Postapplication human reentry or transferable residue data were submitted in support of the Reregistration of Iprodione. In lieu of these data, a surrogate Postapplication exposure assessment was conducted to determine potential risks for the previously mentioned representative scenarios.

Assumptions Used in Postapplication Exposure Calculations (Cancer and Non-Cancer Risks). The assumptions used in the calculations for occupational Postapplication risks include the following items, which are also summarized in Table 14.

- Application rates used for the calculations were derived using the following strategy:

  -- Harvesting grapes = 0.75 lb ai/acre, which is the lower end of application rate range (0.75 and 1.0 lb ai/acre)
  -- Harvesting dry bulb onions = 0.5 lb ai/acre which is the lower end of application rate range (0.5 and 0.75 lb ai/acre)
  -- Weeding and scouting non-harvest vegetables, including beans, rice, potatoes, lettuce and peanuts = 0.75 lb ai/acre which is the average of application rates (0.5, 0.75, and 1.0 lb ai/acre)
  -- Transplanting, pruning, bundling of ornamental and flowers = 3.0 lb ai/acre which is representative of the application rate range (1.4 and 4.0 lb ai/acre)
  -- Harvesting and mowing sod farm turf = 4.1 lb ai/acre which is the average of application rates (2.7 and 5.5 lb ai/acre)
  -- Mowing and maintenance of golf course turf = 3.0 lb ai/acre which is the lower end of the range of application rates (2.7 and 5.5 lb ai/acre) (expected to have frequent prescriptive treatments rather than occasional corrective treatments).

Table 13. Occupational Postapplication Chronic Risks from Iprodione

Days After Treatment	Ornamentals[a] - 20% initial residue			Ornamentals[a] - 10% initial residue			Ornamentals[a] - 5% initial residue		
	DFR (μg/cm^2)[b]	Dermal Dose (mg/kg/day)[c]	MOE[d]	DFR (μg/cm^2)[b]	Dermal Dose (mg/kg/day)[c]	MOE[d]	DFR (μg/cm^2)[b]	Dermal Dose (mg/kg/day)[c]	MOE[d]
0	6.7	0.27	23	3.4	0.14	45	1.7	0.067	91
1	6.1	0.24	25	3.0	0.12	50	1.5	0.061	100
2	5.4	0.22	28	2.7	0.11	56	-	-	-
3	4.9	0.20	31	2.5	0.098	62	-	-	-
4	4.4	0.18	35	2.2	0.088	69	-	-	-
5	4.0	0.16	38	2.0	0.079	77	-	-	-
6	3.6	0.14	43	1.8	0.071	85	-	-	-
7	3.2	0.13	47	1.6	0.064	95	-	-	-
8	2.9	0.12	53	1.5	0.058	100	-	-	-
9	2.6	0.10	59	-	-	-	-	-	-
10	2.3	0.094	65	-	-	-	-	-	-
11	2.1	0.084	72	-	-	-	-	-	-
12	1.9	0.076	80	-	-	-	-	-	-
13	1.7	0.068	89	-	-	-	-	-	-
14	1.5	0.062	99	-	-	-	-	-	-
15	1.4	0.055	110	-	-	-	-	-	-

FOOTNOTES

a This scenario represents the repotting, transplanting, harvesting and pruning of indoor and outdoor ornamentals.. Assumptions include an average application rate of 3.0 lb ai/acre, and a transfer coefficient (T_c) of 7,000 cm^2/hour, and hours exposed per day = 8 hours.

b DFR values derived from surrogate data - Assumed to be 20%, 10%, and 5% of the application rate initially, with a 10% dissipation thereafter.

c Dermal Dose (mg/kg/day) =([DFR (μg/cm^2]* transfer coefficient (T_c) * hours worked per day at the stated activity * 0.001 mg/μg * 0.05 dermal absorption rate/70 kg body weight.

d MOE = NOEL (mg/kg/day)/Dermal Dose (mg/kg/day), where NOEL = 6.1 mg/kg/day.

Table 14. Occupational Postapplication Scenarios and Assumptions for Iprodione

Exposure Activity/Crop or Target	Application Rate (lb ai/acre)	Transfer Coefficient(cm^2/hr)	Exposure Days per Year	Hours Worked per Day	Maximum Number of Applications per Season	Application Interval (days)	PHI[a] (days)
Grapes[b](Harvesting/Pruning/Staking)	0.75	10,000	110	8	4	7	7
Almond Trees[c](Harvesting)	0.5	10,000	60	8	4	7-14	NS (assume zero)
Stone Fruit Trees[d] (Harvesting)	0.75	10,000	60	8	4	7-14	7
Small Vegetables and Fruits, inc. Strawberries[e] (Harvesting)	0.75	3,500	120	8	2-10	7-14	0
Dry Bulb Onions[f] (Harvesting)	0.5	3,500	30	8	5-10	7-14	7
"Non-Harvest Activities in Vegetables, including beans, rice, lettuce, potatoes, peanuts[g] (e.g., weeding, scouting)	0.75	1,000	25	8	2-4	7-14	NA
Ornamentals[h] (Harvesting/Transplanting/ Pruning/Bundling Flowers)	3	2,400	180	4	NA	as required (assume 14 days)	NA
Sod Farms[i] (Harvesting/Mowing)	4.1	1,000	50	8	NA	14	NA
Golf Course Turf[j] (Mowing/Maintenance)	3	500	90	4	NA	14	NA
Ginseng[k](Harvesting/Scouting/Weeding)	0.75	7,000	10	1	10	7-14	36

Footnotes:

NA = Not applicable

NS = Not specified

a PHI values come from Iprodione labels.

b Application rate = lower end of range (0.75 and 1.0 lb ai/acre).

c Application rate = stated rate of 0.5 lb ai/acre. Days of exposure = 12 weeks x 5 days/week. PHI was not specified on label, and assumed to be zero days. Application interval on Iprodione labels not specified in days. Label guideline suggests first application pink bud, 2nd at full bloom, 3rd at petal fall and 4th application at up to 5 weeks after petal fall. For purposes of this assessment, application interval was assumed to be every 7-14 days.

d Application rate = average of 0.5 and 1.0 lb ai/acre rates.

e Application rate = average of rates (0.5 and 1.0 lb ai/acre). Days of exposure = 5-6 days/week, and 6-8 months per year.

f Application rate = lower end of range (0.5 and 0.75 lb ai/acre).

g Application rate = average of rates (0.5, 0.75 and 1.0 lb ai/acre). Days of exposure = once/week x 6 months. The risk calculations are based on an average application interval of 7-14 days. Two crops in this grouping have unique intervals:

- Risks to weeders and scouters of bean fields may be slightly underestimated because workers may be entering the fields closer to the time of application (i.e., 5 to 7 day application intervals), but this is expected to be offset by the low number of applications per season (i.e., 2).
- Risks to peanut farm workers may be slightly overestimated because the application interval for peanuts is 21 days and workers are expected to be entering fields later than the average reentry interval used for this calculation.

h Application rate = average of rates (2 and 4 lb ai/acre). Days of exposure = 5-6 days/week for 6-8 months/year period of pest pressure.

i Application rate = average of rates (2.7 and 5.5 lb ai/acre). Days of exposure = 50 weeks x 1 day/week. Transfer coefficient = weighted average of high exposure activity (harvesting) and low exposure activity (mowing).

j Application rate = lower end of range (2.7 and 5.5 lb ai/acre).

k Application rate = average of rates (0.5 and 1.0 lb ai/acre).

-- Harvesting, scouting, and weeding of ginseng = 0.75 lb ai/acre which is the average of application rates (0.5 and 1.0 lb ai/acre)

- Transfer coefficients (T_c) are assumed to be 10,000 cm^2/hr for high-contact harvesting (i.e., fruit and nut trees and grapes). A transfer coefficient of 7,000 cm^2/hr was assumed for the chronic assessment of ornamental nursery and greenhouse activities; however, a 2,400 cm^2/hr transfer coefficient was used in the cancer assessment for ornamentals to reflect variation in use over a lifetime. The 2,400 cm^2/hr transfer coefficient is the median and mode (i.e., most frequently occuring value) in a data set ranging from 496 cm^2/hr to 10,000 cm^2/hr for transfer coefficients associated with ornamental work (Browner et. al.,1992 and Veerman et. al., 1994). Transfer coefficients are assumed to be 3,500 cm^2/hr for harvesting of low- growing fruit and vegetable crops (e.g., strawberries) and 1,000 cm^2/hr for activities such as weeding and scouting of low growing vegetables. A transfer coefficient of 1,000 cm^2/hr was estimated for harvesting and mowing of sod farms and is an average of the frequent but low T_c activities of mowing and infrequent but high T_c activity of harvesting. Golf course mowing and maintenance activities were assessed using a T_c of 500 cm^2/hr.

- Daily exposure is assumed to occur for 8 hours per day except for ornamental work (cancer assessment only), mowing and maintenance of golf course turf, and harvesting and scouting of ginseng. It is assumed that nursery and greenhouse workeres will harvest, transplant, prune, and bundle, and golf course workers will tend fairways and greens, only half of their work day when averaged over a lifetime.

- Postapplication exposures to scouts and harvesters of ginseng farms are expected to be of high intensity, but for short periods of time (e.g., l hour per day for 10 days of the year).

- The average body weight of 70 kg is used, representing a typical adult.

- Exposure frequency is estimated to be 60 days/year for harvesting of fruit and nut trees (i.e., 12 5-day work weeks), 110 days/year for grapes, 120 days/year for small fruit and vegetable harvesting (including strawberries), 90 days/year for golf course mowing, 180 days/year for activities involving ornamentals, 50 days for sod farm maintenance, 30 days for harvesting of dry bulb onions, 25 days for non-harvesting activities such as weeding and scouting low growing vegetables, etc., and 10 days/year for ginseng harvesting and scouting.

- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.

- Lifetime is assumed to be 70 years.

- Dermal absorption is assumed to be 5 percent, as in the handler assessment[1].

- The Q1* used in the cancer assessment is 4.39 X 10^{-2} mg/kg/day.

- *Restricted Entry Intervals (REIs)*: The Restricted Entry Intervals were estimated by selecting the earliest day after application for which the estimated DFR yields a cancer risk of less than 1E-4. DFRs were assumed to be 20 percent of the application rate initially, with a 10 percent dissipation each day thereafter. Because actual DFR data are not currently available, and 20 percent initial DFRs may be an overestimate, REIs are also presented which correspond to DFRs derived from an initial 10 percent and five percent of the application rate. These DFRs may still be an overestimate for iprodione.

(3) Postapplication Exposure and Non-Cancer Risk Estimates

The chronic Postapplication risks from Iprodione have been assessed using surrogate regression data. The DFR is derived from the application rate assuming an estimated 20 percent of the rate applied as initial dislodgeable residues, and an estimated 10 percent dissipation rate per day[6]. Because actual dissipation data are not currently available, and 20 percent initial dislodgeable residue may be an overestimate, DFRs are also calculated using an estimated ten percent and five percent initial dislodgeable residue. The equations used for the calculations in Table 13 are presented below.

Dislodgeable foliar residues (DFRs) were calculated as follows:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) \times CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) \times F \times (1 - DR)^t$$

Where:

AR	=	average application rate which is highlighted in Table 13
CF	=	conversion factor is 11.2 lb per cm^2/lb ai per acre
F	=	fraction retained on foliage (20 percent, 10 percent, and 5 percent) T
DR	=	daily dissipation rate (10 percent per day)
t	=	days after treatment, and is an assumed average reentry day identified in Table 13.

Daily Absorbed Doses were calculated as follows:

$$Dose\ (mg/kg/d) = \frac{(DFR\ (\mu g/cm^2) \times Tc\ (cm^2/hr) \times CF\left(\frac{1\ mg}{1{,}000\ \mu g}\right) \times Abs \times ED\ (hrs/day))}{BW}$$

Where:

DFR	=	daily DFR, as calculated above for the assumed average reentry day
Tc	=	transfer coefficient; 7,000 cm^2/hr for the transplanting, pruning, repotting, and bundling of ornamental shrubs, trees, vines and flowering and foliage plants
CF	=	conversion factor (i.e., 1 mg/1,000 μg)
Abs	=	dermal absorption (assume 5 percent)
ED	=	exposure duration; 8 hours worked per day for transplanting, pruning, bundling of ornamentals
BW	=	body weight (70 kg)

Chronic MOEs were calculated as follows:

$$Chronic\ MOE = \frac{NOEL\ (mg/kg/day)}{Dose\ (mg/kg/day)}$$

Where:

NOEL = 6.1 mg/kg/day1
Dose = calculated absorbed dermal dose

Table 13 presents the chronic dermal MOEs for the scenario identified with concern for potential chronic occupational exposure.

(4) Postapplication Exposure and Risk Estimates for Cancer

Total cancer risk calculations were made using the formulas for DFR, LADD, and risk presented below. Certain assumptions, including transfer coefficient, application rate, and exposure duration, change with the different scenarios or activities. The assumptions used in the iprodione DFR Postapplication risk calculations are described in the footnotes to Table 14, and are also summarized in the data assumptions section. The estimated cancer risks, assuming an initial 20 percent, 10 percent, and 5 percent DFR, are presented in Table 15.

DFRs were calculated as follows, where:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) x\ CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) x\ F\ x\ (1 - DR)^t$$

AR = application rate. See Table 15, or Postapplication assumptions section for applicable rates for each Postapplication scenario
CF = conversion factor is 11.2 μg/cm^2 per lb/acre
F = fraction retained on foliage (20 percent, 10 percent and 5 percent)
DR = daily dissipation rate (10 percent per day)
t = days after treatment. See Table 14 for the restricted entry interval (this is the day on which the cancer risk estimate is based for each individual scenario).

Lifetime Average Daily Dose (LADD) is calculated as follows:

$$LADD = \frac{DFR * Tc * ET * EF * ED * mg/1000\ \mu g * ABS}{BW * LT * 365\ d/yr}$$

Where:

DFR= dislodgeable foliar residue on day "t" (μg/cm^2)
T_c= transfer coefficient (cm^2/hr) (see Table 14 or Postapplication assumptions discussion)
ET= exposure time (hr/day) (see Table 14 or Postapplication assumptions discussion)
EF= exposure frequency (days/year) (see Table 14 or Postapplication assumptions discussion)
ED= exposure duration (35 years)
ABS= absorption factor (0.05);
BW = body weight (70 kg)
LT = lifetime (70 years).

Table 15. Occupational Postapplication Cancer Risks from Iprodione

Exposure Activity/Crop or Target	20% Initial Dislodgeable Residues[a]				10% Initial Dislodgeable Residues[a]				5% Initial Dislodgeable Residues[a]			
	REI (day)[a]	DFR (μg/cm^2)[c]	LADD (mg/kg/day)[d]	Cancer Risk[e]	REI (day)[a]	DFR (μg/cm^2)[c]	LADD (mg/kg/day)[d]	Cancer Risk[e]	REI (day)[a]	DFR (μg/cm^2)[c]	LADD (mg/kg/day)[d]	Cancer Risk[e]
Grapes (Harvesting/Pruning/Staking)	18	0.25	2.2E-03	9.5E-05	11	0.26	2.3E-03	1.0E-04	4	0.28	2.4E-03	1.0E-04
Almond Trees (Harvesting)	8	0.48	2.3E-03	9.9E-05	1	0.50	2.4E-03	1.0E-04	0	0.28	1.3E-03	5.8E-05
Stone Fruit Trees (Harvesting)	12	0.47	2.2E-03	9.8E-05	5	0.50	2.3E-03	1.0E-04	0	0.42	2.0E-03	8.7E-05
Small Vegetables and Fruits, inc. Strawberries (Harvesting)	8	0.72	2.4E-03	1.0E-04	2	0.68	2.2E-03	9.8E-05	0	0.42	1.4E-03	6.1E-05
Dry Bulb Onions (Harvesting)	0	1.12	9.2E-04	4.0E-05	0	0.56	4.6E-04	2.0E-05	0	0.28	2.3E-04	1.0E-05
"Non-Harvest Activities in Vegetables, including beans, rice, lettuce, potatoes, peanuts (e.g., weeding, scouting)	0	1.68	3.3E-04	1.4E-05	0	0.84	1.6E-04	7.2E-06	0	0.42	8.2E-05	3.6E-06
Ornamentals - 180 days (Harvesting/Transplanting/ Pruning/Bundling Flowers)	16	1.25	2.1E-03	9.2E-05	9	1.30	2.2E-03	9.7E-05	2	1.36	2.3E-03	1.0E-04
Sod Farms (Harvesting/Mowing)	4	6.03	2.4E-03	1.0E-04	0	4.60	1.8E-03	7.9E-05	0	2.30	9.0E-04	3.9E-05
Golf Course Turf (Mowing/Maintenance)	0	6.73	1.2E-03	5.2E-05	0	3.36	5.9E-04	2.6E-05	0	1.68	3.0E-04	1.3E-05
Ginseng (Harvesting/Scouting/Weeding)	0	1.68	1.2E-04	5.1E-06	0	0.84	5.8E-05	2.5E-06	0	0.42	2.9E-05	1.3E-06

Footnotes:

a Actual dissipation data are not available; therefore surrogate DFR values were calculated based on estimated initial dislodgeable residues of 5, 10, and 20 percent.

b REIs are estimated by selecting the earliest day after application for which the estimated DFR yields a cancer risk of less than 1E-4.

c Surrogate DFR values derived from Residential SOPs. Surrogate DFR (μg/cm^2) = Application rate (lb ai/acre) x Conversion factor (μg/cm^2/lb ai/acre) x fraction of active ingredient retained on foliage. Fraction = 0.2, 0.1, and 0.05 for day zero, and dissipates 10% daily thereafter.

d LADD = [DFR (μg/cm^2) x Tc (cm^2/hr) x mg/1,000 μg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x lifetime x 365 days/yr]., where adult body weight = 70 kg, dermal absorption factor is 5%, lifetime = 70 years, years of exposure is assumed to be 35 years, and the DFR value is assumed to stay constant over time for the days exposed (no actual DFR values available for multiple applications over time).

e Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 4.39E-2.

Total cancer risks were calculated using the following formula:

$$RISK = LADD * Q1^*$$

where, $Q1^* = 4.39 \text{ X } 10^{-2}$ $(mg/kg/day)^{-1}$.

Summary of Postapplication Risk Concerns, Data Gaps, and Confidence in Estimates

Postapplication Scenarios with Risk Concerns. The results of the chronic dermal risk assessment indicate that an acceptable MOE (>100) is reached for the transplanting and pruning of ornamentals scenario on the 15th, 8th, and 1st day after treatment for 20 percent, 10 percent, and 5 percent initial DFR, respectively.

The results of the cancer risk assessment, presented in Table 15, indicate that REIs for the various crop groupings range from 0-days to 18-days assuming an initial 20 percent DFR; 0-days to 11-days assuming an initial 10 percent DFR; and, 0-days to 4-days assuming an initial 5 percent DFR. Although the default assumption for the initial DFR is 20 percent, assessments were conducted using 10 and 5 percent initial DFR to provide a range in the case that the actual DFR is lower. At this time, the Agency believes that each scenario is likely to be an overestimate of the post-application cancer risk from iprodione due to the conservative nature of the surrogate dislodgeable residue data.

Based on the lack of data regarding dislodgeable residues for iprodione, and the likelihood that the actual DFR is closest to 5 percent (i.e., data from similar compounds indicate this), a 48-hour restricted-entry interval for iprodione use on grapes and ornamentals will be required, and a 24-hour restricted-entry interval for all other uses of iprodione will be required. Although a 4-day restricted-entry interval is indicated for the grapes scenario, the Agency at this time believest that this is overly conservative when considering the percent of the crop treated with iprodione (10 percent) and the average number of applications (1.2) as documented in *Agricultural Chemical Usage -- Fruits 1994 Summary* (July 1995). The Agency will revisit these restricted-entry interval decisions when actual chemical-specific dislodgeable residue data is available and reviewed (to be submitted October 2000).

(5) Data Gaps, Quality, and Confidence

The following data gaps or uncertainties are associated with this assessment:

- No chemical-specific exposure or transferable residue data were submitted. As a result, all analyses were completed using surrogate data from sources such as PHED and assumptions related to the behavior and environmental fate of the chemical in the environment (e.g., dissipation of transferable residues).

- Factors used to calculate postapplication risks (e.g., hours exposure per day or average reentry day) are based on labeling directions and best professional judgment due to lack of data specific to each crop/activity combination.

- The number of significant figures used to report cancer risks may indicate greater precision than the conservative default assumptions and data reliability can provide.
- Crop groupings for the postapplication assessment are representative of general ranges of expected levels of exposure, and are based on application rate, PHI, exposure activity, and exposure duration. Risks may vary within these crops groupings.
- DFRs are estimated using the residential SOPs. The SOPs are designed to yield conservative estimates of residue levels. For Iprodione, however, these estimates may be less conservative because (1) environmental fate information indicates that Iprodione is likely to degrade more slowly than the 10% per day from the SOPs, and (2) potential additive effects of multiple applications have not been factored into the estimated DFRs.

(6) Residential and other Non-occupational Exposures and Risks

(a) Residential Handler Exposure Scenarios - Data and Assumptions

Residential handler exposure assessments were completed by EPA assuming a "baseline" exposure scenario (for homeowners, short sleeved shirt, short pants, shoes and socks, and no gloves or respirator). PHED values used to estimate daily unit exposure values were taken from the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* document dated December 1997. Table 16 summarizes the caveats and parameters specific to the surrogate data used for each scenario and corresponding exposure/risk assessment. The following assumptions and factors were used in the assessment:

- Maximum application rates for specific crops as recommended by the iprodione labels were used to bracket risk levels associated with the various use patterns. No use data were provided concerning the application rates that are commonly used for iprodione by homeowners, though survey data indicate that is common for homeowners to apply maximum (or higher) rates.
- Generally, the use of PPE and engineering controls are not considered feasible or appropriate for homeowners.
- For homeowner turf management, the following estimates of the square feet of a homeowners garden were used: 20,000 ft^2 for lawns areas, and 1,000 ft^2 for spot treatments.
- Estimates of spray application to small vegetable gardens and lawns include: 5 gallons per day for low pressure handwand and backpack sprayers, and 50 gallons per day for garden hose-end sprayers.
- PHED values represent a handler wearing short sleeve shirt, short pants, shoes and socks, and no gloves or respirator.

Table 17 presents the residential handler exposures and short-term and intermediate-term inhalation risks for iprodione.

Table 16. Residential Exposure Scenario Descriptions for the Use of Iprodione

Exposure Scenario (Number)	Data Source	Standard Assumptions[a]	Comments[b]
Mixer/Loader/Applicator Descriptors			
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (1)	SOPs for Residential Exposure Assessments (12/97)	5 gallons for small vegetable gardens. trees and ornamentals; and 20,000 ft^2 for turf	**Baseline**: Dermal and inhalation data = ABC grades, and hands data = All grade. Dermal = 9-80 replicates; hands = 70 replicates; and inhalation = 80 replicates. Low confidence in hands, dermal data. Medium confidence in inhalation data.
			PPE and Engineering Controls: Not required for assessment.
Mixing/Loading/Applying Using a Backpack Sprayer (2)	SOPs for Residential Exposure Assessments (12/97)	5 gallons on fruit/nut trees, ornamentals, and small vegetable gardens; and 20,000 ft^2 for turf	**Baseline**: Dermal = AB grade; inhalation = A grade; and hands = C grade. Dermal = 9 to 11 replicates; hands = 11 replicates; and inhalation = 11 replicates. Low confidence in dermal, and inhalation data. A 90% protection factor was used to back calculate "no glove" hand data from the gloved scenario.
			PPE and Engineering Controls: Not required for assessment.
Mixing/Loading/Applying Using a Garden Hose-end Sprayer (3)	SOPs for Residential Exposure Assessments (12/97)	50 gallons on trees, ornamentals and small vegetable gardens; and 20,000 ft^2 for turf	**Baseline**: Dermal and inhalation = C grade, and hands = E grade. Dermal, inhalation, and hands = 8 replicates each. Low confidence in all data.
			PPE and Engineering Controls: Not required for assessment.
Mixing/Loading Granulars Using a Belly Grinder (4)	SOPs for Residential Exposure Assessments (12/97)	20,000 ft^2 and 1,000 ft^2 for turf	**Baseline:** Dermal and hands data = ABC grades, inhalation = AB grade. Dermal 20-45 replicates; hands = 23 replicates; and inhalation = 40 replicates. Medium confidence for hands, dermal and high confidence for inhalation.
			PPE and Engineering Controls: Not required for assessment.
Loading/Applying Granulars Using a Push-type Lawn Spreader (5)	SOPs for Residential Exposure Assessments (12/97)	20,000 ft^2 and 1,000 ft^2 for turf	**Baseline:** Dermal and Hands data = C grade, and inhalation data = B grade. Hand = 15 replicates; dermal = 0-15 replicates; and inhalation = 15 replicates. Low confidence in hands, dermal data, and high confidence in inhalation data. A 50% protection factor was used to "back calculate" a short sleeved shirt value from long sleeve shirt data.
			PPE and Engineering Controls: Not required for assessment.
Loading/Applying Granulars by Hand as a Spot Treatment (6)	SOPs for Residential Exposure Assessments (12/97)	1,000 ft^2	**Baseline:** Dermal, hands and inhalation data = ABC grade. Hands, dermal and inhalation = 16 replicates. Medium confidence in all data. A 90% PF was applied to gloved hands data to back calculate "no glove" hand exposure.
			PPE and Engineering Controls: Not required for assessment

[a] Standard Assumptions based on EPA estimates.

[b] "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows: High= grades A and B and 15 or more replicates per body part; Medium= grades A, B, and C and 15 or more replicates per body part; Low= grades A, B, C, D and E or any combination of grades with less than 15 replicates.

NA = Not Applicable

(7) Residential Handler Exposure and Risk Estimates for Cancer

Calculations of lifetime average daily dose (LADD) and cancer risk were performed using the formulas presented previously for the occupational handler cancer assessment. Table 18 presents potential cancer risk estimates from dermal and inhalation exposures to iprodione from residential handling activities.

f. Summary of Risk Concerns for Homeowner-Handlers, Data Gaps, and Confidence in Exposure and Risk Estimates

Short and intermediate-term inhalation risks for homeowner-handlers were assessed as well as total cancer risks.

Homeowner Handler Risks. The calculations of short-term and intermediate-term inhalation risks indicate that inhalation MOEs are greater than 100 at baseline for all scenarios considered:

- (1) mixing/loading/applying sprays with a low pressure handwand;
- (2) mixing/loading/applying using a backpack sprayer;
- (3) mixing/loading/applying using a garden hose-end sprayer;
- (4) loading/applying granulars using a belly grinder; and
- (5) loading/applying granulars with a push-type lawn spreader; and
- (6) loading/applying granulars by hand as spot treatments.

The calculations of potential total cancer risk to homeowner handlers indicate that risks are greater than 1.0E-6 for the following scenarios:

- (1) mixing/loading/applying sprays with a low pressure handwand (turf and small fruits and vegetables only);
- (2) mixing/loading/applying using a backpack sprayer (turf only);
- (3) mixing/loading/applying using a garden hose-end sprayer (all sites except trees);
- (4) loading/applying granulars using a belly grinder for broadcast treatments; and
- (6) loading/applying granulars by hand as spot treatments.

The calculations of potential total cancer risk to homeowner handlers indicate that risks are below 1.0E-6 for all other scenarios.

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- (8) - no PHED data exist for mixing/loading/applying solution as a dip treatment.

Data Quality and Confidence in Assessment. Several issues must be considered when interpreting the homeowner handler risk estimates:

Table 17. Residential Handler Exposures and Short-term and Intermediate-term Inhalation Risks for Iprodione (Baseline)

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (μg/lb ai)	Range of Application Rates[b] (lb ai/A)	Crop Type or Target[c]	Amount Handled per Day[d]	Baseline Inhalation Exposure[e] (mg/day)	Short-term Baseline Inhalation Dose[f] (mg/kg/day)	Int.-term Baseline Daily Inhalation Dose[g] (mg/kg/day)	Baseline Short-term MOE[h]	Baseline Int.-term MOE[i]
Mixer/Loader/Applicator Risks									
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (1)	30	0.0026 lb ai/gal	Fruit/Nut Trees	5 gallons	0.00039	6.5E-6	5.6E-6	3,100,000	1,100,000
		0.01 lb ai/gal	Ornamentals	5 gallons	0.0015	2.5E-5	2.1E-5	800,000	290,000
		0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	0.075	1.3E-3	1.1E-3	15,000	5,500
		0.104 lb ai/gal	Vegetable/Small Fruit Garden	5 gallons	0.016	2.7E-4	2.3E-4	74,000	27,000
Mixing/Loading/Applying Using a Backpack Sprayer (2)	30	0.0026 lb ai/gal	Fruit/Nut Trees	5 gallons	0.00039	6.5E-6	5.6E-6	3,100,000	1,100,000
		0.01 lb ai/gal	Ornamentals	5 gallons	0.0015	2.5E-5	2.1E-5	800,000	290,000
		0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	0.075	1.3E-3	1.1E-3	15,000	5,500
		0.104 lb ai/gal	Vegetable/Small Fruit Garden	5 gallons	0.016	2.7E-4	2.3E-4	74,000	27,000
Mixing/Loading/Applying Using a Garden Hose-end Sprayer (3)	9.5	0.0026 lb ai/gal	Trees	50 gallons	0.0012	2.0E-5	1.7E-5	1,000,000	360,000
		0.01 lb ai/gal	Ornamentals	50 gallons	0.0048	8.0E-5	6.9E-5	250,000	88,000
		0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	0.024	4.0E-4	3.4E-4	50,000	18,000
		0.104 lb ai/gal	Vegetable/Small Fruit Garden	50 gallons	0.049	8.2E-4	7.0E-4	24,000	8,700
Loading/Applying Granulars Using a Belly Grinder (4)	62	0.0941 lb ai/1,000 ft^2	Turf	20,000 ft^2	0.12	2.0E-3	1.7E-3	10,000	3,600
		0.0941 lb ai/1,000 ft^2		1,000 ft^2	0.0058	9.7E-5	8.3E-5	210,000	73,000
Loading/Applying Granulars Using a Push-type Lawn Spreader (5)	6.3	0.0941 lb ai/1,000 ft^2	Turf	20,000 ft^2	0.012	2.0E-4	1.7E-4	100,000	36,000
		0.0941 lb ai/1,000 ft^2		1,000 ft^2	0.00059	9.8E-6	8.4E-6	2,000,000	730,000
Loading/Applying Granulars by Hand as a Spot Treatment (6)	470	0.0941 lb ai/1,000 ft^2	Turf	1,000 ft^2	0.044	7.3E-4	6.3E-4	27,000	9,700
Mixing/Loading/Applying Solution as a Dip Treatment (8)	No Data	No Data	Ag	No Data	No Data	No Data	No Data	No Data	No Data

Footnotes:

a Baseline Inhalation Unit Exposure values taken from PHED V1.1 reflect no respiratory protection.

b Application rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops/sites based on application method. Examples of application rates and source labels include:0.0026 lb ai/gal applicable to stone fruit trees - EPA Reg. No. 264-562;
0.01 lb ai/gal ornamentals - EPA Reg. No. 264-563;
0.125 lb ai/1,000 ft turf - EPA Reg. No. 264-562; and
0.104 lb ai/gal potatoes and carrots - EPA Reg. No. 264-562.

c Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres or gallons treated or applied.

d Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

e Baseline Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/ft^2 or lb ai/gal) * Amount Handled Per Day (ft^2/day or gallons/day).

f Baseline Short-term Daily Inhalation Dose = Baseline Daily Inhalation Exposure (mg/day)/Body Weight (60 kg).

g Baseline Int.-term Daily Inhalation Dose = Baseline Daily Inhalation Exposure (mg/day)/Body Weight (70 kg).

h Baseline Short-term MOE = NOEL (20 mg/kg/day) / Short-term Baseline Daily Inhalation Dose (mg/kg/day).

I Baseline Intermediate-term MOE = NOEL (6.1 mg/kg/day) / Intermediate-term Baseline Daily Inhalation Dose (mg/kg/day).

Table 18. Residential Handlers' Combined Dermal and Inhalation Cancer Risk Assessment for Iprodione (Baseline)

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Range of Application Rates[c](lb ai/A)	Crop Type or Target[d]	Amount Handled per Day[e]	Daily Dermal Exposure[f] (mg/day)	Daily Inhalation Exposure[g] (mg/day)	Baseline Total Daily Dose[h] (mg/kg/day)	Number of Exposures per Year[i]	Baseline LADD[j] (mg/day)	Baseline Total Cancer Risk[k]
Mixer/Loader/Applicator Risk											
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (1)	100	30	0.0026 lb ai/gal	Fruit/Nut Trees	5 gallons	1.3	0.00039	0.00093	4	5.1E-6	2.2E-7
			0.01 lb ai/gal	Ornamentals	5 gallons	5.0	0.0015	0.0036	4	2.0E-5	8.8E-7
			0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	250	0.075	0.18	2	5.2E-4	2.3E-5
			0.104 lb ai/gal	Vegetable/Small Fruit Garden	5 gallons	52	0.016	0.037	4	2.0E-4	8.8E-6
Mixing/Loading/Applying Using a Backpack Sprayer (2)	5.1	30	0.0026 lb ai/gal	Fruit/Nut Trees	5 gallons	0.066	0.00039	0.000053	4	2.9E-7	1.3E-8
			0.01 lb ai/gal	Ornamentals	5 gallons	0.26	0.0015	0.00021	4	1.2E-6	5.3E-8
			0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	13	0.075	0.010	2	2.7E-5	1.2E-6
			0.104 lb ai/gal	Vegetable/ Small Fruit Garden	5 gallons	2.7	0.016	0.0021	4	1.2E-5	5.3E-7
Mixing/Loading/Applying Using a Garden Hose-end Sprayer (3)	30	9.5	0.0026 lb ai/gal	Trees	50 gallons	3.9	0.0012	0.0028	4	1.6E-5	7.0E-7
			0.01 lb ai/gal	Ornamentals	50 gallons	15	0.0048	0.011	4	6.0E-5	2.6E-6
			0.125 lb ai/1,000 ft^2	Turf	20,000 ft^2	75	0.024	0.054	2	1.5E-4	6.6E-6
			0.104 lb ai/gal	Vegetable/ Small Fruit Garden	50 gallons	160	0.049	0.11	4	6.0E-4	2.6E-5
Loading/Applying Granulars Using a Belly Grinder (4)	110	62	0.0941 lb ai/1,000 ft^2	Turf	20,000 ft^2	210	0.12	0.16	2	4.4E-4	1.9E-5
			0.0941 lb ai/1,000 ft^2		1,000 ft^2	10	0.0058	0.0073	2	2.0E-5	8.8E-7
Loading/Applying Granulars Using a Push-type Lawn Spreader (5)	3	6.3	0.0941 lb ai/1,000 ft^2	Turf	20,000 ft^2	5.6	0.012	0.0041	2	1.1E-5	4.8E-7
			0.0941 lb ai/1,000 ft^2		1,000 ft^2	0.28	0.00059	0.00021	2	5.8E-7	2.5E-8
Loading/Applying Granulars by Hand as a Spot Treatment (6)	430	470	0.0941 lb ai/1,000 ft^2	Turf	1,000 ft^2	40	0.044	0.029	2	7.9E-5	3.5E-6

FOOTNOTES

a Baseline PHED V1.1 Dermal Unit Exposure values represent short pants, short sleeved shirt, no gloves, and open mixing/loading. (see *Exposure Scenario Descriptions Table* for further information).

b Baseline PHED V1.1 Inhalation Unit Exposure values reflect no respiratory protection.

c Application rates come from values found in the LUIS report and on Iprodione labels. For some scenarios, a range of application rates is used to represent different crops/sites based on application method. Examples of application rates and source labels include:

0.0026 lb ai/gal applicable to stone fruit trees - EPA Reg. No. 264-562;
0.01 lb ai/gal on ornamentals - EPA Reg. No. 264-563;
0.125 lb ai/1,000 ft^2 on turf - EPA Reg. No. 264-562; and
0.104 lb ai/gal on potatoes and carrots - EPA Reg. No. 264-562.

d Crop Type or Target provides a general description of the intended uses of various products containing Iprodione. Separate categories are presented because of the distinct differences in application rates and acres treated.

e Amount Handled Per Day values are from the EPA estimates of acreage treated, or volume handled in a single day for each exposure scenario of concern based on the application method.

f Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/ft^2 or lb ai/gal) * Amount Handled Per Day (ft^2/day or gallons/day).

g Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/ft^2 or lb ai/gal) * Amount Handled Per Day (ft^2/day or gallons/day).

h Baseline Total Daily Dose = [Baseline Daily Dermal Exposure (mg/day) * 0.05 (Dermal Absorption Factor) + Baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

I Number of Exposures Per Year is based on maximum number of applications which represent private use.

j Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (Number of days exposure per year/365 days per year) * 35 years applied/70 year lifetime.

k Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = 4.39E-2 (mg/kg/day).

- The PHED surrogate data for the garden hose-end sprayer scenario, application with a backpack sprayer scenario, application with a push type granular spreader scenario, and application with low pressure handwand scenario are low confidence due to low number of replicates and/or low quality data.

- The PHED values for loading/applying granulars by hand are based on gloved hand data; a 90% PF was used to estimate bare hand exposure for the baseline scenario.

- Factors used to calculate daily exposures to handlers (e.g., square footage treated per day or gallons of liquid applied) are based on labeling directions and professional judgement due to a lack specific usage data.

- The PHED values for low pressure handwand, backpack sprayer and garden hose-end sprayer are representative for treatment of low- to mid-level shrubs. The exposure data for these scenarios may underestimate exposures to head and upper body when homeowners make applications to trees.

(1) Non-Occupational Postapplication Exposures and Risks

Once sprays and dusts have settled, Postapplication inhalation exposure is not expected to be significant. In addition, an appropriate dermal endpoint was not available for use in assessing non-cancer dermal risks. Consequently, only postapplication cancer risks have been assessed.

Postapplication Exposure Scenarios. EPA has determined that there are crop groups and activities likely to result in non-occupational Postapplication exposures from iprodione. These crop groups/activities were grouped based on the assumed exposure level, PHI, maximum number of applications per season and expected frequency of exposure. These crop groups/activities include the following:

- Grape harvesting, pruning, and staking: assumed to result in higher exposures than other activities such as propping or staking which would have a longer PHI and lower number of days of exposure;
- Harvesting small vegetables and fruits, including strawberries: assumed to result in higher exposures than activities such as scouting, thinning, or weeding , which have longer PHIs and lower exposure frequencies;
- Ornamental shrub, vine and flowering or foliage plant transplanting, pruning, cutting, and bundling: assumed to have high exposure levels and high exposure frequencies, and with greater application rates than those applied to fruits and vegetables;
- Dermal exposure from residue on turf (adult and child);
- Incidental nondietary ingestion of residue on turf resulting from hand-to-mouth transfer (toddler);
- Ingestion of treated turfgrass (toddler); and
- Incidental ingestion of soil from treated areas (toddler).

Although youths, in addition to adults and toddlers, may also engage in Postapplication activities, they are expected to have lower transfer coefficients than adults (i.e., 5,000 cm^2/hour for harvesting fruit from trees as opposed to an adult value of 10,000 cm^2/hour)[6], and lower body weights (i.e., 39 kg as opposed to 70 kg for adults). The proportionally lower values for T_c and body weight would result in similar exposure values for youths and adults. For this reason, a separate assessment for youths has not been performed. The exposure assessment for adults (LADD) would also apply to youths.

Although it is likely that toddlers would be exposed to iprodione from dermal contact with, and incidental ingestion of grass, soil, or hand-to-mouth transfer, no risk assessment was performed for these scenarios because no relevant oral toxicological endpoints have been identified. The acute dietary endpoint of 20 mg/kg/day for iprodione is applied only to females 13+. At present, EPA has no toxicological data to elucidate the effects of iprodione on toddlers. In addition, toddler cancer risks have not been quantified due to the fact that EPA currently has no appropriate means to account for changing exposure parameters (i.e., activity duration, body weight, surface area, and transfer coefficient) as the toddler progresses through various age groups.

The residential post-application scenarios and assumptions for iprodione are outlined in Table 19.

Table 19. Residential Postapplication Scenarios and Assumptions for Iprodione

Exposure Activity/ Crop or Target	Application Rate (lb ai/acre)	Contact Rate (cm^2/hr)[a]	Exposure Days per Year[b]	Years of Exposure	Hours Exposed per Day[a]	Maximum Number of Applications per Season[c]	Application Interval[c] (days)
Grapes (Harvesting/Pruning/Staking)	0.75	10,000	8	35	0.67	4	7
Small Vegetables and Fruits, including Strawberries (Harvesting/Weeding/Staking)	0.75	3,500	24	35	0.67	2-10	7-14
Ornamentals (Transplanting/Pruning / Bundling Flowers)	3	7,000	4	35	0.67	NS	7-14
Adults (Dermal Contact with Turf)	3	1,000	40	35	1	2	NA

FOOTNOTES

NA = Not applicable. NS = Not specified on Iprodione label.

a Values come from *SOPs for Residential Exposure Assessments*[6], except for the turf scenario, which is based on professional judgement (i.e., a contact rate of 1,000 cm^2/hr is more representative for a lifetime of exposure, and 1 hour/day represents the 50th percentile for time spent playing in grass in Exposure Factors Handbook, 1997).

b Exposure days per year are based on Iprodione label directions and professional judgment. Turf exposure = 26 weeks x 1-2 days/wk.

c Values derived from Iprodione labels for agricultural scenarios. Professional judgment employed in assumption of 2 turf applications per growing season..

Data Sources for Scenarios Considered. No chemical-specific Postapplication human reentry or transferable residue data were submitted. In lieu of these data, a Postapplication exposure assessment was conducted using the Residential SOPs to determine potential risks for the representative scenarios.

Assumptions Used in Postapplication Exposure Calculations (Cancer Risks). Assumptions used in the calculations for residential Postapplication risks include the following:

- The cancer risks were assessed for the same day that application was assumed to occur; it is not feasible to set REIs for homeowners.

- A dermal absorption value of 5% was used in this assessment.

- The exposure duration for adults was assumed to be 35 years.

- Transfer coefficients were estimated to be 10,000 cm^2/hr for high-contact harvesting (i.e., grapes); 7,000 cm^2/hr for high contact activities involving ornamental shrubs, vines, flowering and foliage plants; and 3,500 cm^2/hr for harvesting small fruits and vegetables, including strawberries. The dermal transfer coefficient for low-contact turf exposure is estimated to be 1,000 cm^2/hr for adults.

- An average application rate of 3 lb ai/acre was used in the turfgrass and ornamental scenarios (range =1.4 lb ai/acre and 5.5 lb ai/acre). An average application rate of 0.75 lb ai/acre was used for the agricultural crop scenarios (i.e., harvesting of grapes and small fruits and vegetables), and was calculated from the application range of 0.5 to 1.0 lb ai/acre). The residential application rates used in the handler assessment were assessed in units of lb ai/gallon, due to application methods. These same rates were converted to lb ai/acre here, in order to calculate Postapplication risks.

- On the day of application, it was assumed that 20 percent of the application rate was available as dislodgeable residue, because actual DFR data are not currently available, and assuming a 20 percent initial dislodgeable residue may be an over-estimation, DFRs were also derived from an initial 10 percent and 5 percent fo the application rate.

- Adults were assumed to weigh 70 kg.

- The duration of exposure was assumed to be 0.67 hours per day, except for the turf scenario, which has an assumed duration of 1 hour per day.

(2) Postapplication Exposure and Non-Cancer Risk Estimates

No non-occupational crop groups or activities were identified as having potential chronic exposure.

(3) Postapplication Exposure and Risk Estimates for Cancer

Non-occupational Postapplication scenarios were assessed for cancer risk; the results are summarized in Table 20. Total cancer risk calculations for the dermal scenarios were made using the formulas for DFR, LADD, and risk presented previously in the occupational Postapplication discussion.

As stated previously, toddler cancer risks have not been quantified due to the fact that EPA currently has no appropriate means to account for the changing exposure parameters as the toddler progresses through the various age groups.

Table 20. Residential Postapplication Cancer Risks from Iprodione

Exposure Activity/Crop or Target	20 % Initial Dislodgeable Residues			10 % Initial Dislodgeable Residues			5 % Initial Dislodgeable Residues		
	DFR[a] ($\mu g/cm^2$)	LADD[b] (mg/kg/day)	Cancer Risk[c]	DFR[a] ($\mu g/cm^2$)	LADD[b] (mg/kg/day)	Cancer Risk[c]	DFR[a] ($\mu g/cm^2$)	LADD[b] (mg/kg/day)	Cancer Risk[c]
Grapes (Harvesting/Pruning/Staking)	1.7	8.8E-05	3.9E-06	0.84	4.4E-05	1.9E-06	0.42	2.2E-05	9.7E-07
Small Vegetables and Fruits, including Strawberries (Harvesting/Weeding/Staking)	1.7	9.3E-05	4.1E-06	0.84	4.6E-05	2.0E-06	0.42	2.3E-05	1.0E-06
Ornamentals (Transplanting/ Pruning/ Bundling Flowers)	6.7	1.2E-04	5.4E-06	3.4	6.2E-05	2.7E-06	1.7	3.1E-05	1.4E-06
Adults (Dermal Contact with Turf)	6.7	2.6E-04	1.2E-05	3.4	1.3E-04	5.8E-06	1.7	6.6E-05	2.9E-06

FOOTNOTES

a DFR values derived from surrogate data. Surrogate DFR ($\mu g/cm^2$) = Application rate (lb ai/acre) x Conversion factor ($\mu g/cm^2$/lb ai/acre) x fraction of active ingredient retained on foliage. Fraction = 0.2, 0.1, and 0.05 for day zero.

b LADD = [DFR ($\mu g/cm^2$) x Tc (cm^2/hr) x mg/1,000 μg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [70 kg x 70 yr x 365 days/yr], where the DFR value is assumed to stay constant over time for the days exposed (no actual DFR values available for multiple applications over time).

c Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 4.39E-2.

(4) Summary of Postapplication Risks, Data Gaps, and Confidence

Non-occupational postapplication scenarios with risk concerns. The results of the non-occupational Postapplication cancer risk assessment indicate that all residential Postapplication scenarios have risks greater than 1.0E-6.

Data gaps and uncertainties. The following data gaps or uncertainties were associated with this assessment:

- No chemical-specific exposure or transferable residue data were submitted. As a result, all analyses were completed using surrogate data from sources such as PHED and assumptions related to the behavior and environmental fate of the chemical in the environment (e.g., dissipation of transferable residues). Typically, these assumptions are considered to yield conservative estimates. However, because iprodione degrades at a slow rate, the results of this assessment are expected to be somewhat less conservative than would be expected for other chemicals.

- Factors used to calculate Postapplication risks (e.g., hours exposure per day or average reentry day) are based on label directions and professional judgment due to an absence of specific usage data for each scenario.

- Crop groupings for the Postapplication assessment are assumed to be representative of general ranges of exposure, and are based on application rate, PHI, exposure activity and exposure duration. Risks are expected to vary within these crops groupings.

g. Incident Reports

The following data bases have been consulted for the poisoning incident data on the active ingredient iprodione:

OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

Incident Data System (IDS)

Please note that the following cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted.

A pesticide incident occurred in 1994, when a UPS driver was exposed to iprodione after a bag spilled in his truck and he experienced dizziness. No further information on the disposition of the case was reported.

A pesticide incident occurred in 1995, when a male was sprayed with an aqueous use dilution mixture of iprodione after the rupture of a gauge. He experienced numb lips and tongue, tingling fingers, and headache. No further information on the disposition of the case was reported.

A pesticide incident occurred in 1994, when a male was exposed to spray droplets on his face and neck after his garden was sprayed with iprodione. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

A pesticide incident occurred in 1994, when individuals alleged they developed skin rashes while working in their garden three days after iprodione and other pesticides were sprayed on crop fields. No further information on the disposition of the case was reported.

A pesticide incident occurred in 1996, when two workers prepared nonflowering ornamentals for shipment less than one day after foliar application of iprodione and another pesticide. The products were applied at 1 lb and 3 lbs/100 gallons water. The workers wore rubber gloves to wrap loose vines around the main plants and developed a rash on their arms above the glove line the next day. No further information on the disposition of the case was reported.

California Data - 1982 through 1990

Detailed descriptions of 120 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) were reviewed. In 26 of these cases, iprodione was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Iprodione ranked 84th as a cause of systemic poisoning in California. Table 21 below presents the types of illnesses reported by year. None of the cases reported in the table below were reported to have been hospitalized. Table 22 gives the total number of workers that took time off work as a result of their illness.

Table 21. Cases Due to Iprodione Exposure in California Reported by Type of Illness and Year, 1982-1995.

Year	Illness Type					
	[b]Systemic	Eye	Skin	Respir.	[c]Comb.	Total
1982	-	-	-	-	-	-
1983	-	-	-	-	-	-
1984	-	-	2	-	-	2
1985	-	-	-	-	-	-
1986	1	1	-	-	-	2
1987	1	-	1	-	-	2
1988	-	-	-	-	-	-
1989	1	1	-	-	-	2
1990	-	1	4	-	-	5
1991	1	1	1	-	1	4
1992	-	-	-	-	-	-
1993	-	-	1	-	-	1
1994	4	1	2	-	-	7
1995	-	-	1	-	-	1
Total	8.00	5.00	12.00	0.00	1.00	26.00

[b] Category includes cases where skin, eye, or respiratory effects were also reported
[c] Category includes eye/skin illness

Table 22. Number of Persons Disabled (taking time off work) or Hospitalized for Indicated Number of Days After Iprodione Exposure in California, 1982-1995.

Duration	Number of Persons Disabled	Number of Persons Hospitalized
One day	2	-
Two days	1	-
3-5 days	2	-
6-10 days	-	-
more than 10 days	-	-
unknown	-	-

A total of 12 persons had skin illnesses or 46% of 26 persons. Four of these cases occurred in 1990. A total of 8 persons had systemic illnesses or 31% of 26 persons. A variety of worker activities were associated with exposure to iprodione as illustrated in table 23 below.

Table 23. Illnesses by Activity Categories for Iprodione Exposure in California, 1982-1995

Activity Category	Illness Category					
	[b]Systemic	Eye	Skin	Respiratory	[c]Combination	Total
Coincidental	-	-	1	-	-	1
Applicator	3	-	4	-	-	7
Resifield	3	1	6	-	-	10
Other	1	1	-	-	-	2
Mixloader	-	2	-	-	1	3
Driftexp	1	-	-	-	-	1
Clean/Fix	-	1	-	-	-	1
Pack/Proc	-	-	1	-	-	1
Total	8.00	5.00	12.00	0.00	1.00	26.00

[a] Mixloader = mixer and/or loader; Driftexp = exposure to pesticide that has drifted from intended targets; Clean/Fix = cleaning and/or repairing pesticide contaminated equipment; Pack/Proc = packing, processing, or retailing commodities
[b] Category includes cases where skin, eye, or respiratory effects were also reported
[c] Category includes eye/skin illness

According to the above activity categories, resifield (field worker exposed to residue in the field) that affected the skin were associated with the majority of the exposures. The skin illnesses occurred after iprodione was applied to citrus and golf course greens and workers developed itchy rashes on hands, arms, face and legs. The resifield systemic illnesses included symptoms of headache and nausea. The ground applicator systemic illnesses included symptoms of weakness, eye irritation, muscle weakness to exposed side of face, and rashes on hands, neck, and face.

A pesticide incident occurred in 1996 that involved a male strawberry picker that was a harvester and did not have duties that involved handling any pesticides. Examination of the records for the fields in which he worked for 3 months prior to his illness showed potential exposure to 10 different pesticides, including iprodione. He experienced flu-like symptoms and developed tonsillitis, coughing, and nosebleeds and was hospitalized for eight days and was diagnosed with pancytopenia. None of the other members of his crew, which had the same exposures, displayed these symptoms.

National Pesticide Telecommunication Network (NPTN)

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, iprodione was reported to be involved in sixteen human incidents.

Summary/Conclusions: Exposure to iprodione can lead to skin illness requiring medical care. Skin rashes have been reported in field workers exposed to residues of iprodione. A few cases (8) have reported relatively minor systemic symptoms such as headache, nausea, and dizziness. Three of the eight cases were reportedly due to field reentry. However, in none of the systemic cases was the exposure considered a probable or definite cause of the effects.

h. Dietary Exposure and Risk Assessment/Characterization

(1) Dietary Exposures from Food Sources

(a) GLN 860.1200: Directions for Use

EPA examined the registered food/feed use patterns and reevaluated the available residue chemistry database for adequacy in supporting these use patterns. A comprehensive summary of iprodione food/feed use patterns, based on the product labels registered to Rhone-Poulenc is presented in Table 24. Label amendments are required to support continued uses of iprodione on several crops. Details of the required label amendments are presented in the endnotes for GLN 860.1200 (Directions for Use) of appendix IV, Table D.

The Agency classifies the registered Section 24(c) uses of iprodione on clover (seed crop; SLNs OR960011 and OR960012) and on peas (seed treatment; SLNs WA930026, WA930027) to be non-food uses because of adequate regulatory state controls and label use restrictions.

The status of reregistration requirements for each guideline topic is based on the use patterns registered by the basic producer. EPA will require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels and with the use changes required in this RED.

(b) GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in three dissimilar crops (peaches, peanuts, and rice) have been submitted and evaluated. Residues comprising the current iprodione tolerance expression for plants accounted for 95% of the total radioactive residues (TRR) in peaches, 78% of the TRR in peanut hay, 75% of the TRR in rice head/stalks, and 60% of the TRR in rice straw. Other metabolites in each crop individually represented less than 10% TRR and/or less than 0.05 ppm. The residues to be regulated in plants should continue to be the parent, its isomer RP-30228, and metabolite RP-32490, which comprise the current tolerance expression for plants.

(c) GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for livestock metabolism are fulfilled provided label restrictions are in place. An additional ruminant metabolism study will not be required, provided that all applicable iprodione end-use product labels prohibit use on cowpeas and prohibit the feeding of iprodione-treated peanut hay to livestock animals, and that the 1x feeding level (theoretical maximum dietary intake) based on tolerances for feed items does not significantly increase above 30 ppm. If any registrant desires to support use on cowpeas

or the feeding of peanut hay, or if new uses would significantly increase the 1x feeding level above 30 ppm, then a new ruminant metabolism study would be required to identify residues of concern and to generate samples for radiovalidation of an enforcement analytical method. An additional poultry metabolism study is not required.

The residues to be regulated in livestock should continue to be the parent, its isomer RP-30228, and metabolites RP-32490 and RP-36114 which comprise the current tolerance expression for livestock commodities.

(d) GLN 860.1340: Residue Analytical Methods

Methods for determination of residues in/on plant commodities: The Pesticide Analytical Manual (PAM) Vol. II lists a GLC/ECD method, designated as Method I, for the determination of iprodione residues of concern in/on plant commodities. Method I does not use benzene as a reagent and detects residues of iprodione parent, iprodione isomer RP-30228, and iprodione metabolite RP-32490 as individual peaks on GLC. A successful Agency validation of Method I was carried out with kiwifruit.

The Chemistry Branch has determined that the proposed Common Moiety Method, wherein iprodione tolerance residues are all hydrolyzed to dichloroaniline, is less suitable for enforcement than Method I of PAM Vol. II because of the potential for interference and a much longer time required for analysis. Other chemicals that can be converted to the dichloroaniline moiety will be assumed to interfere with detection of iprodione residues, unless the registrant can provide data demonstrating otherwise. The Common Moiety Method, therefore, will not be forwarded to FDA for publication at this time.

The Common Moiety Method is, however, suitable for data collection provided it is modified to incorporate comments from Agency reviews and method validation. The Chemistry Branch notes that additional data are required for confined rotational crops, and the iprodione residues of concern in/on rotational crops have not yet been determined. Because of the presence of conjugates not fully identified, the Common Moiety Method described may ultimately prove the most appropriate method available for determining iprodione residues of concern in/on rotational crops.

The iprodione Phase 4 review waived the requirements for radiovalidation data for the analytical methods for plants since the parent and regulated metabolites are not likely to be bound or conjugated.

Methods for determination of residues in/on livestock commodities: There are presently no methods published in PAM Vol. II for the enforcement of iprodione tolerances for livestock commodities. Morse Laboratories SOP Method-71 has been proposed as an enforcement method for the determination of non-hydroxylated iprodione residues; this method converts non-hydroxylated iprodione residues to dichloroaniline as a common moiety. For the purposes of reregistration, Method-71 should be amended in accordance with the

recommendations of the laboratory which conducted the independent laboratory validation. Because Method-71 uses benzene as a reagent, the registrant should justify the use of this substance, including an explanation of how substitution of a different solvent affects results.

The registrant should additionally provide independent laboratory validation data for the proposed method for determining hydroxylated iprodione residues (e.g., RP-36114) in ruminant milk and tissues. Consistent with iprodione phase 4 review, the registrant should explain why use of benzene and diazomethane as reagents is necessary.

Finally, the registrant should provide and/or develop confirmatory method(s) for the determination of major iprodione residues (parent iprodione and metabolites RP-32490 and RP-36114) in livestock commodities. This requirement is based on the fact that the proposed methods each involve conversion of iprodione residues of concern to dichloroaniline; therefore, there is a concern for interference from other pesticides. If such confirmatory method(s) can be successfully developed and independently validated, then EPA will submit them directly for Agency validation, rather than either of the common moiety methods currently proposed for livestock commodities.

(e) GLN 860.1360: Multiresidue Methods

The registrant has submitted data on the determination of residues of iprodione, iprodione isomer RP-30228, iprodione metabolite RP-32490, and iprodione metabolite RP-36114 using FDA multiresidue methods. These data have been forwarded to FDA. Pending notification from FDA that further data are necessary, the reregistration requirements for multiresidue method testing are satisfied for all iprodione residues in current plant and livestock tolerance expressions.

The 1/94 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that iprodione and iprodione metabolite isomer are completely recovered (>80%) by Multiresidue Methods Section 302 (Luke method; Protocol D), and that recovery is small (<50%) using Multiresidue Methods Section 303 (Mills, Onley, Gaither method; Protocol E, non-fatty foods). Iprodione is not recovered using Section 304 (Mills method; Protocol E, fatty foods).

(f) GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data on plant commodity matrices are fulfilled. The data indicate that residues of iprodione, its isomer RP-30228, and its metabolite RP-32490 are stable under frozen storage conditions for 24 to 34 months in/on representative raw agricultural commodities of oilseeds, non-oily grains, leafy vegetables, root crops, and fruit and fruiting vegetables. No significant decline of residues was observed over the duration of study. These data validate the storage conditions and intervals of samples from the submitted field trials. The reregistration requirements for storage stability data on livestock commodity matrices are also fulfilled. The data submitted provide guidance for storage parameters to be used with future studies. Future magnitude of residue studies should be supported by concurrent storage stability data.

(g) GLN 860.1500: Crop Field Trials

Pending required label amendments for some crops, the reregistration requirements for magnitude of the residue in/on the following raw agricultural commodities (RACs) are fulfilled: almonds (nutmeat and hulls); apricots; beans (dry and succulent); blueberries; boysenberries, broccoli; caneberries; carrots; cherries; currants; garlic; ginseng (dried root); grapes; kiwifruit; lettuce (head and leaf); mustard (Chinese); nectarines; onions (dry bulb); peaches; peanuts (nutmeat and hay); plums (fresh prunes); potatoes; raspberries; rice; strawberries. Overall, adequate field trial data depicting iprodione tolerance residues following treatments according to the maximum registered use patterns have been submitted for the RACs listed above or have been translated where appropriate. Label revisions are required for some crops in order to reflect current Agency policies and/or to reflect the parameters of use patterns for which field trial data are available. Details of the required label amendments are presented in the endnotes for GLN 860.1200 (Directions for Use) of Table B. Refer to "Tolerance Reassessment Summary" section for recommendations with respect to established tolerance levels. The temporary tolerances for tangelos and tangerines, and the time-limited tolerance for cottonseed have expired; therefore, they are not considered in this document.

(h) GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of grapes, peanuts, plums, potatoes, and rice are fulfilled. Iprodione tolerance residues do not concentrate in the processed commodities of peanuts and potatoes. Iprodione tolerance residues concentrate during rice processing, and current tolerances for rice processed commodities are appropriate. Iprodione tolerance residues concentrate in raisins and prunes, and EPA has recommended tolerance levels for these commodities. Refer to "Tolerance Reassessment Summary" section for recommendations with respect to established tolerance levels.

An acceptable cottonseed processing study was also submitted and evaluated in conjunction with the establishment of a time-limited tolerance for cottonseed. The previously requested bean processing data are no longer necessary since the Agency has determined that bean cannery residue is not a significant livestock feed item and has been removed from Table 1 (OPPTS GLN 860.1000).

(i) GLN 860.1480: Meat, Milk, Poultry, and Eggs

The reregistration requirements for magnitude of the residue in livestock are fulfilled. Acceptable ruminant and poultry feeding studies depicting the magnitude of iprodione residues of concern have been submitted and evaluated. Ruminant feeding data are acceptable, up to a 10X feeding level of 200 ppm. A poultry feeding study was acceptable, up to a 10X feeding level of 100 ppm. Data from these feeding studies will be used to reassess the adequacy of the established tolerances for livestock commodities. As noted

above, analytical method, livestock remains an outstanding data requirement. Depending on the development of an acceptable enforcement method to determine individual residues rather than common moieties, it may be necessary to adjust tolerance expressions and levels to reflect the residues detected by analytical enforcement method(s).

(j) GLN 860.1400: Water, Fish, and Irrigated Crops

Phase 4 Review noted that label directions prohibit aquiculture in treated rice fields, and data on fish were not required. If this restriction is removed from the label, then fish studies would be necessary. Phase 4 Review also noted that data on residue decline in water were required for rice, and the registrant had made a commitment to conduct such a study. This requirement remains an outstanding data gap.

(k) GLN 860.1460: Food Handling

Iprodione is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

(l) GLN 860.1850: Confined Accumulation in Rotational Crops

Additional data are required before reregistration requirements for confined rotational crops can be considered fulfilled; data are required on the base hydrolysis of standards. The submitted field rotational study tentatively identified the parent iprodione, its isomer (RP-30228), and metabolites RP-25040 and RP-44247 as the major radioactive residues in/on rotational crop commodities. The metabolites RP-25040 and RP-44247 are not included in the tolerance expression for primary crops. After resolution of this issue, study results will likely be presented to the EPA Metabolism Committee. Depending on whether or not additional rotational crop metabolites need to be regulated, additional field rotational crop data (GLN 860.1900) may be required.

(m) GLN 860.1900: Field Accumulation in Rotational Crops

As noted above, determination of the nature of the residue in confined rotational crops and a decision by the EPA Metabolism Committee on the residues to be regulated in rotational crops are necessary before the Agency can advise the registrant on the residue data required for extensive field trials.

Table 24. Food/Feed Use Patterns Subject to Reregistration for Iprodione

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2, 3]
Almonds						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562] [4]	0.5 lb/A	4	2.0 lb/A	35 days after petal fall	Applications may be made in a minimum of 20 (ground) or 15 (aerial) gallons of water/A. Initial application should be made at pink bud stage and/or if conditions favorable for disease development persist. Three additional applications may be made at full bloom, petal fall, and up to 5 weeks after petal fall.
Apricots (See "Stone Fruits")						
Beans (Dry, Lima, and Snap)						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	2	2.0 lb/A	14 (preforaging interval) or 45 (prefeeding interval for dry bean hay)	Applications may be made in a minimum of 40 (ground) or 10 (aerial) gallons of water/A. Initial application should be made at first bloom to when 10% of the plants have one open bloom. The second application may be made 5 to 7 days later or up to peak bloom. The feeding of snap or succulent bean hay to livestock is prohibited. Use on cowpeas is prohibited.
Blackberries (See "Caneberries")						
Blueberries (See "Bushberries")						
Brassica (Cole) Leafy Vegetables (Seed Crop Only)						
Foliar Ground/aerial	50% WP [OR810055], [WA810052], [AZ880001] 4 lb/gal FlC [AZ880001], [OR960032], [WA960027]	2.0 lb/A	3 (Implied)	6.0 lb/A (Implied)	Not specified (NS)	Use limited to Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower, kale, kohlrabi, radish, rape, rutabaga, and turnips) grown for seed in AZ, CA, OR, and WA. In furrow treatment. Use limited to Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower, kale, kohlrabi, radish, rape, rutabaga, and turnips) grown for seed in AZ, CA, OR, and WA. Applications may be made in a minimum of 20 (ground) or 10 (aerial) gallons of water/A. Application should be made at full bloom, at pod set, and just prior to harvest. Use of treated crops, debris, or screenings for food or feed and the grazing of livestock on treated areas are prohibited.
	50% WP [CA850035]	1.0 lb/A	5	5.0 lb/A	NS	
Broccoli						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	2	2.0 lb/A	0	Applications may be made in a minimum of 40 gallons of water/A. Initial application should be made after thinning (2- to 4-leaf stage) as a directed spray to the base of the plant and the adjacent soil surface. The second application may be made up to the day of harvest.
Bushberries (Including Blueberries, Highbush and Lowbush; Currants; Elderberries; Gooseberries; and Huckleberries)						

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2, 3]
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482]	1.0 lb/A	4	4.0 lb/A	0	Applications may be made in a minimum of 100 gallons of water/A. Initial application should be made at early bloom (5 to 10% bloom) and again at full bloom. Two additional applications may be made at 14-day intervals.
Caneberries (Including Blackberries, Loganberries, Red and Black Raspberries, and Cultivars and/or Hybrids)						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	4	4.0 lb/A	0	Applications may be made in a minimum of 100 gallons of water/A. Initial application should be made at early bloom (5 to 10% bloom) and again at full bloom. Two additional applications may be made at 14-day intervals.
Carrots						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A or 0.5 lb/A (when tank mixed with other fungicides)	4 or 10 (tank mix rate)	4.0 lb/A or 5.0 lb/A (tank mix rate)	0	Applications may be made in a minimum of 10 gallons of water/A. Initial application should be made when conditions become favorable for disease development. Additional applications may be made at 7- to 14-day intervals.
Carrots (continued)						
Seed soak treatment Ground	50% WP [WA940001] 4 lb/gal FlC [WA940006]	0.25 lb/6 gal	1	0.25/6 gal	1	Use limited to seed treatment of carrots in WA. Application should be made as a seed soak. Treat 3 lbs of carrots seeds per 6 gallons of soaking solution for 24 hours at 30 C. Allow the seeds to thoroughly dry before packaging or planting. Use of treated seed for food or feed purposes is prohibited.
Cherries (See "Stone Fruits")						
Chinese Mustard						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	0.5 lb/A	4	2.0 lb/A	10	Use limited to FL. Applications may be made in a minimum of 50 gallons of water/A. Initial application should be made when conditions become favorable for disease development. Additional applications may be made at 7- to 14-day intervals.
Clover (Seed Crop Only)						
Foliar Ground	50% WP [OR960011] 4 lb/gal FlC [OR960012]	1.0 lb/A	2	2.0 lb/A	NS	Use limited to crimson clover grown for seed in OR. Applications may be made with surfactants and in a minimum of 12 gallons of water/A. Initial application should be made when disease first appears. A second application may be made prior to the 10-inch growth stage or no later than May 31. The product labels prohibit the following: use on crimson clover grown for livestock feed; feeding or grazing of livestock on treated crimson clover; cutting of treated crimson clover for forage and hay; and use of harvested seed for sprouting. No portion of the treated field including seed, seed screenings, hay, forage, or stubble may be used for human or animal feed.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2, 3]
Currants (See "Bushberries")						
Elderberries (See "Bushberries")						
Garlic						
In-furrow at planting Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482]	2.0 lb/A	1	2.0 lb/A	--	Application may be made in a minimum of 20 gallons of water/A. Application should be made as an in-furrow spray in sufficient water to obtain thorough coverage of the open furrow and covering soil.
Ginseng						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482]	1.0 lb/A or 0.75 lb/A (when tank mixed with other fungicides)	5	5.0 lb/A	36	Applications may be made in a minimum of 10 gallons of water/A. Initial application should be made when conditions become favorable for disease development. Additional applications may be made at 7- to 14-day intervals.
Gooseberries (See "Bushberries")						
Grapes						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	4	4.0 lb/A	7	Applications may be made in a minimum of 50 gallons of water/A. Initial application should be made at early to mid bloom, the second prior to bunch closing, the third at beginning of fruit ripening, and the fourth prior to harvest.
Huckleberries (See "Bushberries")						
Lettuce (Head and Leaf)						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	3	3.0 lb/A	14	Applications may be made in a minimum of 40 gallons of water/A; aerial application can only be used for the first spray. Initial application should be made at the 3-leaf stage to just after thinning. Two additional applications may be made at 10-day intervals.
Loganberries (See "Caneberries")						
Nectarines (See "Stone Fruits")						
Onions (Dry Bulb)						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532], [CA860064] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	0.75 lb/A or 0.5 lb/A (when tank mixed with other fungicides)	5 or 10 (tank mix rate)	3.75 lb/A or 5.0 lb/A (tank mix rate)	7	Applications may be made in a minimum of 50 (ground), 10 (aerial), or 6 (aerial CA860064) gallons of water/A. Initial application should be made when conditions become favorable for disease development. Additional applications may be made at 7- to 14-day intervals.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2, 3]
Peaches						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	0.5 -1.0 lb/ai	3	3.0	No later than petal fall	Applications may be made in a minimum of 20 gal (ground) or 15 gal (air). Apply at pink bud, full bloom and petal fall.
Peanuts						
Foliar Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482]	1.0 lb/A	3	3.0 lb/A	10	Applications may be made in a minimum of 40 gallons of water/A. Initial application should be made when conditions become favorable for disease development. Two additional applications may be made at 14- to 21-day intervals. The feeding of peanut hay to livestock is prohibited. Use of the 50% WP [EPA Reg. No. 264-532] is limited to states other than CA.
Peas (Seed Treatment)						
Seed treatment Ground	50% WP [WA930026], [WA930027]	2.8 oz/cwt	1	2.8 oz/cwt	--	Use limited to seed treatment of peas in WA. Application should be made in sufficient water to ensure complete seed coating. Seeds should be allowed to dry before packaging or planting. Use of treated seed for food or feed purposes is prohibited. Treated seed must be labeled: "For export to Sweden only - not to be sold or offered for sale in the U.S."
Plums (See "Stone Fruits")						
Potatoes						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482], 4 lb/gal SC/L [264-562]	1.0 lb/A	4	4.0 lb/A	14	Applications may be made in a minimum of 10 gallons of water/A; aerial equipment can only be used for the first application. Initial application should be made when conditions become favorable for disease development. Additional applications may be made at 7- to 28-day intervals.
	1.5 lb/gal SC/L [ID960011] [MO960002], [OR960033],[MN960004]	0.56 lb/A	7	4.0 lb/A		
Foliar Ground	50% WP [CA880019]	1.0 lb/A	2	2.0 lb/A		Use limited to CA. Applications may be made in a minimum of 10 gallons of water/A. Initial application should be made prior to row closing. A second application may be made 28 days later.
	50% WP [CA900013]	1.0 lb/A	4	4.0 lb/A	--	Use limited to greenhouse-grown potatoes in CA. Applications may be made in a minimum of 100 gallons of water/A. Initial application should be made when conditions favorable for disease development persist. Three additional applications can be made at 7- to 10-day intervals. Use of treated commodity for food/feed is prohibited.
Raspberries (See "Caneberries")						

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2, 3]
Rice						
Foliar broadcast Aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482], [264-520]	0.5 lb/A	2	1.0 lb/A	No later than 75% heading stage	Applications may be made in a minimum of 10 gallons of water/A. Initial application should be made between joint movement and booting stages. A second application may be made 14 days after the first application, but no later than 75% heading. Use of 50% WP (EPA Reg. No. 264-532) and 4 lb/gal FlC (EPA Reg. No. 264-520) is limited to states other than CA. Application to areas where catfish and crayfish are commercially cultivated is prohibited. Endangered species restrictions are specified for use in AR.
Stone Fruits (Including Apricots, Cherries, Nectarines, Plums, and Prunes)						
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A	4	4.0 lb/A	7	Applications may be made in a minimum of 20 (ground) or 15 (aerial) gallons of water/A. Initial application should be made at bud stage and/or if conditions favorable for disease development persist. Three additional applications can be made at 7- to 14-day intervals.
Strawberries						
Preplant dip Ground	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482], 4 lb/gal SC/L [264-562]	1.0 lb/100 gal	1	1.0 lb/100 gal	--	Application may be made as a preplant dip (5 minutes) immediately prior to planting.
Foliar Ground/aerial	50% DF [264-524] 50% WP [264-453], [264-532] 4 lb/gal FlC [264-482] 4 lb/gal SC/L [264-562]	1.0 lb/A or 0.5 lb/A (when tank mixed with other fungicides)	4 or 10 (tank mix rate)	4.0 lb/A or 5.0 lb/A (tank mix rate)	0	Applications may be made in a minimum of 100 (ground) or 10 (aerial) gallons of water/A. Initial application should be made no later than 10% bloom. Additional applications can be made at 7- to 14-day intervals.

[1] The restricted entry interval (REI) is 12 hours.

[2] The following rotational crop restrictions are established: (I) beans, broccoli, carrots, Chinese mustard, cotton, garlic, lettuce, onions (dry bulb), peanuts, potatoes, and rice may be rotated after harvest; and (ii) cotton, root crops, and tomatoes may be rotated one month following the last Iprodione application.

[3] Grazing restrictions are established for almonds, grapes, and stone fruits. The grazing of animals in treated orchards is prohibited. The feeding of cover crops grown in treated orchards is prohibited.

[4] Use directions for the 4 lb/gal SC/L (EPA Reg. No. 264-562) are for homeowner use.

(2) Dietary Risk Assessment/Anticipated Residues

EPA calculated specific anticipated residues for determination of upper bound carcinogenic risk from iprodione. It should be noted that some anticipated residues were *higher* than previous estimates because residue estimates were refined with additional data from the USDA's Pesticide Data Program (PDP). As part of a previous Dietary Residue Exposure System (DRES) analysis, anticipated residues based on monitoring data were adjusted for percent crop treated data. EPA has updated these percent crop treated data and this analysis reflects the revised values.

(3) Exposure and Risk From Food Sources

(a) Acute Dietary Risk (Tier 1/2/3/4)

Two analyses of acute dietary exposure and risk were performed using DRES, one for all presently registered commodities and one for all commodities proposed for tolerances.

The DRES detailed acute analysis estimate the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluated individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. The analysis assumed uniform national distribution of iprodione in the commodity supply.

Acute dietary exposure to iprodione was estimated by DRES. Acute dietary exposure estimates are considered to be high end, because exposure estimates are based on tolerance level residues in all foods. High end acute dietary exposure was then compared with the acute NOEL of 20 mg/kg/day for iprodione, and expressed as a margin of exposure (MOE). The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE).

For iprodione, the target MOE for acute dietary risk is 300; MOEs above 300 are not considered to be of concern. For iprodione, the target MOE of 300 includes a 3X uncertainty factor for FQPA considerations. Acute MOEs for iprodione are calculated for females 13+ only because the toxicological endpoint, decreased anogenital distance, was noted in neonates following in utero exposure to iprodione.

DRES results for the acute dietary assessment were of concern for both existing and proposed tolerances for iprodione. Exposure to tolerance level residues on presently registered commodities resulted in an acute dietary exposure of 0.18 mg/kg/day and an MOE of 111 for females 13+years old (13+). Exposure to tolerance level residues on currently registered commodities and those proposed for tolerances results in an acute dietary exposure of 0.30 mg/kg/day and an MOE of 66. As stated above, the target MOE for iprodione is 300. As previously noted, this acute dietary (food only) exposure assessment is conservative because it assumes tolerance level residues on all commodities with present or proposed iprodione tolerances and 100 percent crop treated.

The Registrant submitted an acute Monte Carlo dietary exposure assessment in 1997 which was revised to reflect risk mitigation measures. On September 30, 1998, the Agency found this acute Monte Carlo assessment to be acceptable for regulatory purposes. The assessment uses the Continuing Survey of Food Intake of Individuals (CSFII) 1989-1992 consumption database as translated by Novigen. This database is acceptable.

The Novigen assessment was highly refined, using a distribution of residue levels for commodities and percent crop treated data in the analysis. Field trial data or monitoring data supplied by Rhone-Poulenc were used for all crops. The field trials selected were appropriately matched to the maximum label rates for iprodione as reflected by risk mitigation.

The results of the acute dietary Monte Carlo are provided in table 25 along with the results of the acute dietary analysis using EPA's Dietary Residue Exposure System (DRES). For the acute Monte Carlo dietary risk assessment, using a NOEL of 20 mg/kg/day, females 13+ have MOEs greater than 300 at the 99.9th percentile of exposure.

Table 25. Acute Dietary Risk as Indicated by Margins of Exposure (MOE)*.

Population Subgroup	Dietary Exposure, mg/Kg/day			MOE		
	DRES existing tolerances	DRES proposed tolerances	Monte Carlo 99.9th%tile	DRES existing tolerances	DRES proposed tolerances	Monte Carlo 99.9th%tile
Females 13+	0.18	0.3	0.056839	111	66.6	351

* MOEs from the Novigen Acute Monte Carlo were recalculated using the EPA NOEL (20 mg/kg/day); ** Margin of exposure is the NOEL ÷ the exposure estimate.

(4) Chronic, Non-Carcinogenic Risk (TMRC and ARC)

The total dietary exposure for iprodione, expressed as % Chronic FQPA RfD, was calculated for iprodione using the following equation:

$$\% \text{ Chronic FQPA RfD} = \frac{\text{TMRC or ARC mg/kg/day}}{\text{Chronic FQPA RfD of x mg/kg/day}} \times 100\%$$

Exposure from current registered uses of iprodione results in an estimated risk which represents < 1% of the RfD for all populations.

The chronic analysis for iprodione is a highly refined estimate of dietary exposure. Refinements such as percent crop treated data and anticipated residues have been incorporated. Based on the risk estimates calculated in this analysis, chronic dietary risk from the uses recommended through reregistration, does not exceed EPA's level of concern.

(5) Chronic, Carcinogenic Risk (ARC)

The upper bound carcinogenic risk from food uses of iprodione for the general U.S. population was calculated using the following equation:

Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q_1^*

Based on a Q_1^* of 0.0439 $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be 4.0 x 10^{-6} contributed through all the published uses for iprodione. The overall upper bound risk appears to be above the range the Agency generally considers negligible for excess life time cancer risk. The commodities which contributed the most to this risk figure are stone fruits at 1.4 X 10^{-6} and small fruits and berries at 1.0 X 10^{-6}.

The upper bound cancer risk for all commodities with reassessed tolerances before risk mitigation was calculated to be 3.9 X 10^{-6} before risk mitigation and 1.8 x 10^{-6} after risk mitigation. The commodities which contribute the most to this risk figure are grapes (including wine and sherry) at 1.0 x 10^{-6}, stone fruits at 1.5 X 10^{-6}, and small fruits and berries at 0.6 x 10^{-6}. The upper bound cancer risk based on ARC for all commodities with proposed (reassessed) is above the range the Agency generally considers negligible for excess life time cancer risk.

(6) Drinking Water Exposure

The Agency has evaluated potential drinking water exposure from iprodione in ground and surface water.

(a) Ground Water (modeling/monitoring)

EPA originally had a concern for iprodione in groundwater based on modeling results. However, when EPA conducted a Tier 2 Drinking Water Assessment, they concluded that iprodione leaching to groundwater is expected to be negligible. EPA reviewed readily available groundwater monitoring data for the Tier 2 water assessment. Iprodione has been reported in several small scale studies in areas of the U.S. where it is or is suspected of being used. Impact to ground water source drinking water is expected to be minimal when the known environmental fate and monitoring data, showing all samples below the LOQ, are considered**.**

From April to October 1996 monitoring in 40 wells along the Oregon coastal region was conducted. Eighty-nine samples were collected, up to four samples at some wells over the period of the study, from the 40 wells. All samples were reported as below the level of quantification (LOQ); 0.1 ppb. No correlation with use areas was established, although samples were collected from areas with known grape production.

In another study along the Central Snake River basin in Oregon, 27 wells were sampled for a total of 30 samples. Iprodione was detected in all samples, but were reported as below the level of quantification (0.1 ppb) in all samples. The study was conducted during a three day period during August 1996. No correlation with the use of iprodione was established.

A study conducted in the Lake Superior Western Basin in Wisconsin during July 1995 at two wells reported all samples (5) as below the LOQ of 0.55 ppb. No information on why the samples were collected could be established.

Lastly, the Pesticide In Ground Water Database (*EPA, 1992)* reported one study in Massachusetts during 1986 in which 15 wells were sampled. No samples reported finding iprodione.

Monitoring data are limited by the lack of a correlation between sampling date and the use patterns of the pesticide within the drainage basin studied. Also, the monitored wells were not associated with groundwater drinking water sources.

(7) Surface Water (modeling/monitoring)

Because the tier I drinking water exposure assessment for iprodione showed exposures of concern, EPA conducted a Tier II drinking water exposure assessment. The Tier II assessment for iprodione uses PRZM 2.3 for simulating the agricultural field and EXAMS 2.94 for fate and transport in surface water. Spray drift was simulated using the assumption that 1% of applied iprodione reached surface water at the time of application and 95% of the chemical deposited on the target site. The remaining 4% either remained airborne or deposited on the ground beyond the drainage basin for the pond.

The scenarios chosen for iprodione were a peach orchard in Peach County, Georgia and a grape vineyard in Chautauqua County, New York. Scenarios were chosen to represent sites that were expected to produce runoff greater than 90% of the sites where the appropriate crop is grown. Model simulations were made with the maximum application rates, maximum number of yearly applications, and the shortest recommended application interval (Table 26). Tier II upper tenth percentile EECs are presented in Table 27. The EECs have been calculated so that in any given year, there is a 10% probability that the maximum average concentration of that duration in that year will equal or exceed the exposure estimate (EEC) at the site.

The Tier II EECs are based on a high-end exposure scenario for the use of a pesticide on a peaches. The meteorology and agricultural practice are simulated at the site over multiple (in this case, 23-34) years such that the probability of an EEC occurring at that site can be estimated. EECs were calculated for Rovral (iprodione) as this was the formulation registered for use on the specific crops.

To represent the use on peaches, three applications were made prior to petal fall according to label directions at specific intervals (14 days after first application and again 7 days later) beginning with bud emergence. All applications were assumed to made by ground spray.

On grapes, four applications were made during the growth cycle; at mid-bloom, prior to bunch closing, beginning of fruit ripening, and seven days before harvest. Approximate

pesticide application dates in the growth cycle were established with the assistance of the lead viticulturist from the Fredonia Regional Extension Office in New York. All applications were are made by ground spray equipment directly onto the growing plant.

Table 26. Usage Practice for Modeling Iprodione.

Chemical	Crop	Application Method	Application Rate Iprodione (lb acre^{-1})	Maximum Annual Applications	Application Interval
Iprodione	Peaches	Ground Spray	1.0	3	14/7 days
	Grapes	Ground Spray	2.0	4	Variable

Table 27. Tier II Upper 10th Percentile EECs for Iprodione Use on Peaches and Grapes.

Crop	Aerobic Soil Metabol. Rate ($t_{1/2}$)	Estimated EEC's (ug/l)					
		Max.	4 Day	21 Day	60 day	90 Day	Long Term Mean
Peaches	90 Day	14.7	13.8	11.0	8.1	6.7	1.5
Peaches	45 Day	12.7	11.9	9.4	7.2	6.1	1.4
Grapes	90 day	13.0	11.5	10.0	7.6	7.4	2.8
Grapes	45 day	10.3	8.6	5.5	3.6	3.6	1.1

PRZM2.3 is a runoff model, which can estimate the off-site movement of synthetic organic chemicals from agricultural fields over a period of up to 36 years. PRZM2.3 was developed to simulate the transport and transformation of field-applied pesticides in the crop root zone and the vadose zone taking into account the effects of agricultural management practices. It is considered to be appropriate for modeling most agricultural field crops on mineral soils in the US. Using input variables such as pesticide fate properties, soil characteristics, soil/crop management practices, and daily weather, PRZM2.3 can simulate a pesticide's fate and transport in/on soil and plants, leaching to the bottom of the root zone, water runoff and soil erosion. The output that is linked to EXAMS 2.94 includes estimated runoff volume, sediment yield, and associated edge of the field pesticide losses (which constitute pesticide loadings to edge of the field surface water).

Surface water models such as EXAMS 2.94 simulate pesticide fate and transport in surface water and sediment. Input includes runoff volume, and pesticide losses dissolved in runoff water and adsorbed to eroding soil (from PRZM2.3) as well as pesticide fate properties, and receiving water characteristics. Output includes estimated peak and various average pesticide concentrations dissolved in the water column, adsorbed to suspended sediment, and adsorbed to bottom sediment as a function of time and location.

It should be noted that PRZM2.3/EXAMS 2.94 were designed for use in ecological risk assessment. Drinking water taken from surface water tends to come from bodies of water that are substantially larger than a 1 hectare by 2 meters deep pond. As in the case of the Tier 1 screen, PRZM2.3/EXAMS 2.94 assumes that the entire basin (a 10 hectare field)

receives an application of the chemical. In virtually all cases, basins large enough to support a drinking water utility contain some fraction of area which does not receive the chemical. Furthermore, there is always at least some flow (in a river) or turn over in a reservoir or lake. Pesticide concentrations modeled using PRZM2.3/EXAMS 2.94 represent upper-bound concentrations that may actually occur in small surface water features (e.g., ponds and streams). Therefore, PRZM2.3/EXAMS 2.94 should be considered as a screen. PRZM2.3/EXAMS 2.94 may over-estimate the actual drinking water concentrations.

Screening models such as PRZM2.3/EXAMS 2.94 are best used to determine that a chemical poses little or no exposure. If, a risk assessment performed using an high-end/upper-bound exposure modeled by PRZM2.3/EXAMS 2.94 does not exceed EPA's level of concern, then there would be no reason to refine the assessment.

(8) Drinking Water Risk

In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground and surface water. For iprodione, modeling was used to estimate surface water concentrations because of very limited surface water monitoring data. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of concern (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations.

EPA believes the PRZM2.3/EXAMS 2.94 model estimates to be overestimations of concentrations of iprodione expected in drinking water at the consumer tap. Iprodione is expected to be removed through treatment at most drinking water utilities by coagulation followed by sedimentation and by continued metabolism. Given low concentrations estimated in surface water (1-3 ppb) and the likelihood of removal through treatment, the Agency does not believe iprodione will be present in drinking water above the DWLOC. To confirm that iprodione concentration estimates are overestimates, a surface water monitoring study for iprodione is needed from Rhone-Poulenc. Since this is a non-guideline study, the surface water monitoring study will be forwarded to Rhone-Poulenc via a separate Data Call-In after review by the Office of Management and Budget (OMB). If the results of the study indicate that there is a concern with concentrations of iprodione in surface water, additional risk mitigation may be taken by the Agency.

The equations below were used to calculate the $DWLOC_{chronic}$ based on aggregate exposure to iprodione through food and drinking water.

*Exposure to iprodione in drinking water (mg/kg/day) = chronic Rf D - (food exposure + residential exposure)

[* The chronic FQPA RfD is 0.02 mg/kg/day. Food exposure is taken from the chronic DRES analysis for each subpopulations for which a DWLOC value is calculated. Residential exposures equal zero.]

Exposure (adults) (mg/kg/day) = 0.02 mg/kg/day - (0.0002 mg/kg/day + 0) = 0.0198 mg/kg/day

$DWLOC_{chronic}$ for adult males (ug/L) = (0.0198 mg/kg/day) (70 kg) ÷ (2L) (10^{-3} mg/ug) = 693 ug/L

$DWLOC_{chronic}$ for adult females (ug/L) = (0.0198 mg/kg/day) (60 kg) ÷ (2L) (10^{-3} mg/ug) = 594 ug/L

Exposure (child) (mg/kg/day) = 0.02 mg/kg/day - (0.0003 mg/kg/day + 0) = 0.0197 mg/kg/day

$DWLOC_{chronic}$ for child (ug/L) = (0.0197 mg/kg/day) (10 kg) ÷ (1L) (10^{-3} mg/ug) = 197 ug/L

Conservative model estimates of a long-term average concentration of iprodione in surface water associated with use on peaches and grapes range up to a few parts per billion (1 to 3 ug/L). The estimated concentrations in surface water are much lower than EPA's calculated drinking water levels of concern (DWLOCs) for the above subpopulations for chronic exposure and risk assessments.

EPA also calculated $DWLOC_{acute}$. The equations below were used to calculate the $DWLOC_{acute}$ based on aggregate exposure through food and drinking water.

Acute Exposure to iprodione in dw (mg/kg/day) = (NOEL/MOE) - food exposure (mg/kg/day). The NOEL = 20 mg/kg/day; The acceptable MOE = 300. The food exposure is based on exposure for the population females 13+ at the 99.9th percentile of exposure (0.055851 mg/kg/day).

Exposure (females 13+) (mg/kg/day) = (20/300) - (0.055851 mg/kg/day) = 0.0108 mg/kg/day
$DWLOC_{acute}$ = (0.0108 mg/kg/day)(60 kg) / (2L/day x 10^{-3} mg/kg/day) = 324 ug/L

EPA compared concentration estimates from PRZM2.3/EXAMS 2.94 model to the calculated DWLOC value for females 13+ to provide a screening-level (qualitative) risk estimate for iprodione in surface water. Conservative model estimates of maximum concentrations in surface water associated with use on peaches and grapes range from 10-15 ppb (ug/L). The estimated concentrations in surface water are much lower than EPA's DWLOC (324 ug/L) for the population of females 13+.

EPA also calculated DWLOC values for the short-term endpoint and compared concentration estimates from the PRZM/EXAMS 2.94 model to calculated DWLOC values to provide a screening level (qualitative) risk estimate for iprodione in surface water. If screening model estimates exceed the DWLOC values, monitoring data may be required. DWLOC values for short-term risk assessments are calculated below for adults only. Residential handler exposure scenarios for short- and intermediate-term inhalation exposure are not applicable to children. As per OPP's interim guidance on aggregate risk assessments, if an oral endpoint is needed for short-term risk assessment for incorporation of food, water,

or oral hand-to-mouth exposures into an aggregate assessment, and only dermal or inhalation endpoints have been selected, the acute oral endpoint is used to incorporate the oral component into the aggregate risk.

*Exposure to iprodione in drinking water (mg/kg/day) = acute FQPA RfD - (food exposure + residential exposure)

[* The acute FQPA RfD is 0.06 mg/kg/day. Food exposure is taken from the chronic DRES analysis for each subpopulations for which a DWLOC value is calculated. Residential exposures are taken from Table 14. Residential Short- and Intermediate-Term Inhalation Risks at Baseline.]

Exposure (adults) (mg/kg/day) = 0.06 mg/kg/day - (0.0002 mg/kg/day + 0.002 mg/kg/day) = 0.0578 mg/kg/day

$DWLOC_{chronic}$ for adult males (ug/L) = (0.0578 mg/kg/day) (70 kg) ÷ (2L) (10^{-3} mg/ug) = 2000 ug/L

$DWLOC_{chronic}$ for adult females (ug/L) = (0.0578 mg/kg/day) (60 kg) ÷ (2L) (10^{-3} mg/ug) = 1700 ug/L

EPA also calculated DWLOC values for the intermediate-term endpoint and compared concentration estimates from the PRZM/EXAMS 2.94 model to calculated DWLOC values to provide a screening level (qualitative) risk estimate for iprodione in surface water. If screening model estimates exceed the DWLOC values, monitoring data may be required. DWLOC values for intermediate-term risk assessments are calculated below for adults only. Residential handler exposure scenarios for short- and intermediate-term inhalation exposure are not applicable to children. As per EPA interim guidance on aggregate risk assessments, if an oral endpoint is needed for intermediate-term risk assessment for incorporation of food, water, or oral hand-to-mouth exposures into an aggregate assessment, and only dermal or inhalation endpoints have been selected, the oral endpoint on which the FQPA RfD is based is used to incorporate the oral component into the aggregate risk.

*Exposure to iprodione in drinking water (mg/kg/day) = chronic FQPA RfD - (food exposure + residential exposure)

[* The chronic FQPA RfD is 0.02 mg/kg/day. Food exposure is taken from the chronic DRES analysis for each subpopulations for which a DWLOC value is calculated. Residential exposures are taken from Table 14. Residential Short- and Intermediate-Term Inhalation Risks at Baseline.]

Exposure (adults) (mg/kg/day) = 0.02 mg/kg/day - (0.0002 mg/kg/day + 0.0017 mg/kg/day) = 0.0181 mg/kg/day

$DWLOC_{chronic}$ for adult males (ug/L) = (0.0181 mg/kg/day) (70 kg) ÷ (2L) (10^{-3} mg/ug) = 633 ug/L

$DWLOC_{chronic}$ for adult females (ug/L) = (0.0181 mg/kg/day) (60 kg) ÷ (2L) (10^{-3} mg/ug) = 543 ug/L

As noted above, conservative model estimates of a long-term average concentration of iprodione in surface water associated with use on peaches and grapes range up to a few

parts per billion (1 to 3 ug/L). The estimated concentrations in surface water are much lower than EPA's calculated drinking water levels of concern (DWLOCs) for the above subpopulations for short- and intermediate-term exposure and risk assessments. EPA uses average residues in water and food in all aggregate risk assessments, except in the acute aggregate assessment, where high-end food and water residues are used. Model estimates of iprodione in ground water were not considered for comparison to DWLOC values.

i. Food Quality Protection Act Considerations

(1) Cumulative Risk for 3,5-Dichloroaniline

Need for Assessment

Section 408(b)(2)(D)(V) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments.

Although at present the Agency is still considering how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Iprodione is structurally related to Vinclozolin and procymidone, which belong to the imide class. Each of these three pesticides can metabolize to 3,5-dichloroaniline (3,5-DCA). FQPA requires EPA to estimate cumulative risk from consumption of food and water containing 3,5-DCA derived from iprodione, vinclozolin, and procymidone.

Hazard Identification for 3,5-DCA

The Agency has determined that it is not necessary to include exposure to DCA derived from vinclozolin and procymidone in a cumulative exposure assessment for *iprodione* per se for the following reasons: iprodione residues are measured as DCA by the analytical method, thus any DCA formed from iprodione is accounted for in the iprodione exposure assessment. Based on available metabolism data (discussed below) the contribution of DCA from vinclozolin and procymidone to the total chronic iprodione dietary exposure is less than an order of magnitiude. Therefore, inclusion of DCA from vinclozolin and procymidone in the iprodione chronic exposure assessment would not have a significant

impact on the risk estimates. A similar negligible contribution is expected for acute dietary exposure.

3,5-DCA is not a registered pesticide; therefore, there are no FIFRA toxicology data for this compound. In the past, EPA has used the Q_1^* for p-chloroaniline (PCA) to assess the carcinogenic risk for other structurally related chloroanilines. The EPA policy on chloroanilines specifies that chloroaniline metabolites should be considered to be toxicologically equivalent to PCA unless there is sufficient evidence that the metabolite is not carcinogenic. No other toxicological endpoints have been identified for DCA.

Further refinement to the DCA exposure estimates are being conducted in conjunction with the vinclozolin RED. This is being done to reflect risk mitigation measures proposed for vinclozolin as well as new percent crop treated information.

A Q_1^* of 6.38 X 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents has been calculated for p-chloroaniline. This Q_1* is based on the spleen sarcoma rate in male rats from an NTP bioasssay, linearized low dose multistage model, and the 3/4s interspecies scaling factor.

Exposure Assessment

Exposure to 3,5-DCA will be evaluated from the following sources: residues of iprodione- and Vinclozolin-derived 3,5-DCA in food and wine, residues of procymidone-derived 3,5-DCA in imported wine, and 3,5-DCA residues in water from agricultural uses of iprodione and vinclozolin. There are no US registrations for procymidone; therefore, an evaluation of exposure to procymidone-derived 3,5-DCA in water is not appropriate.

(2) Iprodione-derived 3,5-DCA residues in food

Metabolism data submitted to fulfill guideline requirements as part of the re-registration of iprodione indicated that 3,5-DCA represented 1% TRR (total radioactive residue) in eggs, smaller proportions in other livestock commodities, and was not detected in primary or rotational crops. One percent of the iprodione residues as estimated in a chronic DRES analysis (US population) would be appropriate values for use in an assessment for 3,5-DCA.

An iprodione chronic DRES analysis was performed in March 1997, and some numerical estimates were run in September 1998 with mitigation measures in place. This analysis used highly refined anticipated residues. The estimated exposure for total red meat was 0.002668 ug/kg/day, for total poultry was 0.001999 ug/kg/day, and for total dairy was 0.004552 ug/kg/day. The estimated exposure for iprodione that will convert to 3,5-DCA can be calculated by multiplying by 0.001 to convert ug to mg, and by multiplying by 0.01 to account for the 1% TRR. The estimated dose of iprodione that will convert to 3,5-DCA is 0.00000009219 mg/kg/day.

However, iprodione is also applied to grapes, which are then fermented to produce wine. Using an estimated risk of 0.5 x 10^{-6} for grapes, wine and sherry only, and the

iprodione Q_1^* of 0.0439 $(mg/kg/day)^{-1}$, an exposure of 0.0000114 was estimated for residues of iprodione in wine. Assuming that 10% of the iprodione converts to 3,5-DCA, the estimated dose of iprodione that will convert to 3,5-DCA is 0.00000114 mg/kg/day.

These residues of iprodione must also be converted to 3,5-DCA. $MW_{iprodione} = 330.17$

Dose = (0.00000009219 mg/kg/day) (162.02 /330.17) = 0.000000045 mg/kg/day of 3,5-DCA

Dose = (0.00000114 mg/kg/day) (162.02 / 330.17) = 0.00000054 mg/kg/day of 3,5-DCA

(3) Vinclozolin-derived 3,5-DCA residues in food

Metabolism data submitted to fulfill guideline requirements as part of the re-registration of vinclozolin indicated that DCA represented 9.6% TRR in peaches, smaller proportions in strawberries and was not detected in lettuce or grapes. Ten percent of the vinclozolin residues as estimated in a chronic DEEM™ analysis would be appropriate values for use in an assessment for 3,5-DCA. It was determined to still include grapes, wine in the analysis based on the metabolism studies for procymidone in which the 3,5-DCA metabolite was not detected in grapes, but is formed in wine.

Using these residues a chronic DEEM™ analysis for vinclozolin was performed on 9/28/98. The total anticipated residue contribution for vinclozolin is 0.000122 mg/kg/day. The estimated exposure for residues of vinclozolin that can be expected to convert to 3,5-DCA in food can be calculated by multiplying by 0.1. The total estimated dose for vinclozolin that will convert to 3,5-DCA is 0.0000122 mg/kg/day.

Thus, the estimated dose for residues of 3,5-DCA can be determined by:

Dose = (0.0000122 mg/kg/day) (162.02 / 286.11) = 0.0000069 mg/kg/day of 3,5-DCA

(4) Procymidone-derived 3,5-DCA Residues in Wine

The tolerance for procymidone is for imported wine only. The 3,5-DCA metabolite was not detected in grapes, but occurs during fermentation. Anticipated residues in wine are at 0.3 ppm for parent procymidone, and 0.06 ppm for its 3,5-DCA metabolite.

The estimated dose is calculated by:

$$A \times B \times C \times D \times E \times G / F$$

where
A = concentration of 3,5-DCA in wine = 0.06 ppm
B = 25%, percent of imported wine consumed in the US
C = 20%, percent crop treated
D = 8 fl. ounces wine / day
E = 29.57 g/fl. ounce (conversion factor)
F = 70 kg, default male body weight
G = 0.001 (conversion factor g to kg)

The estimated dose of residues of 3,5-DCA in wine that are derived from procymidone is 0.0000101 mg/kg/day.

(5) 3,5-DCA Residues in Water from Iprodione

A Tier 2 EEC (Estimated Environmental Concentration) was estimated for 3,5-DCA from the degradation of iprodione as applied to peaches. For Tier 2, two models, PRZM2.3 and EXAMS2, are used to estimate concentrations of pesticide contaminants in surface water. PRZM2.3 (Pesticide Root Zone Model) can be linked to EXAMS2 (EXposure Analysis Modeling System) for a direct transfer of data.

Using PRZM 2.3 for simulating the transport of the pesticide off the agricultural field and EXAMS 2 for fate and transport of the chemical in surface water, the Agency estimated the concentration of iprodione in surface water as a result of an application to peaches for a chronic exposure to be 1.5 ppb.

However, it is possible to refine this assessment by assuming that only some of the iprodione converts to 3,5-DCA. A soil photolysis study indicates that a value of 30 % (the highest percentage found in any of the studies examined) would be reasonable to account for the iprodione that is actually converted to 3,5-DCA. Thus, the concentration of iprodione that can be expected to convert to 3,5-DCA can be estimated by:

(1.5 ppb iprodione)(0.3) = 0.45 ppb iprodione that will convert to 3,5-DCA in surface water

This can be converted to ppb of 3,5-DCA using the same MW ratio.

Thus, ppb 3,5-DCA = (0.45 ppb iprodione) (162.02 /330.17) = 0.22 ppb of 3,5-DCA

(6) 3,5-DCA Residues in Water from Vinclozolin

Using GENEEC, a Tier 1 EEC (Estimated Environmental Concentration) was calculated for 3,5-DCA from the degradation of vinclozolin as applied to onions.

EFED estimated the concentration of vinclozolin in surface water as a result of an application on onions for a chronic exposure to be 3.27 ppb. However, 20% is the maximum of the parent vinclozolin that would be expected to convert to 3,5-DCA, based on a field dissipation study which was extrapolated to water.
Thus, (3.27) (0.2) = 0.65 vinclozolin that will convert to 3,5-DCA in surface water.

This can be converted to ppb of 3,5-DCA using the same MW ratio.

Thus, ppb 3,5-DCA = (0.65 ppb vinclozolin)(162.02 /286.11) = 0.37 ppb of 3,5-DCA

(7) Cumulative Risk from all sources of 3,5-DCA

The carcinogenic risks are estimated by multiplying the dose by the Q_1^*, 6.38 X 10^{-2} $(mg/kg/day)^{-1}$. The total carcinogenic risk for consumption of food and wine containing residues of 3,5-DCA as a result of applications of iprodione, vinclozolin, and procymidone is 9.5 x 10^{-7} as shown in table 28.

Table 28. Estimated Excess Cancer Risk Values for 3,5-DCA.

Route of Exposure	Exposure, mg/kg/day	Excess Cancer Risk Estimate
Iprodione-derived DCA in food	0.000000045	2.9 X 10^{-9}
Vinclozolin-derived DCA in food	0.000069	4.4 X 10^{-7}
Procymidone-derived DCA in wine	0.0000101	4.8 X 10^{-7} *
Iprodione-derived DCA in wine	0.00000054	2.6 X 10^{-8} *
Total 3,5-DCA in Food and Wine only		9.5X 10^{-7}

* The risk for consuming wine is weighted by the ratio 52/70 which assumes that wine is not consumed during the first 18 years of a 70 year lifetime.

This may be an over-estimate. Metabolism studies for iprodione and vinclozolin were used to estimate the amount of 3,5-DCA present in various commodities by using TRRs to convert iprodione or Vinclozolin exposures to 3,5-DCA exposures. There is an uncertainty to the risk estimate in that a surrogate Q_1^* is being used for 3,5-DCA. However, due to the structural similarities of 3,5-DCA and PCA, EPA believes that for 3,5-DCA, the use of the PCA Q_1^* represents an upper-bound. These are the best risk numbers that can be estimated by EPA.

Because drinking water data on DCA residues in water are not available, EPA compared the conservative screening-level model estimates of iprodione concentrations in surface water to drinking water levels of concern (DWLOCs) for DCA. Since the cumulative risk from food and wine is less than 1 x 10^{-6}, a DWLOC can be estimated:

$(1 \times 10^{-6}) - (9.5 \times 10^{-7}) = 0.5 \times 10^{-7}$

$0.5 \times 10^{-7} / 0.0638\ (mg/kg/day)^{-1} = 7.8 \times 10^{-7}$ mg/kg/day

$(7.8 \times 10^{-7}$ mg/kg/day) (70 kg)(1000 ug/mg) (day/2L), which is approximately 0.03 ug/L or ppb

The estimated concentrations of 3,5-DCA in water from applications of iprodione was 0.22 ppb and is less than the DWLOC calculated for the cancer risk assessment. From applications of vinclozlin, the model estimated concentrations of DCA in surface water was 0.37 ppb. This is above the DWLOC calculated for the cancer risk assessment; however, the Agency recognizes that the model estimates are very conservative (upper bound estimates associated with high uncertainty) and are not likely to be representative of what might be expected in drinking water. That is, the difference between the model estimate for

concentrations of DCA in surface water and the DWLOC calculated for DCA in drinking water is probably insignificant. To confirm this, the Agency is requesting that the registrant submit a surface water monitoring study. This study will replace existing modeled surface water monitoring data with more accurate data, and will enhance known surface water monitoring data. If, with the submission of this data, the drinking water level of concern for iprodione is exceeded, the Agency may require further risk mitigation measures.

4. Aggregate Exposure and Risk Assessment/Characterization

Aggregate exposure and risk is estimated by combining dietary (food and water) and residential exposures.

a. Acute Aggregate Risk

Estimated excess cancer risk values for 3,5-DCA policy is to include exposures to iprodione residues in food and water only to calculate the aggregate acute dietary risk. However, EPA notes that exposure to iprodione residues in food alone exceed EPA levels of concern for acute dietary risk. At this point in time and until the exposure to iprodione in the diet is reduced or a more refined acceptable risk assessment is provided, any additional exposure to iprodione through drinking water would only cause acute risk estimates to further exceed EPA's level of concern. In effect, the drinking water level of concern (DWLOC) for acute effects of iprodione below the Agency's level of concern. Although Iprodione uses are not expected to impact ground water (available monitoring data show levels at or below limits of quantification and detection), upper bound estimates of iprodione in surface waters from conservative screening models indicate concentrations of a few parts per billion.

b. Chronic Aggregate Risk

The chronic aggregate risk assessment for iprodione will include risk estimates associated with dietary exposure through food, water, and registered residential uses. Anticipated residues and percent crop-treated data for commodities with published tolerances result in an exposure to iprodione through food which represents up to 1.6% of the chronic FQPA RfD for the most exposed subpopulation in the U.S. (non-nursing infants , <1 year old). Exposure to all other groups is less than or equal to 1% of the chronic FQPA RfD.

EPA has calculated drinking water levels of concern (DWLOCs) for chronic exposure to iprodione from commodities with published tolerances in drinking water for the following four subpopulations: the general U.S. population/Hispanics (690 ppb), females, 13-19 years old (590 ppb), and non-nursing infants, <1 year old (197 ppb). These subpopulations were selected because they contain the individuals believed to be those most highly exposed subpopulations representing males, females, and children and infants, respectively. A conservative estimate (tier 1) of average concentrations of iprodione in

surface water is 1 to 3 ppb. The estimated average concentration of iprodione in surface water is less than EPA's levels of concern. Therefore, based on the risk assessments calculated in this analysis, it appears that the chronic aggregate risk from iprodione in the diet and drinking water (no residential use scenario was identified for chronic exposure) associated with registered uses of iprodione is not of concern. Estimated average concentrations of iprodione in ground water were not available for comparison against DWLOC values; however, based on iprodione's physical/chemical characteristics and available, but limited monitoring data, it is not expected to significantly impact ground water.

No chronic exposure scenarios for residential uses of iprodione were identified; therefore, no chronic exposure was included in the aggregate risk estimate.

Therefore, based on the available information, EPA concludes with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable chronic aggregate human health risk estimate at this time. EPA bases this determination on a comparison of estimated concentrations of iprodione in surface water to back-calculated "levels of concern" for Iprodione in drinking water. The estimate of Iprodione in surface water is derived from a water quality model that uses conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of iprodione on drinking water as a part of the aggregate risk assessment process.

c. Cancer Aggregate Risk

Because individual cancer risk estimates for exposures to iprodione residues through food and residential uses each exceed EPA's level of concern individually, combined exposures through these routes results in an aggregate risk that further exceeds EPA's level of concern. Any additional exposure through water would cause the risk estimate to further exceed EPA's level of concern. Effectively, the DWLOC for cancer below the Agency's level of concern. Combined exposure and risk estimates for each of the residential exposure scenarios plus dietary exposure to iprodione residues results in cancer risk estimates that are all equal to or greater than 10^{-6}. Individual risks associated with dietary exposure and residential exposures must be reduced before additional exposure through drinking water would be acceptable. Aggregate exposures from combined inhalation and dermal exposures and the resultant cancer risk estimates for iprodione are given in Table 29.

d. Short-term Aggregate Risk

Aggregate risk estimates associated with short-term risk includes exposures to average residues of iprodione in the diet (food and water) and inhalation exposure (1 to 7 days in duration) through the residential application of iprodione. The default assumptions

used in this aggregate risk estimate are that the homeowner's inhalation exposure to iprodione is equivalent to an oral exposure (100% absorption of the inhaled residues) and the acute oral endpoint (acute FQPA RfD of 0.06 mg/kg/day) was used to incorporate dietary exposures into the aggregate assessment. (As per OPP's interim guidance on aggregate risk assessments, if an oral endpoint is needed for short-term risk assessment for incorporation of food, water, or oral hand-to-mouth exposures into an aggregate assessment, and only dermal or inhalation endpoints have been selected, the acute oral endpoint is used to incorporate the oral component into the aggregate risk.) The toxic endpoint selected for the short-term risk assessment for exposures to iprodione through inhalation is the acute oral endpoint also selected for the acute dietary risk assessment, i.e., the acute FQPA RfD. Therefore, the aggregate short-term risk assessment was based on the acute FQPA RfD. The uncertainty factor for both the acute dietary and the short-term inhalation risk assessments is 300. The aggregate risk assessment includes exposures to average concentrations of iprodione residues in the diet from commodities with existing tolerances, and the high-end exposure scenario associated with homeowners applying iprodione with a belly grinder to a lawn. The resulting risk represents 3.6% of the acute FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It is assumed that children and infants do not apply pesticides. Although average residues of iprodione in drinking water were not available, DWLOCs for this short-term aggregate risk assessment were calculated. They were: for the U.S. population (2000 ppb), and for females representing women 13+ years of age and nursing (1700 ppb). As stated above, based on the available information on iprodione's impact on surface and ground water, EPA believes that iprodione's impact on drinking water will not affect the aggregate short-term risk significantly. Therefore, EPA concludes with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable short-term aggregate human health risk estimate at this time. Any change in use pattern would necessitate a reassessment of iprodione risk estimates.

e. Intermediate-term Aggregate Risk

Aggregate risk estimates associated with intermediate-term risk includes exposures to average residues of iprodione in the diet (food and water) and inhalation exposure (7 days to several months in duration) through the residential application of iprodione. The default assumptions used in this aggregate risk estimate are that the homeowner's inhalation exposure to iprodione is equivalent to an oral exposure (100% absorption of the inhaled residues) and the chronic oral endpoint (chronic FQPA RfD of 0.02 mg/kg/day) was used to incorporate dietary exposures into the aggregate assessment. The toxic endpoint selected for the intermediate-term risk assessment for exposures to iprodione through inhalation is the chronic oral endpoint also selected for the chronic dietary risk assessment, i.e., the chronic FQPA RfD. Therefore, the aggregate intermediate-term risk assessment was based on the chronic FQPA RfD. The uncertainty factor for both the chronic dietary and the intermediate-term inhalation risk assessments is 300. The aggregate risk assessment includes exposures to average concentrations of iprodione residues in the diet from commodities with

existing tolerances, and the high-end exposure scenario associated with homeowners applying iprodione with a belly grinder to a lawn. The resulting risk represents 9.5% of the chronic FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It is assumed that children and infants do not apply pesticides. Although average residues of iprodione in drinking water were not available, DWLOCs for this intermediate-term aggregate risk assessment were calculated. They were: for the U.S. population (630 ppb), and for females representing women 13+ years of age and nursing (540 ppb). As stated above, based on the available information on iprodione's impact on surface and ground water, EPA believes that iprodione's impact on drinking water will not affect the aggregate intermediate-term risk significantly. Therefore, EPA concludes with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable intermediate-term aggregate human health risk estimate at this time. Any change in use pattern would necessitate a reassessment of iprodione risk estimates.

Table 29. Aggregate Dietary and Residential Handlers Exposure and Cancer Risk Estimates for Iprodione.

Residential Exposure Scenario	Range of Application Rates lb ai/A	Crop Type or Target	Baseline Total Daily Dose mg/kg/day	Number of Exposures per Year	LADD mg/kg/day from residential Exposure	Dietary ARC mg/kg/day	Combined LADDmg/kg/day diet + residential	Cancer Risk
Residential Handler Risk								
Mixing/Loading/Applying Sprays with a Low Pressure Handwand (1)	0.0026 lb ai/gal	Fruit/Nut Trees	0.00093	4	5.1E-6	9.13E-5	9.6E-5	4.2E-6
	0.01 lb ai/gal	Ornamentals	0.0036	4	2.0E-5	9.13E-5	1.1E-4	4.8.0E-8
	0.125 lb ai/1,000 ft^2	Turf	0.18	2	5.2E-4	9.13E-5	6.1E-4	2.7E-5
	0.104 lb ai/gal	Vegetable/ Small Fruit Garden	0.037	4	2.0E-4	9.13E-5	2.9E-4	1.3E-5
Mixing/Loading/Applying Using a Backpack Sprayer (2)	0.0026 lb ai/gal	Fruit/Nut Trees	0.000053	4	2.9E-7	9.13E-5	9.2E-5	4.0E-6
	0.01 lb ai/gal	Ornamentals	0.00021	4	1.2E-6	9.13E-5	9.2E-5	4.0E-6
	0.125 lb ai/1,000 ft^2	Turf	0.010	2	2.7E-5	9.13E-5	1.2E-4	5.2E-6
	0.104 lb ai/gal	Vegetable/ Small Fruit Garden	0.0021	4	1.2E-5	9.13E-5	1.0E-4	4.5E-6
Mixing/Loading/Applying Using a Garden Hose-end Sprayer (3)	0.0026 lb ai/gal	Trees	0.0028	4	1.6E-5	9.13E-5	1.1E-4	4.7E-6
	0.01 lb ai/gal	Ornamentals	0.011	4	6.0E-5	9.13E-5	1.5E-4	6.6E-6
	0.125 lb ai/1,000 ft^2	Turf	0.054	2	1.5E-4	9.13E-5	2.4E-4	1.0E-5
	0.104 lb ai/gal	Vegetable/ Small Fruit Garden	0.11	4	6.0E-4	9.13E-5	6.9E-4	3.0E-5
Loading/Applying Granulars Using a Belly Grinder (4)	0.0941 lb ai/1,000 ft^2	Turf	0.16	2	4.4E-4	9.13E-5	5.3E-4	2.3E-5
	0.0941 lb ai/1,000 ft^2		0.0073	2	2.0E-5	9.13E-5	1.1E-4	4.9E-6
Loading/Applying Granulars Using a Push-type Lawn Spreader (5)	0.0941 lb ai/ 1,000 ft^2	Turf	0.0041	2	1.1E-5	9.13E-5	1.0E-4	4.5-6
	0.0941 lb ai/ 1,000 ft^2		0.00021	2	5.8E-7	9.13E-5	9.2E-5	4.0E-6
Loading/Applying Granulars by Hand as a Spot Treatment (6)	0.0941 lb ai/ 1,000 ft^2	Turf	0.029	2	7.9E-5	9.13E-5	1.7E-4	7.5E-6

(1) Endocrine Disruption

The available toxicology data for iprodione suggest that it is associated with endocrine effects. However, the extent of these effects and the mode of action are not yet fully understood.

Rhone-Poulenc, the iprodione registrant has proposed that the mode of action for the production of Leydig cell tumors by iprodione is disruption of testosterone biosynthesis. The proposed mode of action and the supporting data have been discussed previously in this document. This proposed mode of action is not fully understood at this time.

Also, a special rat developmental toxicity study with iprodione showed decreased anogenital distance (AGD) at the mid and high dose level (120 and 250 mg/kg/day). However, there were only marginal differences in AGD between the dose levels.

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects.

C. ENVIRONMENTAL RISK ASSESSMENT

1. Environmental Fate Assessment

The database for iprodione is largely complete. The major routes of dissipation are hydrolysis in neutral and alkaline environments (half-lives pH 7 = 4.7 days; pH 9 = 27 minutes) and microbial degradation under both aerobic and anaerobic conditions. The overall result of these mechanisms of dissipation appears to indicate that iprodione has low to intermediate persistence in the environment. The results obtained in the field confirm the expected low persistence of iprodione ($t_{1/2}$=3-7 days).

The major degradate observed in the laboratory was RP30228 [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide], which was present in the majority of the laboratory studies. The chemical was also present at high concentrations in the field. A degradate of toxicological concern, 3,5-dichloroaniline (RP-32596), was found in several of the laboratory studies in low to moderate amounts. Its persistence and mobility are not well understood at this time. Additional studies are needed (aerobic soil metabolism and batch equilibrium) to help characterize the fate of this toxic degradate and to better estimate its expected environmental concentrations in both surface water and ground water.

Iprodione consists of white crystals. Its water solubility is 13 mg/L; its octanol water partition coefficient is 1259; and it's vapor pressure is $2.7x10^{-7}$ torr.

a. Degradation and Metabolism

(1) Chemical Degradation

Hydrolysis plays an important role in the degradation of iprodione under neutral and alkaline aquatic conditions. The hydrolysis rate is pH dependent. Iprodione hydrolyzed with half-lives of 131 days, 4.7 days, and 27 minutes in sterile aqueous buffered solutions at pH's 5, 7, and 9, respectively. The major degradates observed were RP35606 [(dichloro-3,5 phenyl)-1 isopropyl carbamoyl-3]-2 acetic acid, with a maximum of 11.9% of the applied at pH 5, and RP30228, with a maximum of 93.3% of the applied at pH 9.

Iprodione degraded slowly under aqueous photolysis conditions (estimated half-life of 67 days) in pH 5 buffered solutions irradiated continuously with a UV-filtered xenon-arc lamp. No major degradates ($\geq$10% of the applied) were observed.

Soil photolysis also does not appear to be an important route of dissipation for iprodione. On irradiated soils, iprodione degraded with an observed DT_{50} of 7-14 days in sandy loam soil that was irradiated with a xenon-arc lamp for 8.8 hours/day for 30 days. However, in the dark controls, [^{14}C]iprodione degraded with an observed DT_{50} of 14-21 days. Therefore, degradative processes other than photolysis must have been responsible for the disappearance of iprodione in the irradiated system. This would be predicted by the results of the photodegradation in water study and the absorption spectrum (max. <250 nm). The major degradates observed in the irradiated soil were RP32596 [3,5-dichloroaniline], (with a maximum of 27.94% of the applied at 14 days), a mixture of RP25040 [3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine] and LS720942 (with a maximum of 13.75% of the applied at day 7), and RP30228 (with a maximum of 7.72% immediately posttreatment).

(2) Microbial Degradation

Iprodione degraded with an observed DT_{50} of 14-30 days in aerobic sandy loam soil that was incubated in the dark at 25 C and 75% of 0.33 bar moisture for 276 days. The following degradates were observed; RP30228, with a maximum of 6.92% of the applied at 14 days, RP32596, with a maximum of 9.02% of the applied at 30 days, and RP25040, with a maximum of 9.47% of the applied at 30 days. Unextracted soil ^{14}C-residues were 75.8 to 86.9% of the applied at 181-276 days (last test interval). Volatile residues totaled 5.27% of the applied at 276 days (of which 5.23% was $^{14}CO_2$).

Aerobic aquatic metabolism is an important route of dissipation for iprodione. It degraded with an observed DT_{50} of 3-7 days in a flooded silt loam sediment system incubated in the dark. The major degradates were RP30228, with a maximum of 64.6% of the applied at 14 days, and RP32490 [1-(3,5-dichlorophenyl)-3-carbamoyl hydantoin], with 14.6% of the applied at 2 days. RP32596 was a maximum of 9.9% of the applied in the sediment at 30 days.

Iprodione degraded with an observed DT_{50} of 7-14 days in anaerobic silt loam sediment. The major degradates observed were RP30228, with a maximum of 70.7% of the applied at 14 days, and RP32490, with a maximum of 8.4% of the applied at 30 days.

As discussed above, the rate at which iprodione undergoes chemical hydrolysis is pH dependent. As such, it could be expected that degradation in soils with pH's at or above 7 would be more rapid than in acidic soils due to this additional route of dissipation. A close inspection of the data indicates that the soils in the photolysis on soil and the aerobic soil metabolism studies were slightly acidic to neutral (6.92 and 5.75, respectively). Furthermore, the degradate profiles for these studies were different than those observed in the hydrolysis study. It appears reasonable to conclude that the degradation in these two studies was primarily due to metabolism and not chemical hydrolysis.

On the other hand, in the aerobic aquatic and anaerobic aquatic metabolism studies, the pH's were neutral to slightly basic (anaerobic aquatic soil pH 6.4, water pH 7.4; aerobic aquatic soil pH 6.64, water pH 8.5). The degradate profiles in these studies were similar to those seen in the hydrolysis study (with the major degradate RP30228). It appears that in these studies, hydrolysis could have played a major role in the decomposition of iprodione.

(3) Mobility

Based on batch equilibrium experiments, iprodione was very mobile in sand soil:calcium chloride solution slurries. Iprodione was mobile in sandy loam and loamy sand, and somewhat mobile in clay soil solution slurries. Iprodione showed low mobility in loam sediment:calcium chloride solution slurries. The organic matter content appears to be the primary factor affecting the mobility of iprodione in soils. Mobility decreases as the organic matter content of the soil or sediment increases. Freundlich K_{ads} values were $\leq$0.20 for the sand soil, 2.16 for the loamy sand soil, 2.45 for the sandy loam soil, 6.52 for the clay soil, and 43.09 for the loam sediment.

In a column leaching study with aged iprodione, the residues were very mobile in columns of sand soil, mobile to slightly mobile in columns of loamy sand soil, and slightly mobile in columns of sandy loam and clay soils. The columns were treated with aged (28-29 days) iprodione at 10µg/g and leached with 20 in. of 0.01 M calcium chloride. In the sand soil columns, an average of 52% of the applied radioactivity was recovered from the leachates. For all the other soil columns, $\leq$1% of the applied was recovered from the leachates. Five degradates were identified in the column segments or leachates: RP25040, RP30228, RP32596, RP35606, and RP36221.

Iprodione is not expected to volatilize substantially since its vapor pressure is relatively low (2.7×10^{-7} torr). Its calculated Henry's constant is also low (9.02×10^{-9} atm m^3/mol). In addition, the available aerobic soil metabolism study shows that only 5.27% of the applied had volatilized after 276 days in a sandy loam soil. Of this, 5.23% was $^{14}CO_2$.

(4) Field Dissipation

Two terrestrial field dissipation studies are available. In both studies, iprodione was applied 8 times to carrots at 1 lb ai/A/application. The study conducted in San Juan Bautista, California showed a half-life of 7 days in the 0-15 cm soil layer of a silt loam soil. The degradates RP30228 and RP32490 were recovered from the 0-15 and the 15-30 cm soil depths. Iprodione and its degradates

were not detected below the 30 cm soil level. RP30228 was a maximum average of 0.47 ppm at 28 days after treatment; declining only to 0.15 ppm at 538 days. RP32490 was observed at relatively low levels ($\leq$0.09 ppm) in the field.

In the study conducted in North Carolina, the observed half-life was less than 3 days in the 0-15 cm soil depth of a loamy sand soil. RP30228 and RP32490 were observed only in the 0-15 cm soil depth. No residues of these degradates or iprodione were detected below 15 cm. The concentrations of RP30228 were lower (ranging from 0.01 to 0.08 ppm until 492 days). A third degradate, RP32596 [3,5-dichloroaniline] was observed at high concentrations in the laboratory experiments, but was not monitored in the field.

The soil pH's in the field studies varied from slightly acidic (pH 6.2-6.8) in a loamy sand in Clayton, NC to slightly basic (pH 7.9-8.0) in a silt loam soil in San Juan Bautista, CA. Based on these studies, pH alone was not a good predictor of the relative rates of dissipation of iprodione (<4 days in NC, 7 days in CA). However, since RP30228 was a major degradate recovered in the field, it appears that hydrolysis may be an important route of degradation in the field.

At this time, EPA does not have an Aquatic Field Dissipation Study of iprodione. Based upon the two available aquatic metabolism studies and a hydrolysis study, it is reasonable to assume that iprodione will not persist in aquatic environments.

(5) Accumulation

In a supplemental Accumulation in Irrigated Crops study, iprodione, and its degradates RP30228 and RP32490 were not detected (<0.05 ppm) in sorghum (whole plant), soybeans (seeds, pods, trash), sweet potatoes (roots), cotton (whole plant, bolls), or soil irrigated with water from flooded plots of silt loam soil planted to rice.

The iprodione octanol/water partition coefficient is slightly greater than 1000 (actual 1258). This would indicate limited potential for bioaccumulation. According to the submitted study, iprodione bioaccumulated in bluegill sunfish, with maximum bioaccumulation factors of only 116X for nonedible tissues, 51X for edible tissues, and 72X for whole fish. Depuration was rapid ($t_{½}$ < 1 day). The following degradates were detected (>5% of the recovered) in the fish, besides parent iprodione: RP32490, RP25040, RP30228, and RP36119.

(6) Spray Drift

Iprodione may be applied through chemigation, aerially, and by foliar ground spray equipment. No specific spray drift studies were reviewed.

(7) Terrestrial Exposure Assessment

Nongranular applications: The terrestrial exposure assessment is based on Hoerger and Kenaga (1972), as modified by Fletcher et al (1994)[1]. Terrestrial estimated environmental concentrations

[1] Hoerger, F., and E.E. Kenaga. 1972. Pesticide residues on plants: Correlation of representative data as a basis for estimation of their magnitude in the environment. In F. Coulston

(EECs) for nongranular formulations were derived from maximum application rates incorporating dissipation rates for iprodione. Uncertainties arise from a lack of data on interception and dissipation from foliar surfaces.

Granular applications: EECs for broadcast granular applications are calculated on the basis of mass (in mg) per area (square foot), corrected for the fraction of the pesticide left on the surface. For unincorporated broadcast applications, the entire fraction of the pesticide is assumed to remain on the surface.

Table 30. EECs on Avian and Mammalian Food Items From Applications of 1 lb ai/A (from Hoerger & Kenaga, 1972, modified by Fletcher et al, 1994).

Food Items	Max. EEC (ppm) 1 lb ai/A	Mean EEC (ppm) 1 lb ai/A
Short grass	240	85
Tall grass	110	36
Broadleaf plants and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

(8) Water Resource Assessment

(a) Ground Water Assessment

Despite the fact that iprodione is mobile to highly mobile in some soils (K_{ads}=≤0.20-43.09), it is unlikely that it will leach to ground water because of its rapid degradation in the environment, as demonstrated by the hydrolysis rate at pH's 7 and 9 (half-life: 4.7 days and 27 minutes, respectively), the soil metabolism rate (DT_{50}: 14-30 days aerobic, 7-14 days anaerobic) and the field dissipation half-lives (<3-7 days). In addition, because iprodione is typically applied as a foliar treatment, degradation/metabolism on the plant surface and/or absorption by plants will further mitigate the potential for ground water contamination. However, iprodione has some potential to persist and leach under certain conditions, i.e., acidic soils with low microbial populations and high permeability.

Readily available sources of ground water monitoring data were reviewed for the presence of iprodione. Samples collected during 1995 and 1996 were reported to the Office of Water's STORET system. Samples were not correlated with specific use information, however, crops that iprodione is typically applied to were grown in the sampled watersheds.

From April to October 1996 monitoring in 40 wells along the Oregon coastal region was conducted. Eighty-nine samples were collected- up to four samples at some wells over the period

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and F. Korte, eds., *Environmental Quality and Safety: Chemistry, Toxicology, and Technology*, Georg Thieme Publ, Stuttgart, West Germany, pp. 9-28.

Fletcher, J.S., J.E. Nellessen, and T.G. Pfleeger. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Tox. Chem. 13:1383-1391.

of the study, from the 40 wells. All samples were reported as below the level of quantification (LOQ); 0.1 ppb. No correlation with use areas was established, although samples were collected from areas with known grape production.

In another study along the Central Snake River basin in Oregon, 27 wells were sampled for a total of 30 samples. Iprodione was detected in all samples, but were reported as below the level of quantification (0.1 ppb) in all samples. The study was conducted during a three day period during August 1996. No correlation with the use of iprodione was established.

A study conducted in the Lake Superior Western Basin in Wisconsin during July 1995 at two wells reported all samples (5) as below the LOQ of 0.55 ppb. No information on why the samples were collected could be established.

Lastly, the Pesticide In Ground Water Database (*EPA, 1992)* reported one study in Massachusetts during 1986 in which 15 wells were sampled. No samples reported finding iprodione.

(b) Surface Water Assessment

Iprodione can contaminate surface water at application by spray drift. Moderate fractions of applied iprodione should be available for runoff for several days post-application. The low to moderate soil/water partitioning of iprodione indicates that runoff will be primarily by dissolution in runoff water as opposed to adsorption to eroding soil.

Iprodione will hydrolyze fairly rapidly in neutral to highly alkaline waters. Biodegradation will also contribute significantly to the dissipation of iprodione in surface waters with adequate microbiological activities, thereby somewhat offsetting large decreases in abiotic hydrolysis rates with decreasing pH (half-life of 131 days at pH 5). However, in acidic waters that also have low microbiological activities and long hydrologic residence times, iprodione should be somewhat more persistent than in neutral to alkaline waters due to substantially lower hydrolysis rates. Iprodione is stable to direct aqueous photolysis and has a low volatilization from water potential (Henry's Law constant = 9.02×10^{-9} atm*m^3/mol). The DT_{50} under anaerobic conditions (anaerobic aquatic metabolism DT_{50} of 7-14 days) is comparable to the DT_{50} under aerobic conditions (aerobic aquatic metabolism DT_{50} of 3-7 days) indicating that iprodione will not persist in typically anaerobic sediments and deep waters.

The low soil/water partitioning of iprodione indicates that it will probably readily partition into the water column. Dissolved concentrations in the water column will be less than dissolved concentrations in sediment pore water, but should still be within a somewhat comparable range. The low octanol/water partitioning of iprodione (log K_{ow} = 3.1) indicates that its bioaccumulation potential is probably low.

The Office of Drinking Water has not established a MCL or any HALs for iprodione. However, according to the Report on Pesticides Which May Pose Dietary Risk: RfD Exceeders 1991-1996 dated March 27, 1997 it has been identified by EPA/OPP as having potential to pose dietary risk (chronic toxicity).

Surface water monitoring data were extracted from the U.S. EPA's Office of Water STORET Database maintained on the IBM mainframe at Research Triangle Park, North Carolina.

Iprodione was monitored in four surface water features in the central coastal region of California near Santa Cruz in 1994. It is known that iprodione was applied in the watershed of the monitored sites according to the data owners. All four samples exceeded the minimum detection limit (0.1 ppb) on the day of sampling; the date of pesticide application was not ascertained prior to sampling. Concentrations ranged from 1.07 ppb at Hawkins Slough to 3.53 ppb in a drainage ditch from a nearby field. The mean of the four samples was 2.7 ppb.

Surface water monitoring conducted at three sites on the Oregon coast in 1996 indicated detection of iprodione in all samples (three single day samples). However, all were below the level of quantification (LOQ) of 0.1 ppb. No correlation to use areas was established.

Preliminary aquatic EECs are estimated using GENEEC (ver. 1.2), a screening model that provides an upper-bound estimate of EECs on a high exposure site. The GENEEC program uses basic environmental fate values (adsorption to soil, degradation in soil before runoff and in water) and pesticide label information (rates, intervals, incorporation, method of application) to estimate the EECs in a one-hectare, two-meter deep pond following the treatment of a 10 hectare field. The runoff event occurs two days after the last application. The model accounts for direct deposition of spray drift onto the water body (assuming 5% of the application rate for aerial spray applications and 1% for ground spray applications). When risk quotients (RQs) for aquatic organisms are exceeded, refined aquatic EECs are calculated using PRZM (ver. 2.3)/EXAMS 2.94.

Table 31. Environmental fate parameters used to predict iprodione EECs.

Parameter	Value
water solubility (ppm)	13 ppm
K_{oc}	327
aerobic soil metabolism, t1/2	90 days[1]
hydrolysis t1/2, pH 7	Stable
aerobic aquatic metabolism, t1/2	21 days[2]
aqueous photolysis t1/2	Stable

[1]The observed aerobic soil metabolism DT_{50} was 30 days. The value was multiplied by a factor of 3 to account for variability with such studies and the absence of more than one study.
[2]The observed aerobic aquatic metabolism DT_{50} was 7 days. The value was multiplied by a factor of 3 to account for variability with such studies and the absence of more than one study.

The Pesticide Root Zone Model (PRZM2.3) simulates pesticides in field runoff on daily time steps, incorporating runoff, infiltration, erosion, and evapotranspiration. The model calculates foliar dissipation and runoff, pesticide uptake by plants, microbial transformation, volatilization, and soil dispersion and retardation. The Exposure Analysis Modeling System (EXAMS 2.94) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep).

Table 32. Estimated Environmental Concentrations (EECs) For Aquatic Exposure from Aerial Application on Selected Uses Using GENEEC and PRZM/EXAMS 2.94.

Site	ApplicationRate x No/Interval (da)	----- Estimated Environmental Concentrations (EECs), ug/l -----					
		Peak	4-day	21-day	56/60-day	90-day	long-term avg
Tier 1: GENEEC							
Peanuts	1.0 x 3/14	70	66	49	29	--	--
Almonds	0.5 x 4/14	45	42	31	19	--	--
Grapes	1.0 x 4/14	88	83	62	37	--	--
Peaches	1.0 x 4/7	98	93	68	41	--	--
Potatoes	1.0 x 4/10	94	89	66	40	--	--
Onions	0.75 x 5/7	89	84	62	37	--	--
Strawberries	1.0 x 4/10	92	87	64	39	--	--
Turf - Full year[1]	5.45 x 26/14	4	4	3	2	--	--
Turf - Half year	5.45 x 13/14	1280	1210	890	540	--	--
		1030	970	720	430	--	--
Tier 2: PRZM2.3/EXAM II 1 in 10 year EECs							
Grapes	2.0 x 4/Var	13.0	11.5	10.0	7.6	7.4	2.8
Peaches	1.0 x 3/7-14	14.7	13.8	11.0	8.1	6.7	1.5

[1] The turf, lawn, golf course, etc. uses had no limit to the number of applications per year nor a maximum annual application rate. Therefore, for estimating maximum exposure, it was assumed that iprodione could be use year-round in the Southern U.S., where the growth cycle of turf grass is year-round. In the Northern U.S., iprodione is expected to be applied up to 6 months out of the year, from April thru September. Approaching the assessment in this fashion, bounds the maximum potential exposures from use on turf relative to climate.

(c) Drinking Water Assessment

The estimated concentrations provided below for drinking water are for the parent iprodione and for 3,5-dichloroaniline. If other degradates are included in the tolerance expression or are of toxicological concern, then it may be necessary to re-evaluate monitoring data to determine its usefulness in a risk assessment.

(d) Ground Water Sources

A preliminary ground water assessment was made using SCI-GROW[2] to estimate the "maximum" ground water concentration from the application of a pesticide to crops. SCI-GROW is based on the fate properties of the pesticide (i.e., the median K_{oc} and mean aerobic soil metabolism half-life), the application rate, and the existing body of data from small-scale ground water monitoring studies. The model assumes that the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimates. As such, the estimated "maximum" concentration derived using SCI-GROW should be considered a high-end to bounding estimate of "acute" exposure. The concentration for parent iprodione estimated using SCI-GROW is approximately 0.3 ppb for all use except turf. For turf uses, due to the uncertainty associated with the frequency of use, concentrations were estimated to be as high as 11.7 ppb. The results of this model should be compared to available monitoring data when determining the potential for human exposure.

[2] Barrett, M. 1997. SCI-GROW; "A proposed method to determine screening concentrations estimates for drinking water from ground water sources." Draft. USEPA/OPP/EPA, September 1997.

Absence of appropriate fate data for the degradate 3,5-dichloroaniline did not permit a quantitative estimate in ground water. However, due to the low estimated K_{oc} and the persistence of 3,5-dichloroaniline, it appears that it has a high potential to leach to ground water. No ground water monitoring data were available for this assessment.

(e) Surface Water Sources

Tier II surface water drinking water EECs were calculated using PRZM2.3 to simulate the agricultural field and EXAMS 2.94 for fate and transport in surface water. Spray drift was simulated using the assumption that 1% of applied iprodione reached surface water at the time of application and 95% of the chemical deposited on the target site. The remaining 4% either remained airborne or deposited on the ground beyond the drainage basin for the pond.

Environmental fate parameters used to predict iprodione EECs were presented earlier. The scenarios chosen for iprodione were a grape vineyard in Chautauqua County, New York and a peach orchard in Peach County, Georgia. Crop specific inputs to PRZM are presented in the Use Characterization section. Scenarios were chosen to represent sites that were expected to produce runoff greater than 90% of the sites where the appropriate crop is grown. Model simulations were made with the maximum application rate for a 34-year period. Tier II one-in-ten year (upper tenth percentile) EECs are presented in Table 32. The EECs have been calculated so that in any given year, there is a 10% probability that the maximum average concentration of that duration in that year will equal or exceed the EEC at the site.

The upper 90% confidence bound on the overall mean concentrations of iprodione were 2.8 ug/l from the application to grapes, and 1.5 ug/l from the application to peaches. These upper 90% confidence bounds are the best value to use in cancer risk assessments as they are the best estimate of lifetime mean concentrations. The maximum 1 in 10 year concentrations are 13.0 ug/L from the application to grapes and 14.7 ug/L from the application to peaches. These values are the suggested value for use in acute risk assessments.

Estimated surface water concentrations of 3,5-dichloroaniline attributable to the breakdown of parent iprodione can be estimated using the percent conversion from the submitted fate studies. The estimated upper bound concentration of 3,5-dichloroaniline from the degradation of iprodione is based on a maximum conversion of 30 percent seen in an acceptable soil photolysis study. The 90% upper bound on the overall mean concentrations for iprodione use on peaches and grapes from the Tier II estimates were multiplied by a factor of 0.3 to account for a 30% conversion of parent to 3,5-dichloroaniline. It is believed that this represents a maximum conversion, given the much lower degree of conversion seen in the soil metabolism and field studies. It is likely that the actual concentrations of 3,5-dichloroaniline will be lower, based on evidence in the studies that showed a decline in concentration with time. Thus, the estimated concentration of 3,5-dichloroaniline attributable

to the breakdown or transformation of iprodione is 0.45 ug/l (peaches) and 0.84 ug/l (grapes). The degree of uncertainty associated with this estimate is considered to be high, therefore, the error surrounding this estimate may likewise be high. Such factors as applying laboratory test conditions to the field and degradation and transformation pathways not captured by the soil photolysis study may contribute to either overestimating or underestimating actual environmental concentrations.

(9) Use of Screening Estimates for Drinking Water Assessments

EPA recommends that the EECs generated from PRZM/EXAMS 2.94 (for surface water sources) be used for drinking water risk assessments for iprodione. The monitoring data reported here are not considered reliable for use in drinking water assessments because they were not well-correlated with the use patterns for iprodione or to drinking water intakes. Furthermore, an insufficient number of both samples and sites are available to draw any supportable scientific conclusions as to the extent of surface water contamination from the use of iprodione. The model predictions provide a screen to eliminate those chemicals that are not likely to cause drinking water problems. Exceedances in drinking water risk assessments using the screening model estimates do not necessarily mean a problem actually exists but point to the need for better data (such as monitoring studies specifically designed to relate water concentrations to usage) on which to make a decision. It is possible that the additional data will show no problem; it is also possible that the data will show that in some instances a problem may still exist. If degradates are to be included in the tolerance expression, the monitoring data may have to be re-evaluated for usefulness and/or the modeling data will have to be re-calculated to include the appropriate degradates.

Concentrations estimated using SCI-GROW (ground water sources) should be used with caution for drinking water risk assessment purposes. Estimates for uses other than turf may reflect conservative "upper bound" estimates of concentrations likely to be found in some highly vulnerable ground water sources. Estimates for turf use should be examined further pending receipt of better use characterization data. Monitoring data in known use areas do not support the presence of iprodione at concentrations estimated using SCI-GROW on turf, i.e., more than 2 orders-of-magnitude greater.

2. Ecological Effects Hazard Assessment

For acute exposure, iprodione is practically nontoxic to slightly toxic to birds, practically nontoxic to small mammals, relatively nontoxic to bees, moderately toxic to freshwater fish, moderately to highly toxic to freshwater invertebrates, moderately toxic to estuarine and marine fish, and moderately to highly toxic to estuarine and marine invertebrates. Chronic toxicity studies established the following NOEC values and ecological endpoints affected: 300 ppm for birds (decreased hatchling body weight); 500 ppm for small mammals (decreased fetal weight); >0.26 ppm for freshwater fish (larval survival); >0.17 ppm

for freshwater invertebrates (offspring/female, mean percentage survival, growth); >3.5 ppb for estuarine and marine invertebrates (offspring/female/reproductive day).

Notice that the toxicity testing does not test all species of birds or fish. Only two surrogate species for both freshwater fish and birds are used to represent all freshwater fish species (2000+) and bird species (680+) in the United States. For mammals, acute studies are usually limited to the Norway rat or the house mouse. Estuarine/marine testing is limited to a crustacean, mollusk, and fish. Also, reptiles and amphibians are not tested. The assessment makes the assumption that the bird and reptilian toxicities are the same. The same assumption applies to amphibians and fish. Therefore, without definitive testing, it is assumed that the conclusions regarding hazards of iprodione to birds and fish apply to other vertebrate animals that are not currently tested.

(1) Toxicity to Terrestrial Animals

(a) Birds, Acute and Subacute

Table 33. Avian Acute Oral Toxicity.

Species	% ai	LD50 (mg/kg)	Toxicity Category [1]	MRID No. Author/Year	Study Classification[2]
Northern bobwhite quail *(Colinus virginianus)*	96.2	>2000[3]	"practically nontoxic"	41604101 Culotta et al /1990	Core
Northern bobwhite quail *(Colinus virginianus)*	Tech, %a.i. unknown	930[4] (744-1163)	"slightly toxic"	Acc# 232703 McGinnis /1973	Core
Mallard duck *Anas platyrhynchos*	Tech, %a.i. unknown	10,437	"practically nontoxic"	Acc# 232703 McGinnis /1974	Supplemental

[1] "Practically nontoxic" is given to chemicals with LD_{50}s greater than 2000 mg/L and "slightly toxic" designates chemicals whose LD_{50} falls in a range between 501 to 2000 mg/kg (Brooks (1973).
[2] Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)
[3] Study conducted with 23-week old birds.
[4] Study conducted with 14-day old birds.

Because the LD_{50} falls in the range of 501 to > 2000 mg/kg, iprodione is "slightly toxic to practically nontoxic" to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 41604101 and Acc# 232703).

Table 34. Avian Subacute Dietary Toxicity.

Species	% ai	5-Day LC50 (ppm)[1]	Toxicity Category[2]	MRID No./ Author/Year
Northern bobwhite quail *(Colinus virginianus)*	96.2%	>5620[3]	"practically nontoxic"	41604102/ Driscoll et al./1990
Mallard duck *(Anas platyrhynchos)*	96.2%	>5620[4]	"practically nontoxic"	41604103/Driscoll et al.

[1] Test organisms observed an additional three days while on untreated feed.
[2] "Practically nontoxic" is the designation for chemicals with LC50s above 5000 ppm based on Brooks'(1973) classification scheme.
[3] There was 20% mortality at 5620 ppm at the end of the study.
[4] There was no mortality at the end of the study.

Because the LC_{50} values are greater than 5000 ppm, iprodione is "practically nontoxic" to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID # 41604102 and 41604103).

(b) Birds, Chronic

Table 35. Avian Reproduction.

Species/ Study Duration	% ai	NOEC/LOEC (ppm)	LOEC/ Endpoints	MRID No./ Author/Year
Northern bobwhite quail *(Colinus virginianus)*	95%	300/1000	hatchling body weight	00099126/ Beavers & Fink//1981
Mallard duck *(Anas platyrhynchos)*	95%	300/1000	fewer 14-day old survivors	00086840/ Beavers & Fink//1981

The guideline (71-4) is fulfilled (MRID00099126 and 00086840).

(2) Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported in Table 36 below.

Table 36. Mammalian Toxicity

Species/Study Duration	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID No. /Acc No.
Laboratory mouse 96 hours	99.6	LD50	3050 mg/kg	mortality	232701
Laboratory rat	97.7%	LD50	4468 mg/kg	mortality	42306301
Laboratory rat 96 hours	41.6%	LD50	1160 mg/kg (1070-1260)(female)	mortality	236497
"	"	"	1540 (1140-2080) (male)	"	"
"	"	"	1170 (919-1480) (male and female)	"	"
Dog 1 year	96.5%	Feeding	NOEL = 100, LOEL = 600	Hematopoieticchanges- RBC, Hgb and HCT counts were lower than in the controls	255951 144391 41327001 42211101
Rat 3 generation	Tech. % not reported	Reproduction	Repro. NOEL = 500 ppm and LEL = 2000 ppm	decreased fetal weight	232712
Rat 2 generation	96.2%	Reproduction	Parental toxicity NOEL = 300 ppm, LOEL = 1000 ppm Repro. toxicity NOEL = 1000 ppm, LOEL = 2000 ppm	Parental effects decrease body weight, body weight gain, and food consumption in both sexes, Reproductive effects decreased pup viability and body weight & and an increased incidence of clinical signs in the pups during the lactation period.	41871601
Rat 2-year	94.5% and 95.7%	Feeding/ carcinogenic	Anti-androgenic (male) NOEC= 150ppm LOEC= 300 ppm	Testicular hyperplasia, reduced spermatozoa in epididymis adrenal effects	42637801 42787001

The results indicate that technical iprodione is "practically nontoxic" and formulated iprodione is "slightly toxic" to small mammals on an acute oral basis.

(a) Insects

A honey bee acute contact study using the TGAI is required for iprodione because its use on almond, apricot, beans, blueberry, cherry, clover, cotton, grapes, mustard, cabbage, nectarine, onion, peach, peanuts, and plum will result in honey bee exposure. Results of this test are in table 37 below.

Table 37. Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (μg/bee)	Toxicity Category[1]	MRID No. /Author/Year	Study Classification
Honey bee *(Apis mellifera)*	Percentage unknown	>120.86	"relatively nontoxic"	44262061/ Atkins/1975	Core

[1] Based on Atkin (et al. 1981; MRID No.: 44038201) LD50 values above 11 μg/bee are "relatively nontoxic".

The results indicate that iprodione is "relative nontoxic" to bees on acute contact basis. The guideline (141-1) is fulfilled (MRID No. 44262021).

(3) Toxicity to Freshwater Aquatic Animals

(a) Freshwater Fish, Acute

Table 38. Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	% ai	96-hour LC50 (ppm) (measured/nominal)	Toxicity Category	MRID No./Author/Year	Study Classification
Bluegill sunfish *(Lepomis macrochirus)*	95.06%	6.3 (5.2-7.7) /(nominal)	"moderately toxic"	Acc#234810 Calmbacher/1978	Core
Bluegill sunfish *(Lepomis macrochirus)*	96.2%	3.7 (3.3-4) (mean measured conc.)	"moderately toxic"	41604104 Sousa/1990	Core
Bluegill sunfish *(Lepomis macrochirus)*	TEP 50%	7.8 (6.9-8.9) (as a.i.) (mean measured conc.)	"moderately toxic"	40489203 Surprenant/1987	Core
Channel catfish *(Ictalurus punctatus)*	95%	3.1 (2.6-3.6) (mean measured conc.)	"moderately toxic"	470254018 Swigert et al/1986	Supplemental
Rainbow trout *(Oncorhynchus mykiss)* static	96.2%	4.1 (2.9-7) (mean measured conc.)	"moderately toxic"	41604105 Sousa/1990	Core
Rainbow trout *(Oncorhynchus mykiss)* static	95.06%	4.2(3.2-5.6) (nominal)	"moderately toxic"	Acc#234810 Calmbacher et al./1978	Supplemental

[1] Brooks (et al.,1973) toxicity classification indicates that LC50 values >1 to 10 ppm are "moderately toxic".

Because the LC_{50} falls in the range of >1 to 10 ppm, iprodione is "moderately toxic" to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID# Acc# 234810, 41604104, 40489203, 41604105).

(b) Freshwater Fish, Chronic

Table 39. Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

Species/ Study Duration	% ai	NOEC/LOEC (ppm)	MATC[1] (ppm)	Endpoints Affected	MRID No. / Author/Year	Study Classification
Fathead Minnow (*Pimephales promelas*)	100	>0.26<0.55	0.38	Larval survival	40550801/ Surprenant/1988	Core

[1] defined as the geometric mean of the NOEC and LOEC.

The data indicate that exposure to concentrations greater than 0.26 ppm significantly reduce larval fish survival. The guideline (72-4) is fulfilled (MRID No.: 40550801).

(c) Freshwater Invertebrates, Acute

Table 40. Freshwater Invertebrate Acute Toxicity

Species/(Static or Flow-through)	% ai	48-hour LC50/EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No./ Author/Year	Study Classification
Waterflea *(Daphnia magna)*	96.2%	0.24(.21-.31) (mean measured conc.)	"highly toxic"	41642001/McNamara/1990	Core
Waterflea *(Daphnia magna)*	94.5%	0.43(0.31-0.60) (nominal)	"highly toxic"	Acc#232703/Roberts/1977	Core
Waterflea *(Daphnia magna)*	94.5%	7.2(6.0-8.6) (nominal)	"moderately toxic"	Acc#232703/Algirdas/1977	Core
Waterflea *(Daphnia magna)*	TEP 50%	0.36(0.34-0.39) (as a.i.) (mean measured conc.)	"highly toxic"	40489206/Surprenant/1988	Core
Waterflea *(Daphnia pulex)*	TEP 50%	5.8(3.2-10.3) (nominal) (72 hr)	"moderately toxic"	Acc#232703/Ambrosi et al. 1977	Supplemental
Waterflea *(Daphnia pulex)*	Tech. % unknown	4.0(2.9-5.5) (nominal) (72 hr)	"moderately toxic"	Acc#232703/Ambrosi et al. 1977	Supplemental
Juvenile crayfish *(Procambarus simulans)*	95%	>4.1 (mean measured conc.) (7-day)	"moderately toxic"	00162223McAllister et al.1986	Supplemental

[1] Brooks (et al., 1973) classification indicates the LC50 of 0.1 to 1 ppm are in the "highly toxic" range and those greater than 1 to 10 ppm are in the "moderately toxic" range.

Because the LC_{50}/EC_{50} fall in the range of 0.24 to 10 ppm, iprodione is "highly to moderately toxic" to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID No.: 40489206, 41642001, Acc No. 232703).

(d) Freshwater Invertebrate, Chronic

Table 41. Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species/ Flow-through)	% ai	21-day NOEC/LOEC (ppm)	MATC[1] (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	100	>0.17<0.33	0.24	Offspring/female,Mean percentagesurvival, growth	40489201 Surprenant /1988	Core

[1] defined as the geometric mean of the NOEC and LOEC.

The data indicate that concentrations greater than 0.17 ppm significantly reduce mean percentage survival, growth and the number of offspring produced per female. The guideline (72-4) is fulfilled (MRID No.:40489201).

(4) Toxicity to Estuarine and Marine Animals

(a) Estuarine and Marine Fish, Acute

Table 42. Estuarine/Marine Fish Acute Toxicity

Species/(Static or Flow-through)	% ai	96-hour LC_{50} (ppm) (measured)	Toxicity Category[1]	MRID No. Author/Year
Sheepshead minnow *(Cyprinodon variegatus)*	95	7.7 (7.1-8.4)	"moderately toxic"	40489205 Surprenant/1988

[1] Brooks (et al.,1973) classification indicates that LC50s greater than 1 to 10 ppm are "moderately toxic".

Iprodione is "moderately toxic" to estuarine/marine fish on an acute basis. The guideline (72-3a) is fulfilled (MRID No. 404892-05).

(b) Estuarine and Marine Fish, Chronic

Because the acute LC_{50} is greater than 1 ppm, an estuarine/marine fish early life-stage toxicity test using the TGAI is not required for iprodione.

(c) Estuarine and Marine Invertebrates, Acute

Table 43. Estuarine/Marine Invertebrate Acute Toxicity

Species/Static or Flow-through	% ai.	96-hour LC50/EC50 (ppm) (measured)	Toxicity Category[1]	MRID No. Author/Year	Study Classification
Eastern oyster (shell deposition) *(Crassostrea virginica)*	95	2.3 (2.02-2.5)	"moderately toxic"	40489202/ Surprenant/1987	Core
Mysid *(Americamysis bahia)*	100	0.68 (0.54-1)	"highly toxic"	40489204/Surprenant/1987	Core

[1] Based on Brook's (et al. 9173) toxicity categories indicate that chemicals with an LC50 between 0.1 and 1 ppm are "highly toxic".

Because the iprodione LC_{50}/EC_{50}s fall in the range of >0.1-10 ppm, iprodione is "highly toxic" to "moderately toxic" to estuarine/marine invertebrates on an acute basis. The guideline (72-3b and 72-3c) is fulfilled (MRID No.: 40489202, 40489204).

(d) Estuarine and Marine Invertebrate, Chronic

Table 44. Estuarine/Marine Invertebrate Life-Cycle Toxicity

Species/(Static Renewal or Flow-through)	% ai	21-day NOEC/LOEC (ppm)	MATC[1] (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Mysid *(Americamysis bahia)*	100	>0.0035 <0.0075	0.0055	Offspring/female/reproductive day	40832201 Surprenant/1988	Core

[1] defined as the geometric mean of the NOEC and LOEC.

The data indicate that concentrations greater than 3.5 ppb (0.0035 ppm) significantly reduce the number of offspring produced by each female. The guideline (72-4) is fulfilled (MRID No.:40832201).

(e) Freshwater and Estuarine Field Studies

Following is a summary of the trends observed in the Aquatic Residue Monitoring study (MRID 419836-01) that was found to be supplemental. The study area was limited in size to five fields, 125 to 202 acres each. The small study size significantly miscalculates the amount of iprodione entering watersheds in the rice regions. In addition, sample collection methods may have contributed to low reported chemical concentrations.

Iprodione was aerially applied at 0.5 lbs a.i./A, twice on five 125 to 202 acre rice fields in southern U.S. (Louisiana, Texas and Arkansas). The applications were at 13 to 14 day intervals. Some of the monitoring sites were in freshwater habitats and the others were located in estuarine (brackish) habitats.

In the water, iprodione concentrations ranged from <MDL to 121.1 ug/L in the 5 study sites. Concentrations were less than 2.00 ug/L within 7 days after draining into the lotic environments.

Iprodione's major degradate, RP-30228, had concentrations ranging from <MDL to 35.19 ug/L. This degradate appeared to be more persistent than iprodione. It often had maximum concentrations at the same time as iprodione. The average water concentrations at the 25 monitoring stations over the length of the study were 0 ug/L to 34.4 ug/L for iprodione and 0 ug/L to 13.7 ug/L for RP-30228. The maximum 21-day mean concentrations of iprodione ranged from 0 to 54.2 ug/L in fresh water and from 3.3 ug/L to 7.1 ug/L in estuarine water. The maximum 21-day mean concentrations of RP-30288 ranged from 0 ug/L to 24.4 ug/L in fresh water and from 2.3 ug/L to 5.3 ug/L in estuarine water. Residue concentrations of both compounds tended to be higher in the drainage ditches and decreased with distance and dilution at the downstream monitoring stations. The highest concentrations in the drainage ditches generally occurred from off-target spray drift, after rainfall events and after draining of the rice fields.

In the sediments, iprodione was observed sporadically and was associated with the highest observed iprodione water concentrations. The range in sediment was <MDL to 80.36 ug/kg. Iprodione was observed more frequently in drainage ditches close to the rice fields. Iprodione concentrations in the sediment were generally less than in the water and persisted less. Iprodione was rarely detected below the top 2.5 cm layer in the sediment. RP-30228 was detected in the sediments more frequently and at higher concentrations than iprodione, ranging from <MDL ton 181.05 ug/kg. The concentrations in the sediment were generally higher than in the water. However, the detections were sporadic and generally lasted a short period of time.

It was observed that the trends observed in the field were similar to those observed in the aerobic and anaerobic aquatic metabolism studies (i.e. relatively high concentrations and more persistence of RP-30288 and lower concentrations of RP-32490, another degradate).

(5) Toxicity to Plants

(a) Terrestrial

As iprodione is a fungicide, terrestrial plant testing is not currently required.

(b) Aquatic Plants

Results of Tier II toxicity testing on the technical/TEP material are in table 45.

Table 45. Nontarget Aquatic Plant Toxicity (Tier II)

Species	% ai	EC50/ NOEC (ppm)	MRID No./ Author/Year	Study Classification
Nonvascular Plants				
Green algae *Kirchneria subcapitata* (formerly *selenastrum capricornutum*)	96.2	2.0/0.14	41604107 Giddings/1990	Core
Marine diatom *Skeletonema costatum*	96.2%	0.33/0.03	41604109/ Giddings/ /1990	Core (but not required)
Blue-green algae *Anabaena flos-aquae*	96.2	>1.3	41604110 Giddings/1990	Supplemental[2] (but not required)

[1] Use of sonification to separate the cells is not allowed for this species.
[2] Test must give an EC_{50} result to be core.

The results of the Tier II studies indicate the requirement for a study conducted with the vascular plant, *Lemna*, is still outstanding. As the label has application rates up to 22 lbs a.i., the registrant must either test *Lemna* up to this rate (or the limit of solubility), or establish an EC_{50} value for this plant. The studies conducted with *Navicula and Anabaena* do not need to be re-done, as tests with these aquatic plants are not required to support the uses of fungicides.

3. Ecological Risk Assessment

To evaluate the potential risk to nontarget organisms from the use of iprodione products, risk quotients (RQs) are calculated from the ratio of estimated environmental concentrations (EECs) to ecotoxicity values. RQs are then compared to levels of concern (LOCs) for determination of potential ecorisk and the consideration of regulatory action.

(1) Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as a liquid product, the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk. The predicted 0-day maximum residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb ai/A are in table 46 below.

Table 46. Estimated Environmental Concentrations (EECs) on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A

Food Items	EEC (ppm)[1]
Short grass	240
Tall grass	110
Broadleaf/forage plants, and small insects	135
Fruits, pods, seeds, and large insects	15

[1] Maximum EEC are for a 1 lb ai/A application rate and are based on Fletcher *et al.* (1994).

(a) Birds

i) Non-granular Products

The toxicity data indicate that iprodione is practically nontoxic to birds as the dietary LC_{50} values are greater than 5620 ppm, which was the highest concentration tested. When the toxicity is this low, it is unlikely that birds feeding on vegetation and insects contaminated with a pesticide are likely to be at risk. As iprodione is nontoxic and since the toxicity value cannot be precisely expressed, it is reasonable to conclude that nongranular iprodione is not an acute risk to birds.

ii) Granular Products

The only granular applications are broadcast treatments of turf, including golf course turf and ornamental lawns and turf. Acute risk from granular formulations is calculated with the LD_{50} per square foot risk index. The number of lethal doses (LD_{50}s) that are available within one square foot

immediately after application ($LD_{50}s/ft^2$) is used as the risk quotient for granular/bait products. The following table shows the RQs for songbirds (20g), upland gamebirds (180g) and waterfowl (1000g) for granular applications.

Table 47. Avian Risk Quotients for Granular Products (Broadcast) Based on a Northern Bobwhite Quail LD50 of 930 mg/kg.

Site	Application Method/Rate in lbs ai/A	Body Weight (g)	LD50 (mg/kg)	Acute RQ[1] ($LD50/ft^2$)
Ornamental Lawns & Turf	1.4	20	930	0.78***
	1.4	180	930	0.09
	1.4	1000	930	0.02
Ornamental Lawns & Turf	3	20	930	1.68***
	3	180	930	0.19*
	3	1000	930	0.04
Golf Course Turf,	4.1	20	930	2.28***
	4.1	180	930	0.26**
	4.1	1000	930	0.05

[1] $RQ = \frac{\text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/Lbs}/43{,}560 \text{ ft}^2/\text{A})}{LD_{50} \text{ mg/kg} * \text{Weight of Animal (g)} / 1000 \text{ g/kg}}$

*** exceeds acute high, acute restricted and acute endangered species LOCs.
** exceeds acute restricted and acute endangered species LOCs.
* exceeds acute endangered species LOC

An analysis of the results indicates that for broadcast applications of granular products, avian acute high risk, restricted use, and endangered species LOCs are exceeded at application rates equal to or above 1.4 lbs a.i./A for songbirds and small juveniles; endangered species LOC is exceeded for upland gamebirds and other mid-sized birds at rates of 3 lbs a.i./A. and greater; and restricted use LOC is exceeded for the same birds at 4.1 lbs a.i./A. Large birds are not at risk from exposure to granules of iprodione .

iii) Seed Treatments

Iprodione is also used an antifungal seed treatment for peas, ornamental trees, ornamental herbaceous plants and grasses. Birds may be exposed to pesticides by ingesting treated seeds. They also may be exposed by other routes, such as by drinking water contaminated by treated seeds. The number of lethal doses ($LD_{50}s$) that are available within one square foot immediately after application ($LD_{50}s/ft^2$) is used as the RQ for treated seeds. Risk quotients are calculated for a 20 g songbird. The two tables below assume that the treated seeds are not incorporated into the soil and are available to foraging birds. The acute RQs for applications to seed to prevent fungus are in table 48 an 49.

Table 48. The Number of Treated Seeds Needed to Reach the Northern Bobwhite Quail LD_{50} of 930 mg/kg for a 0.02 kg Bird.

Seeds/oz	Seeds/Cwt	A.I. Lb/cwt of seed	Lbs a.i./Seed	Mg a.i./seed	LD50 (mg/kg)	Bird wt	Seeds/$LD50^2$
Peas/90	144,000	0.175	1.22×10^{-6}	0.55	930	02	34
Trees[1]/1420	18,272,000	0.1308	7.16×10^{-9}	0.003			6,200
Zinnia/3200	5,120,000	0.1308	2.55×10^{-8}	0.012			1,550
Tall Fescue/11115	17,784,000	0.1308	7.35×10^{-9}	0.003			6,200

[1] 1989. Rules for Testing Seeds, Association of Official Seed Analysts, Journal of Seed Technology Vol.12, No. 3 ; [2] Seeds/LD_{50} = (LD_{50} x Body Weight)/Mg a.i. per seed

This table indicates that: 1) It takes significantly fewer large seeds to reach lethal dose and 2) A bird can more easily ingest a lethal dose of iprodione by foraging on larger treated seeds (peas) than on smaller treated seeds.

Table 49. Avian Acute Risk Quotients for Treated Seeds Based on a Northern Bobwhite Quail LD_{50} of 930 mg/kg and Weight of a Small Songbird (20g).

Lbs of seed/A	Oz of seed/A	No. seeds/oz	Seeds/A	Seeds//ft^2	Mg a.i./seed	mg a.i./ft^2	LD50/ft^2
Peas/220	3,520	90	316,800	7	0.55	4.0	0.22
Trees[2]/25	400	1,420	568,000	13	0.026	0.3	0.02
Zinnia/200	3,200	3,200	10,240,000	235	0.0116	2.7	0.15
Tall Fescue/12	192	11,115	2,134,080	49	0.018	0.2	0.01

[1] USDA 1966-Yearbook of Agriculture - Seeds
[2] 1989. Rules for Testing Seeds, Association of Official Seed Analysts, Journal of Seed Technology Vol.12, No. 3

This table indicates that the LOC for restricted use is exceeded only for pea seeds, and the LOC for risks to endangered species is exceeded for pea and zinnia seeds.

(b) Birds--Chronic Risks

i) Nongranular Applications

In order to calculate chronic risks, the lower NOEC value from the avian reproduction study is compared to estimated residues from multiple applications. The "FATE" program was used to calculate the EEC values. The initial concentration was based on the maximum residue value for short range grass (1 lb a.i./A equals 240 ppm). The half-life value of 30 days was taken from the aerobic soil metabolism study, as foliar degradation studies were not conducted. Iprodione has over forty registered agricultural uses, but the application rates are similar in terms of rate, number of applications and interval between applications. Therefore, the application scenarios used to calculate the estimated residues do not list specific crops. Each simulation was run for 120 days, and the maximum residue and average residue during that period were used to determine the possibility of chronic avian risk. Avian chronic risk quotients based on average residues for multiple, broadcast applications of non-granular products are in table 50.

Table 50. Avian Chronic Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on both the Mallard Duck and Bobwhite Quail NOEC of 300 ppm and Maximum and Average Residues.

Application Rate in lbs a.i./A	Number of Applications	Application Interval in Days	Maximum EEC[1] (ppm) and Average EEC[1] (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
1.0	4	7	766	300	2.55+
			320	300	1.07+
1.0	4	14	630	300	2.10+
			311	300	1.04+
0.5	2	14	207	300	0.69
			81	300	0.27
2.0	1	n/a	480	300	1.60+
			163	300	0.54
4.0	2	14	1655	300	5.52+
			644	300	2.15+
5.45	2	14	2255	300	7.52+
			878	300	2.93+
22	2	14	9101	300	30.3+
			3543	300	11.80+

[1] Assumes degradation using FATE program.
+ Exceeds chronic LOC for nonendangered and endangered species.

An analysis of the results indicate that for multiple applications of nongranular products of iprodione that the avian chronic level of concern (LOC) is exceeded at a registered maximum application rate of 1.0 lb a.i./A applied 4 times seasonally with 7 to 14 days between applications. The 2.0 lbs a.i./A rate applied once refers to the use on garlic where the pesticide is applied in-furrow. Although the maximum residues for this use exceed the LOC, the application method reduces exposure to birds, although the magnitude of this reduction cannot be quantified. The greatest chronic risk to birds is presented by the rates greater than or equal to 4 lbs a.i./A, all of which pertain to use on turf, ornamental trees and ornamental plants.

There currently are no methods to calculate chronic risks to birds from exposure to granular formulations and seed treatments.

(c) Mammals-Acute Risks

Estimating the potential for adverse effects to wild mammals is based upon EEB's draft 1995 SOP of mammalian risk assessments and methods used by Fletcher *et al.* (1994). The concentration of iprodione in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (usually the rat or the mouse LD_{50}) by the % (decimal of) body weight consumed. A RQ is then determined by dividing the EEC by the derived LC_{50} value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds).

However, as the LD_{50} value for technical iprodione is practically nontoxic, based on a laboratory mouse LD_{50} of 3050 mg/kg and a laboratory rat LD_{50} of 4468 mg/kg, the only application rates likely to produce residues great enough to present risks to nontarget mammals are those for turf and ornamental uses. Therefore, for acute and chronic risks from multiple applications of nongranular

iprodione, only the scenario based on residues for short rangegrass, which represent the "worst case scenario" is presented. The acute RQs for broadcast applications of nongranular products are in table 51 below.

i) Nongranular Products

Table 51. Mammalian Acute Risk Quotients for Single Application of Liquid Products (Broadcast) Based on a Mouse LD50 of 3050 mg/kg.

Site	Rate/ in lbs ai/A	Body Weight (g)	% Body Weight Consumed	Mouse LD_{50} (mg/kg)	EEC/(ppm) Short Grass	EEC/(ppm) Forage & Small Insects	EEC/(ppm) Large Insects & Seeds	Acute RQ[1] Short Grass	Acute RQ Forage & Small Insects	Acute RQ Large Insects & Seeds
Agri crops	1.0	15	95	3050	240	135	15	0.07	0.04	0.01
		35	66					0.05	0.03	0.01
		1000	15					0.01	0.01	0.00
Garlic	2.0	15	95	3050	480	270	30	0.15*	0.08	0.01
		35	66					0.10	0.06	0.01
		1000	15					0.02	0.01	0.00
Turf & Ornam.	4.0	15	95	3050	960	540	60	0.20**	0.17*	0.02
		35	66					0.21**	0.12	0.01
		1000	15					0.05	0.03	0.01
Turf & Ornam.	5.45	15	95	3050	1308	736	82	0.41**	0.23**	0.03
		35	66					0.28**	0.16	0.02
		1000	15					0.06	0.04	0.00
Turf & Ornam.	22.0	15	95	3050	5280	2970	330	1.64***	0.93***	0.10
		35	66					1.14***	0.64***	0.07
		1000	15					0.26	0.15	0.02

[1] $RQ = \frac{\text{EEC (ppm)}}{LD_{50}\text{ (mg/kg)}/\%\text{ Body Weight Consumed}}$

* The LOC for acute risk to endangered species is exceeded;

** The LOCs for acute risk to endangered species and restricted use are exceeded;

*** The LOCs for high acute risk, restricted use and acute risk to endangered species have been exceeded.

An analysis of the results indicates that for single applications of nongranular products of iprodione, the LOCs for acute risk to endangered species is exceeded for application rates equal to and greater than 2.0 lbs a.i./A; the LOC for restricted use is exceeded at rates equal to or greater than 4.0 lbs a.i./A; and the LOC for high acute risk is exceeded at rates equal to or greater than 22 lbs a.i./A.\

Table 52. Mammalian Acute Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on a Mouse LD_{50} of 3050 mg/kg.

Site	Rate/in lbs ai/A	No. of Applications	Application Interval (Days)	Body Weight (g)	% Body Weight Consumed	RatLD_{50} (mg/kg)	EEC(ppm) Short Grass	Acute RQ[1] Short Grass
Agri. Crops	1.0	4	7	15	95	3050	766	0.24**
				35	66			0.17
				1000	15			0.04
Agri. Crops	1.0	4	14	15	95	3050	630	0.20**
				35	66			0.14*
				1000	15			0.04
Ornamental Plants and Trees	4.0	2	14	15	95	3050	1655	0.52***
				35	66			0.36**
				1000	15			0.08
Turf and Ornamentals	5.45	2	14	15	95	3050	2255	0.70***
				35	66			0.49**
				1000	15			0.11
Ornamental Plants and Trees	22.0	2	14	15	95	3050	9101	2.83***
				35	66			1.97***
				1000	15			0.45

[1] $RQ = \frac{\text{EEC (ppm) * \% Body Weight Consumed}}{LD_{50}\text{ (mg/kg)}}$

* The LOC for acute risk to endangered species is exceeded.
** The LOCs for acute risk to endangered species and restricted use are exceeded.
*** The LOCs for high acute risk, restricted use and acute risk to endangered species have been exceeded.

An analysis of the results indicates that for multiple applications of nongranular products of iprodione, the LOCs for restricted use and acute risks to endangered species are exceeded for agricultural crops treated with 1.0 lb a.i./A; and that the LOCs for high acute risk, restricted use and acute risks to endangered species are exceeded for turf and ornamentals treated with rates equal to or greater than 4.0 lbs a.i./A.

ii) Granular Products

The following table shows the acute risks from exposure to granular products using the LD_{50} /ft^2 approach.

Table 53. Mammalian Risk Quotients for Granular Products (Broadcast) Based on a Mouse LD_{50} of 3050 mg/kg.

Site/Application Method	Rate in lbs ai/A	Body Weight (g)	LD_{50} (mg/kg)	Acute RQ[1] (LD_{50}/ft^2)
Ornamental Lawns & Turf	1.4	15	3050	0.32**
	1.4	35	3050	0.14
	1.4	1000	3050	0.01
Ornamental Lawns & Turf	3	15	3050	0.68***
	3	35	3050	0.29**
	3	1000	3050	0.01
Golf Course Turf	4.1	15	3050	0.93***
	4.1	35	3050	0.40**
	4.1	1000	3050	0.01

[1] $RQ = \frac{\text{App. Rate (lbs ai/A) * (453,590 mg/Lbs/43,560 ft}^2\text{/A)}}{LD_{50}\text{ mg/kg * Weight of Animal (g) * 1000 g/kg}}$

* indicates that endangered species LOC has been exceeded.
** indicates that both endangered species and restricted use LOCs have been exceeded.
***indicates that all three LOCs have been exceeded: endangered species, restricted use, and acute high risk.

An analysis of the results indicate that for broadcast applications of granular products, mammalian acute high risk, restricted use, and endangered species LOCs are exceeded at single application rates equal to or above 3 lbs a.i./A. Rates less than 3 lbs a.i./A only exceed the LOCs for restricted use and acute risks to endangered species.

iii) Seed Treatments

The use of iprodione as a seed treatment was thoroughly analyzed for birds. Therefore, it will not be repeated extensively in this mammal section. Iprodione is less toxic to mammals than to birds (LD_{50}s of 3050 mg/kg and 930 mg/kg, respectively). The two tables for seed treatments indicate that the iprodione-treated pea seeds present the greatest risk to birds. The pea seeds/LD_{50} index is 34 for birds. As iprodione is about 3.3 times more toxic to birds than mammals, the pea seeds/LD_{50} index is equivalent to 112 for mammals. Likewise The LD_{50}/square foot index for a small bird (20 grams) is 0.22. This index converts for a similar sized small mammal to a value of 0.06. This value indicates that the risk of seed treatments to small mammals is relatively low.

(d) Mammals-Chronic Risks from Nongranular Products

Table 54. Mammalian Chronic Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on a Rat NOEC of 500 ppm in a Reproduction Study and Maximum and Average Residues.

Application Rate in lb a.i./A	Number of Applications	Application Interval in Days	Maximum EEC[1] (ppm) and Average EEC[1] (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
1.0	4	7	766	500	1.53+
			320	500	0.64
1.0	4	14	630	500	1.26+
			311	500	0.62
0.5	2	14	207	500	0.41
			81	500	0.16
2.0	1	n/a	480	500	0.96
			163	500	0.54
4.0	2	14	1655	500	3.31+
			644	500	1.29+
5.45	2	14	2255	500	4.51+
			878	500	1.76+
22	2	14	9101	500	18.2+
			3543	500	7.09+

[1] Assumes degradation using FATE program.
+ Exceeds chronic LOC for nonendangered and endangered species.

The results indicate that for multiple broadcast applications of nongranular products of iprodione the mammalian chronic level of concern is exceeded at registered maximum application rates equal to or above 1.0 lb a.i./A for maximum estimated residues and 4.0 lbs a.i./A for average residues.

(e) Insects

Currently, EPA does not assess risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions. The bee contact LD_{50} study

indicates that the iprodione is "relatively nontoxic". Therefore, precautionary label to protect bees is not required.

(2) Exposure and Risk to Nontarget Freshwater Aquatic Animals

EPA calculated the EECs for iprodione using the GENeric Expected Environmental Concentration Program (GENEEC). The EECs are used to assess acute and chronic risks to aquatic organisms. Acute risk assessments were performed using peak EEC values for single and multiple applications. Chronic risk assessments were performed using the 21-day EECs for invertebrates and fish, as this is the time interval analogous to the exposure periods in the chronic studies (21 days and 34 days, respectively).

The GENEEC program uses basic environmental fate data and pesticide label application information to estimate the expected EECs following treatment of 10 hectares. The model calculates the concentration (i.e. EEC) of a pesticide in a one hectare, two meter deep pond, taking into account the following: (1) adsorption to soil or sediment (2) soil incorporation (3) degradation in soil before washoff to a water body and (4) degradation within the water body. The model also accounts for direct deposition of spray drift into the water body (assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively). When multiple applications are permitted the interval between applications is included in the calculations. Several different intervals between applications were used and are indicated in the table below for each site that was modeled. The environmental fate parameters used in the model for this pesticide are: soil K_{OC} 327, solubility 13 ppm, aerobic soil metabolism half-life 90 days, aerobic aquatic metabolism half-life 21 days, stable to hydrolysis and photolysis. The K_{OC} value is the average of two soils (sandy loam and loamy sand) from the equilibrium study.

The nine listed crops comprise approximately 71 percent of the total active ingredient applied annually. For the turf, lawn, and golf course uses, no limit to the number of applications nor maximum annual application rates were reported in either the label directions or the LUIS report. Therefore, it was assumed that the pesticide could be applied year-round in the southern U.S. and for half the year in the northern U.S.

Iprodione has one aquatic use, rice. For this use EPA assumes a simple dilution of the amount applied to a surface acre of water at a depth of six inches for a peak EEC. In addition, water residue data from the rice monitoring study are also used to calculate aquatic risk quotients. The methods used in the monitoring study may have underestimated the concentrations of iprodione measured during the course of the study. Therefore, risk quotients calculated with these data likely underestimate the risks that organisms in the rice regions encounter.

Table 55. Estimated Environmental Concentrations (EECs) For Aquatic Exposure.

Site	Application Rate x No/Interval (da)	Peak EEC (ppb)	4-Day EEC (ppb)	21 - DayEEC (ppb)	56 - Day EEC (ppb)
GENEEC					
Peanuts	1.0 x 3/14 (G)[1]	70	66	49	29
Almonds	0.5 x 4/14 (A)	45	42	31	19
Grapes	1.0 x 4/14 (G)	88	83	62	37
Peaches	1.0 x 4/7 (A)	98	93	68	41
Potatoes	1.0 x 4/10 (A)	94	89	66	40
Onions	0.75 x 5/7 (A)	89	84	62	37
Strawberries	1.0 x 4/10 ((G)	92	87	64	39
Cotton	0.15 X 1 (G)	4	4	3	2
Turf - Full Year	5.45 x 26/14 (G)	1280	1210	890	540
Turf - Half Year	5.45 x 13/14 (G)	1030	970	720	430
Rice - Direct Applic.	0.5 x 2/14 (A)	367	----	---	---
Rice - Monitoring Study	0.5 x 2/14 (A)	121.1 peak (on field) 55.2 peak (off field)		54.2 (on field) 30 (FW off field) 7.1 (SW)	26.7 (on field) 12 (FW off field) 2.5 (SW)

[1](G) = ground application to crop. (A) = aerial application to crop.

(a) Freshwater Fish

The highest peak EEC value for agricultural crops treated with iprodione is 98 ppb from aerial applications of peaches. When this EEC is compared to the lowest freshwater fish LC_{50} value of 3.1 ppm (channel catfish) the resultant RQ is 0.03, which is below the Levels of Concern (LOCs) for high acute risk, restricted use and acute risks to endangered fish species. Likewise, the highest 21-day EEC for agricultural crops is 68 ppb, also for peaches. The resultant chronic RQ is 0.26, which is below the LOC for chronic risks. Therefore, it can be concluded that the agricultural uses of iprodione do not present acute or chronic risks to freshwater fish.

However, the turf scenarios present acute and chronic risks to freshwater fish. These two use patterns plus the rice use are presented in the tables 56.

Table 56. Risk Quotients for Turf and Rice Scenarios for Freshwater Fish Based On a Channel Catfish LC50 of 3.1 (2.6- 3.6) ppm and a Fathead Minnow NOEC of 0.26 mg/L.

Site/Rate in lbs ai/A.	No. of Apps	LC50 (ppm)	NOEC (ppm)	EEC Initial/Peak (ppm)	EEC 21-Day Ave. (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC)
Turf - Full Yr.	5.45 (26)	3.1	0.26	1.28	0.890	0.42**	3.42+
Turf - Half Yr.	5.45 (13)	3.1	0.26	1.030	0.720	0.33**	2.77+
Rice - Direct App.	0.5 (2)	3.1	0.26	0.367	---	0.12*	---
Rice - Monitor. Stdy.	0.5 (2)	3.1	0.26	0.121 (field)	0.054 (field)	0.04	0.02
Rice - Monitor. Stdy.	0.5 (2)	3.1	0.26	0.055 (off field)	0.030 (off field)	0.02	<0.01

* indicates that only the endangered species acute LOC has been exceeded.
** indicates that both the restricted use and endangered species acute LOCs have been exceeded.
+ indicates that the chronic LOC for nonendangered and endangered species has been exceeded.

The RQs from the table indicate that the restricted use LOC is exceeded for the turf and rice (direct application) scenarios. The chronic risk RQs are also exceeded for both turf scenarios.

(b) Freshwater Invertebrates

Unlike the freshwater fish results, LOCs were exceeded for a number of use scenarios for the freshwater invertebrates. Therefore, all scenarios listed in the EEC table are included in table 57 below.

Table 57. Risk Quotients for Freshwater Invertebrates Based On a Water Flea EC_{50} of 0.24 ppm and a Water Flea NOEC of 0.17 ppm.

Site/Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	NOEC (ppm)	EEC Initial/Peak (ppm)	EEC 21-Day Average (ppm)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC)
Peanuts/1.0 (3)	0.24	0.17	0.070	0.049	0.29**	0.29
Almonds/0.5 (4)	0.24	0.17	0.045	0.031	0.19**	0.18
Grapes/1.0 (4)	0.24	0.17	0.088	0.062	0.37**	0.36
Peaches/1.0 (4)	0.24	0.17	0.098	0.068	0.41**	0.40
Potatoes/1.0 (4)	0.24	0.17	0.094	0.066	0.39**	0.39
Onions/0.75 (5)	0.24	0.17	0.089	0.062	0.37	0.36
Strawberries/1.0 (4)	0.24	0.17	0.092	0.064	0.38**	0.38
Cotton/0.15 (1)	0.24	0.17	0.004	0.003	0.02	0.03
Turf - Full Yr.5.45 (26)	0.24	0.17	1.28	0.890	5.33***	5.24+
Turf - Half Yr.5.45 (13)	0.24	0.17	1.030	0.720	4.29***	4.24+
Rice - Direct Applic.0.5 (2)	0.24	0.17	0.367	---	1.53***	---
Rice - Monitor. Stdy. 0.5 (2)	0.24	0.17	0.121 (field)	0.054 (field)	0.50***	0.32
Rice - Monitor. Stdy. 0.5 (2)	0.24	0.17	0.055 (off field)	0.030 (off field)	0.23**	0.18

* indicates that only the endangered species acute LOC has been exceeded.
** indicates that both the restricted use and endangered species acute LOCs have been exceeded.
+ indicates that the chronic LOC for nonendangered and endangered species has been exceeded.

The RQs from the table indicate that cotton is the only use that does not produce risk quotients that exceed any LOCs. Both turf scenarios and the peak concentration at the edge in the rice field exceed the LOCs for high acute risk, restricted use and acute risk to endangered species. The other crops listed exceed the LOCs for restricted use and endangered species acute risks.

Only the turf scenarios produced RQs high enough to exceed the LOC for chronic risks to freshwater invertebrates.

(3) Exposure and Risk to Estuarine and Marine Animals

(a) Fish

The highest peak EEC value from aerial applications of peaches is 98 ppb. When this EEC is compared to the estuarine fish LC_{50} value of 7.7 ppm the resultant RQ is 0.01, which is below the Levels of Concern (LOCs) for high acute risk, restricted use and acute risks to endangered fish species. The two turf uses produce EECs of 1280 ppb and 1030 ppb, which result in RQs of 0.17 and 0.13, respectively, exceeding the LOC for acute risks to endangered estuarine/marine fish and restricted use.

(b) Invertebrates

Unlike the estuarine fish results, LOCs were exceeded for a number of use scenarios for the freshwater invertebrates. Therefore, all scenarios listed in the EEC table are included in table 58 below.

Table 58. Risk Quotients for Estuarine/Marine Invertebrates Based On a Mysid LC_{50}/EC_{50} of 680 ppb and a Mysid NOEC of 3.5 ppb.

Site/Rate in lbs ai/A	No. of Apps.	LC50 (ppb)	NOEC (ppb)	EEC Initial/Peak (ppb)	EEC 21-Day Average(ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC)
Peanuts	1.0 (3)	680	3.5	70	49	0.10**	14.00
Almonds	0.5 (4)	680	3.5	45	31	0.07*	8.90
Grapes	1.0 (4)	680	3.5	88	62	0.13**	17.70
Peaches	1.0 (4)	680	3.5	98	68	0.14**	19.40
Potatoes	1.0 (4)	680	3.5	94	66	0.14**	18.90
Onions	0.75 (5)	680	3.5	89	62	0.13	17.70
Strawberries	1.0 (4)	680	3.5	92	64	0.14**	18.30
Turf - Full Yr.	5.45 (26)	680	3.5	1280	890	1.88***	254.3+
Turf - Half Yr.	5.45 (13)	680	3.5	1030	720	1.51***	205.7+
Rice - Direct Applic.	0.5 (2)	680	3.5	367	---	0.54***	---
Rice - Monitor. Stdy.	0.5 (2)	680	3.5	121 (field)	54 (field)	0.18**	15.40
Rice - Monitor. Stdy.	0.5 (2)	680	3.5	55 (off field)	7.1 (off field)	0.08*	2.03

* indicates that only the endangered species acute LOC has been exceeded.
** indicates that both the restricted use and endangered species acute LOCs have been exceeded.
***indicates that the high acute risk, restricted use and endangered species LOCs have been exceeded.
+ indicates that the chronic LOC for nonendangered and endangered species has been exceeded.

The table indicates that with regard to acute risks to estuarine invertebrates, use of iprodione on cotton does not exceed any acute LOCs; use on almonds exceeds only the endangered species LOC; and the other agricultural crops exceed both the endangered species and the restricted use LOCs. Both turf scenarios and the use on rice exceed the high risk, restricted use and endangered species LOCs.

All uses exceed the LOC for chronic risks to nonendangered and endangered estuarine/marine invertebrates.

(4) Exposure and Risk to Nontarget Plants

(a) Aquatic Plants

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from the rice use. For iprodione the aquatic plant risk assessment for acute high risk to nonvascular plants is done by comparing the EECs used in the aquatic animal risk assessment to the EC_{50} value for green algae and marine diatoms. Risks to endangered non-vascular plants are done using the NOEC values. To date there are no known non-vascular plant species on the endangered species list. The risks to endangered

and nonendangered vascular plants cannot be determined as there are currently no valid data for this group of aquatic plants. Acute RQs for non-vascular plants are in table 59.

Table 59. Acute Risk Quotients for Aquatic Plants based upon a Green Algae (Kirchneria subcapitate) EC_{50} of 2.0 mg a.i./L and a NOEC of 0.14 mg/L and a Marine Diatom EC_{50} of 0.33 mg/L and a NOEC of 0.03 mg/L.

Site/Rate in lbs ai/A	No. Of Apps.	EEC (ppm)	Species	EC_{50}	NOEC	RQ (EEC/ EC_{50})	RQ (EEC/ NOEC)
Agric. Crops	1.0 (4)	0.098	algae diatom	2.0 0.33	1.4 0.03	0.05 0.30	0.07 3.27
Turf - Full Year	5.45 (26)	1.28	algae diatom	2.0 0.33	1.4 0.03	0.64 3.88	0.92 42.7
Turf - Half Year	5.45 (13)	1.03	algae diatom	2.0 0.33	1.4 0.03	0.52 3.12	0.74 34.3
Rice - Direct Appl.	0.5 (2)	0.367	algae diatom	2.0 0.33	1.4 0.03	0.18 1.11	0.26 12.2
Rice - Monitor. Study	0.5 (2)	0.121 (field)	algae diatom	2.0 0.33	1.4 0.03	0.06 0.37	0.09 4.03
Rice - Monitor. Study	0.5 (2)	0.055 (off field)	algae diatom	2.0 0.33	1.4 0.03	0.03 0.17	0.04 1.83

RQs for the freshwater algae are below all levels of concern. RQs for the marine diatom exceed the LOC for high acute risk for the turf uses and direct application to rice fields. All uses exceed the endangered species LOC; however, no marine diatoms are listed with USFWS as "endangered". EPA does not perform assessments for chronic risk to aquatic plants.

(b) Exposure and Risk to Endangered Species

Endangered species are likely to be impacted acutely and chronically as follows:

Acute risks -- birds and mammals from granular applications to lawns and turf at rates $\geq$ 1.4 lb a.i./A; mammals from single applications of nongranular products at rates $\geq$ 2.0 lb a.i./A and multiple applications at rates $\geq$ 1.0 lb a.i./A; freshwater fish from multiple applications to turf and single and multiple applications to rice; estuarine fish from multiple applications to turf; freshwater and estuarine invertebrates from all uses but cotton.

Chronic risks -- birds and mammals from multiple applications at $\geq$ 1.0 lb a.i./A for all crops; freshwater fish and invertebrates from multiple applications to turf; estuarine invertebrates from all uses.

Currently there are no estuarine invertebrates on the Endangered and Threatened Species listings from US Fish and Wildlife Service.

The Agency has developed a program (the "Endangered Species Protection Program") to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At

present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

4. Risk Characterization

The risk quotients on the previous pages indicate that the greatest acute and chronic risks to wildlife and aquatic organisms, including aquatic plants, are the granular and nongranular uses on turf and ornamentals. The primary reason is that iprodione is applied at very high rates and with great frequency on these sites.

The database for iprodione is largely complete. The major routes of dissipation are hydrolysis in neutral and alkaline environments (half-lives pH 7 = 4.7 days; pH 9 = 27 minutes) and microbial degradation under both aerobic and anaerobic conditions. The overall result of these mechanisms of dissipation appears to indicate that iprodione has low to intermediate persistence in the environment. The results obtained in the field confirm the expected low persistence of iprodione ($t_{1/2}$=3-7 days).

A degradate of toxicological concern, 3,5-dichloroaniline (RP-32596), was found in several of the laboratory studies in low to moderate amounts. Its persistence and mobility are not well understood at this time. Additional studies are needed (aerobic soil metabolism and batch equilibrium) to help characterize the fate of this toxic degradate and to better estimate its expected environmental concentrations in both surface water and ground water.

Despite the fact that iprodione is mobile to highly mobile in some soils, it is unlikely that it will leach to ground water because of its rapid degradation in the environment. In addition, because iprodione is typically applied as a foliar treatment, degradation/metabolism on the plant surface and/or absorption by plants will further mitigate the potential for ground water contamination.

The RQ values for avian acute risk (single application of nongranular products) indicate that the uses of iprodione on turf and ornamentals may exceed the acute LOCs for high risk. However, these calculated risk quotients are the upward bounds of risk, with the actual level of risk being lower. As iprodione is nontoxic and as the toxicity value cannot be precisely expressed, it is reasonable to conclude that nongranular iprodione is not an acute risk to birds.

Although the agricultural uses are not a high risk to fish and wildlife and aquatic plants, the use on rice demonstrates a high risk to freshwater and estuarine invertebrates and aquatic plants. Rice agriculture is a unique practice in that the chemical is applied aerially to water-covered fields which adjoin waterways rich in aquatic life. The physical arrangement of the fields and waterways permits direct application of aerially applied pesticides into the waterways when the fields are treated.

For seed treatments, iprodione-treated pea seeds present the greatest risk to birds. The peas seeds/LD_{50} index is 34 seeds. As iprodione is about 3.3 times more toxic to birds than mammals, the pea seeds/LD_{50} index is equivalent to 112 for mammals. Likewise, the LD_{50}/square foot index for a small bird (20 grams) is 0.22. This index converts for a similar sized small mammal to a value of 0.06. This value indicates that the risk of seed treatments to small mammals is relatively low.

Of the many variables [soil type, bird stresses, bird behavior (nesting, mating, feeding young)] that can influence seed selection and amount of consumption, the significance of the depth that a seed is planted is unknown. Planting depth appears to be related to the size of the seed. Larger seeds are planted deeper: pea seeds 1-2 inches, trees 1 inch, flowers ½ inch, and grass seeds near or on the surface. If we assume deeper seeds are less likely to be found and eaten, it is less likely that birds will ingest enough of iprodione-contaminated seeds to exceed the LD_{50}. On the other hand, small seeds like tall fescue are basically laying on the surface and can be easily found, but a foraging bird would need to eat many contaminated small seeds to exceed the LD_{50}. Another factor, which is difficult to quantify, is the spillage of treated seeds on the ground when planters are filled or pulled up. All these factors indicate that birds can be exposed to contaminated seeds in the fields, but behavior and environmental conditions can exacerbate or lessen the hazard to birds.

Iprodione is listed as an endocrine disrupter in the *Special Report on Environmental Endocrine Disruption: An Effects Assessment and Analysis*, EPA, 1997. It is an anti-androgen, chemically related to vinclozolin, with similar effects noted in the ovary, testis and sex gland of rodents. Altered parental behavior and reduced embryo survival were observed in avian reproduction studies. In addition, reproduction impairment was also observed in invertebrates.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing iprodione active ingredients. The Agency has completed

its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing iprodione. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of iprodione, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of iprodione and to determine that iprodione can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that at this time all products containing iprodione as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that most uses of iprodione are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing iprodione, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient in this case, the Agency has sufficient information on the health effects and on the environmental fate and effects of iprodione. The Agency has determined that iprodione products, if labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality and Protection Act of 1996, the Agency has determined that there is reasonable certainty that no harm will result to infants and children or the general population from aggregate exposure to iprodione. Therefore, the Agency concludes that all products containing iprodione are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that existing uses of iprodione are eligible for reregistration subject to conditions imposed in the RED. These include removal of all residential uses of iprodione (residential turf, residential ornamentals and residential vegetable/small fruit gardens) from product registrations due to cancer risk concerns. Also, to protect handlers of granular iprodione products, removal of belly grinder application method from iprodione product registrations. Lastly, to mitigate risks to birds, removal of herbaceous ornamental seed treatment from all iprodione registrations.

Rhone-Poulenc has already requested these changes to the iprodione registrations. In order for an iprodione product to be eligible for reregistration, these uses must be removed from the label.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for iprodione. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Populations

EPA has determined that the established tolerances for iprodione meet the safety standards under the FQPA amendments to Section 408 (b)(2)(D) for the general population. In reaching this determination, EPA has considered available information on the aggregate exposures from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from iprodione and other chemicals with a similar mechanism of toxicity.

Five aggregate exposure and risk assessments were conducted for iprodione. These risk assessments reflect non-occupational exposures and include combined exposures to iprodione through food and water in the diet, and through homeowner uses. They are: (1) acute dietary; (2) chronic dietary; (3) cancer; (4) short-term; and, (5) intermediate-term risk assessments.

Acute Aggregate Risk

The aggregate acute dietary risk estimate includes exposure to iprodione residues in foods and water. Iprodione uses are not expected to significantly impact ground water, surface water has concentrations of a few parts per billion, and the drinking water level of concern for acute effects of iprodione is below the Agency's level of concern. For the acute dietary exposure and risk assessment, the toxic endpoint selected for risk assessment was the NOEL of 20 mg/kg/day based on decreased anogenital distance (AGD) in male offspring observed in the developmental study in rats, in which the LOEL was 120 mg/kg/day. The FQPA safety factor is applied for acute dietary risk assessment for only females 13+ because the endpoint (decrease AGD) is an *in utero* effect occurring during prenatal exposures.

Chronic (Non-Cancer) Aggregate Risk

The chronic aggregate risk assessment for Iprodione includes risk estimates associated with dietary exposure through food, water, and registered residential uses. Anticipated residues and percent crop-treated data for commodities with published tolerances result in an exposure to Iprodione through food which represents up to 1.6% of the chronic FQPA RfD for the most exposed subpopulation in the U.S. (non-nursing infants , <1 year old). Exposure to all other groups is less than or equal to 1% of the chronic FQPA RfD.

Chronic aggregate risk from Iprodione in the diet and drinking water associated with registered uses of iprodione is not of concern. Estimated average concentrations of Iprodione in ground water were not available for comparison against DWLOC values; however, based on Iprodione's physical/chemical characteristics and available, but limited monitoring data, iprodione is not expected to significantly impact ground water.

No chronic exposure scenarios for residential uses of iprodione were identified; therefore, no chronic exposure was included in the aggregate risk estimate.

Cancer Aggregate Risk

Without risk mitigation measures in place, combined exposure and the risk estimates for each of the residential exposure scenarios plus dietary exposure to iprodone residues results in cancer risk estimates that are all greater than 10^{-6}. The first step in reducing the cancer aggregate risk is to make ineligible for reregistration all those residential uses which are greater than 10^{-6}. Based on the current risk assessment, Rhone-Poulenc has agreed to cancel all residential uses of iprodione. With these mitigation measures in place cancer risks from residential uses of iprodione are expected to be zero.

For dietary cancer risk, with no risk mitigation measures in place, the upper bound dietary cancer risk estimate (3.9×10^{-6}) exceeds EPA's level of concern. With risk mitigation measures in place, the upper bound dietary cancer risk estimate is approximately 1.8×10^{-6} and is within the range the Agency generally considers negligible for excess life-time cancer risk. This risk estimate was based the new use pattern per the risk mitigation measures in this document, which is based on a refined estimate of dietary exposure using the most recent percent crop-treated data (1995) and anticipated residue data from monitoring programs (USDA's PDP) and field trials.

Iprodione residues are not expected to exceed the Agency's drinking water level of concern for either acute and chronic exposure..

Short-term Aggregate Risk

Aggregate risk estimates associated with short-term risk includes exposures to average residues of iprodione in the diet (food and water) and inhalation exposure (1 to 7 days in duration) through the residential application of iprodione. The resulting risk represents 3.6% of the acute FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It is assumed that children and infants do not apply pesticides. The Agency believes that iprodione's impact on drinking water will not affect the aggregate short-term risk significantly. Therefore, the Agency concludes with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable short-term aggregate human health risk estimate at this time.

Intermediate-term Aggregate Risk

Aggregate risk estimates associated with intermediate-term risk includes exposures to average residues of Iprodione in the diet (food and water) and inhalation Exposure (7 days to several months in duration) through the residential application of Iprodione. The resulting risk represents 9.5% of the chronic FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It is assumed that children and infants do not apply pesticides. The Agency believes that Iprodione's impact on drinking water will not affect the aggregate intermediate-term risk significantly. Therefore, the Agency concludes with reasonable certainty that residues of Iprodione in drinking water (when considered along with Exposure from food and residential uses) would not result in an unacceptable intermediate-term aggregate human health risk estimate at this time. Subject to the conditions imposed by this RED are met by the registrant, the Agency concludes that aggregate risks for the general population resulting from iprodione uses are not of concern.

Cumulative Risk for 3,5-Dichloroaniline

Although at present the Agency is working to define a policy for applying the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Iprodione is structurally related to vinclozolin and procymidone, which belong to the imide class. Each of these three pesticides can metabolize to 3,5-dichloroaniline (3,5-DCA). FQPA requires EPA to estimate cumulative risk from consumption of food and water containing 3,5-DCA derived from iprodione, vinclozolin, and procymidone.

3,5-DCA is not a registered pesticide; therefore, there are no FIFRA toxicology data for this compound. In the past, EPA has used the Q_1^* for p-chloroaniline (PCA) to assess the carcinogenic risk for other structurally related chloroanilines. The EPA policy on chloroanilines specifies that chloroaniline metabolites should be considered to be toxicologically equivalent to PCA unless there is sufficient evidence that the metabolite is not carcinogenic.

The cumulative carcinogenic risk estimate for consumption of food and wine containing residues of 3,5-DCA as a result of use of iprodione, vinclozolin, and procymidone is $9.5 \times 10^{-7.}$ This may be considered to be a conservative estimate. Metabolism studies for iprodione and vinclozolin were used to estimate the amount of 3,5-DCA present in various commodities by using Total Radioactive Residues (TRRs) to convert iprodione or vinclozolin exposures to 3,5-DCA exposures. There is another uncertainty in the risk estimate in that a surrogate Q_1^* is being used for 3,5-DCA. However, due to the structural similarities of 3,5-

DCA and PCA (parachloroaniline), EPA believes that for 3,5-DCA, the use of the PCA Q_1^* represents an upper-bound estimate. Based on this risk estimate, at this time this risk estimate is within the range the Agency generally considers negligible for excess life-time cancer risk.

Further refinement to the DCA exposure estimates are being conducted in conjunction with the vinclozolin RED. This is being done to reflect risk mitigation measures proposed for vinclozolin. The end-result of these proposed mitigation measures will be a decrease in DCA exposure, resulting in a lower cancer risk estimate.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for iprodione meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to toxic effects of iprodione residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from iprodione residues, EPA considered the completeness of the data base for developmental and reproductive effects, the nature of the effects observed, and other information.

The decision to apply an additional safety factor to ensure the protection of infants and children from exposure to iprodione, as required by the FQPA, was elevated to the EPA Office of Pesticide Programs Division Directors from the FQPA Safety Factor Committee. The Division Directors met April 7, 1998, and determined that the additional 10X FQPA safety factor for enhanced sensitivity to children (as required by FQPA) should be reduced to 3X. The rationale for this decision is based on: (1) no enhanced susceptibility to rats and rabbits in developmental studies and a two-generation reproduction study in rats; (2) the critical endpoint for acute dietary risk assessment (decreased AGD) was seen at a high dose (120 mg/kg/day) and there were only marginal differences in the degree of decreased AGD between the doses 20 mg/kg/day (2.44), 120 mg/kg/day (2.32) and 250 mg/kg/day (2.10) thus indicating the “true” NOEL could be higher than the one established at 20 mg/kg/day; (3) the proposed mode of action of Iprodione is disruption of testosterone biosynthesis; (4) the use of a realistic dietary exposure data (refined using monitoring data and percent crop treated); and, (5) the endpoints selected for both the acute (AGD) and the chronic (histopathology of male reproductive system) risk assessments are based on developmental/reproductive effects.

EPA estimates that iprodione residues in the diet of infants and children account for under 1% of the RfD. The aggregate exposure from all sources of iprodione account for under 1 % of the RfD for infants and children. Therefore, the Agency concludes that aggregate risks for infants and children resulting from uses of iprodione are not of concern.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Risk Mitigation

To lessen human health risk, residential risk, worker risk, and ecological and water-quality risks posed by iprodione, Rhone-Poulenc has voluntarily requested the following mitigation measures.

- *To protect human health from acute dietary and carcinogenicity concerns:*

    - For iprodione use on strawberries, increase the pre-harvest interval from 0-days to up to but not after first flower. In addition, reduce the tolerance for strawberries to the limit of quantitation (0.05 ppm).

    - For iprodione use on all stone fruit (apricots, cherries, nectarines, plums, and prunes), increase the pre-harvest interval from 7-days to up to but not after petal fall (approximately 45 - 90-day pre-harvest interval). In addition, reduce the tolerances for all stone fruit, including peaches, to limit of quantitation (0.05 ppm).

    - For iprodione use on table grapes (fresh, cooked, canned, juice, raisin or otherwise; mitigation does *not* include wine and sherry grapes), reduce the application rate from 4 times per season to one application per season at early- to mid-bloom. Tolerances remain unchanged consistent with this RED (10 ppm).

Based on a monte carlo and DRES model runs conducted by both the Agency and Novigen, Inc., these risk mitigation measures result in an acceptable acute dietary MOE of 351 for females 13+ (acceptable MOE = 300), and an upperbound cancer risk of approximately 1.8×10^{-6}, which is within the range that the Agency currently views as acceptable. Field trial studies to measure the new residue-levels in these food commodities (strawberries, stone fruit) based on these new pre-harvest intervals is required for confirmatory purposes.

Furthermore, with these mitigation measures in place, the drinking water level of concern is expected to be below the Agency's level of concern and thus have a negligible contribution for both the acute dietary risk and aggregate cancer risk for iprodione. To confirm this, the Agency requests that a surface water monitoring study be submitted.

Also in regard to these acute dietary/dietary cancer risk mitigation measures, the Agency notes that the registrant, Rhone-Poulenc, Inc.,will be submitting new mechanistic studies which may or may not alter the human cancer risk assessment for Leydig cell tumors. Rhone-Poulenc contends that this newly submitted data could potentially show that the Q* calculated for the rat Leydig cell tumors would not be appropriate for risk quantification, and that a non-threshold (MOE) approach or a revised Q* approach using the mouse liver tumor would be more appropriate. Rhone-Poulenc argues that such a change would potentially resolve most risk issues for iprodione with no, or minimal, mitigation. The Agency will continue to analyze this new data, and if those data are found to be accurate, the Agency will revisit these risk mitigation measures.

Lastly, it should be noted that these risk mitigation measures will bring iprodione to within its limit for aggregate dietary and cancer risk, thus allowing for additional uses, providing that those new uses have negligible risk contribution, such as iprodione uses on cotton.

- *To protect residential users from cancer risks:*

Rhone-Poulenc has requested to cancel all residential uses of iprodione. These uses are:

- Iprodione residential use on turf;.

- Iprodione residential uses on vegetables/small fruit gardens;

- Iprodione residential uses on ornamentals;

- *To protect non-target organisms:*

- Limit the maximum number of applications on non-residential turf, lawn, golf course, ornamental trees, and ornamental plants from "unlimited" to 6 per year, with the maximum annual application of up to but no more than 24 lbs. active ingredient.

- Except for use of the product on golf courses, include label warnings requiring a vegetative buffer strip of at least 25-feet for application of iprodione adjacent to water bodies such as lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, and commercial fish ponds.

- For use on golf courses, the following statement will be included on the label: “for golf courses only, do not apply to turf cut higher than 1" on golf holes where water bodies are present.”

- Include label warnings to prevent application of iprodione when wind direction is toward aquatic area.
- Rhone-Poulenc has requested to cancel all herbaceous ornamental seed treatment uses of iprodione, based on risks to birds.
- For rice use only, continue to include endangered species restrictions in the state of Arkansas (for the fat pocketbook pearly mussel and its habitat).

• *To protect handlers of liquid formulations (mixers/loaders/applicators):*

- In aerial/chemigation application, mixers and loaders must must wear double-layer clothes, chemical-resistant gloves and dust/mist respirators.

- In ground boom application, in orchard airblast sprayer application, and in professional application using a low-pressure/high-volume hand sprayer, mixers and loaders must wear chemical-resistant gloves. Applicators using a low-pressure/high-volume handsprayer must wear chemical-resistant gloves.

- In high-pressure hand wand application, mixers, loaders, and applicators must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirators.

- In low-pressure hand wand application, mixers, loaders, and applicators must wear chemical-resistant gloves.

- In backpack sprayer application, mixers, loaders, and applicators must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirators.

• *To protect handlers of wettable powder formulations (mixers/loaders):*

- In aerial/chemigation application (all agricultural uses), mixers and loaders must use water-soluble bags.

- In ground boom application, mixers and loaders must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirators.

- In orchard airblast application, and in professional application to turf using a low-pressure/high-volume hand sprayer, mixers and loaders must wear chemical-resistant gloves.

• *To protect handlers of dry flowable formulations (mixers/loaders):*

- In chemigation application to turf, mixers and loaders must must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirator.

- In ground boom application, mixers and loaders must wear double-layer clothes and chemical-resistant gloves.

- *To protect handlers of granular formulations (mixers/loaders/applicators):*
  - Belly-grinder application risks are greater than 10^{-4} with maximum PPE, therefore, application using a belly grinder is ineligible for reregistration.
  - Using push-type spreader application, loaders and applicators must wear chemical-resistant gloves.

- *To protect workers:*

  - The restricted-enty interval is increased from 12-hours to 48-hours for use of iprodione on grapes and ornamentals, and to 24-hours for all other iprodione uses. Early entry workers must wear coveralls, chemical-resistant gloves, shoes, and socks. The 48-hour and the 24-hour restricted-entry intervals are default intervals based on (1) the lack of data regarding dislodgeable residues for iprodione; and, (2) the Agency's general concern regarding post-application exposure from iprodione. The Agency will revisit these restricted-entry interval decisions when dislodgeable residue data is available and reviewed (October 2000).

3. Tolerance Reassessment Summary

Tolerances for iprodione are published in 40 CFR §180.399. Tolerances had been established in/on almonds, apricots, beans, blueberries, boysenberries, broccoli, caneberries, carrots, cherries, currants, garlic, ginseng, grapes, kiwi, lettuce, onions, nectarines, peaches, peanuts, plums, potatoes, raspberries, rice and strawberries. The available data support the established tolerances with the proposed reassessments: revoke raspberries; lower the tolerance on grapes from 60 ppm to 10 ppm, and on peaches from 20 ppm to 0.05 ppm; and raise the tolerance on prunes from 20 ppm to 80 ppm, poultry fat from 3.5 ppm to 7 ppm, poultry liver from 5 ppm to 7 ppm, and poultry meat by-products from 1 ppm to 7 ppm. Based on the dietary risk mitigation measures in this RED, there will be interim tolerances set for strawberries and all stone fruits at the level of quantitation (0.05 ppm).

Tolerances for residues of iprodione in/on plant commodities [40 CFR §180.399 (a), (c), and (d)(1), and 40 CFR §180.31], processed food commodities [40 CFR §185.3750], and processed feed commodities [40 CFR §186.3750] are expressed in terms of the combined residues of Iprodione parent, its isomer, and one metabolite. Following evaluation of acceptable plant metabolism studies, the Agency has determined that the iprodione residues of concern that warrant regulation in/on plant commodities should continue to be those that comprise the current tolerance expression for plants.

Tolerances for residues of iprodione in livestock commodities [40 CFR §180.399 (b)] are expressed in terms of the combined residues of iprodione parent, its isomer, and two metabolites, all expressed as iIprodione equivalents. Following evaluation of acceptable livestock metabolism studies, The Agency has determined that the Iprodione residues of concern that warrant regulation in livestock commodities should continue to be those that comprise the current tolerance expression for livestock.

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes (OPPTS GLN 860.1000), iprodione tolerances for certain RACs which have been removed from the livestock feeds table need to be revoked. Some commodity definitions must also be corrected. A summary of Iprodione tolerance reassessments is presented in Table 60.

Tolerances Listed Under 40 CFR §180.399 (a)

Pending label amendments for some crops, adequate data are available to reassess the established tolerances for the following commodities, as defined: almonds, hulls; almonds, nutmeat; beans, dried, vine hay; beans, dry; beans, forage; beans, succulent; blueberries; boysenberries; broccoli; caneberries; carrots; currants; garlic; ginseng; grapes; kiwi fruit (imported); lettuce; onions, dry bulb; peaches; peanuts; peanut forage; peanut hay; peanut hulls; potatoes; raspberries; rice, grain; rice, and straw.

Explanations and rationales for tolerance adjustments of certain RACs are presented below.

Bean forage and hay: Provided labels are amended such that Iprodione use on cowpeas is prohibited, no tolerances are required on the forage and hay of beans. Therefore, the established tolerances for "beans, dried, vine hay" and "beans, forage", each established at 90 ppm, should be revoked.

Blueberries and currants: The available field trial data for blueberries will be translated to currants.

Boysenberries and raspberries: The established tolerances of 15 ppm for boysenberries and raspberries should be revoked since Iprodione residues on these crops, as a result of registered uses, are covered by the established tolerance for caneberries.

Ginseng: The appropriate RAC for ginseng is dried root (Table 1, OPPTS GLN 860.1000). A Section 408 tolerance of 4 ppm for "ginseng, root, dried" should be established concomitant with the revocation of the tolerance of 2 ppm for "ginseng".

Grapes: Review of residue chemistry data determined that appropriate tolerance levels are 10 ppm for grapes and 15 ppm for the processed commodity raisins.

Peanut, hay: The registrant has submitted label amendments to prohibit the feeding of peanut hay to livestock in order to mitigate risk. The Agency previously recommended that the established tolerance for peanut hay should be revoked. The established tolerances for peanut forage and hulls should be revoked since these items are not considered significant livestock feed items (Table 1, OPPTS GLN 860.1000).

Tolerances Listed Under 40 CFR §180.399 (b)

Following evaluation of acceptable livestock metabolism studies, the Agency has determined that the residues to be regulated in livestock should continue to be the parent, its isomer RP-30228, and metabolites RP-32490 and RP-36114 which comprise the current tolerance expression for livestock. With the evaluation that livestock feeding data are acceptable, and with the completion of Phase 5 review of livestock feed items, tolerances can be reassessed for livestock commodities. If an acceptable enforcement method is developed to determine individual tolerance residues rather than common moieties, it may be appropriate to lower tolerance levels for livestock commodities.

Tolerances Listed Under 40 CFR §180.399 (c)

Adequate data are available to reassess the established tolerance for chinese mustard.

Tolerances Listed Under 40 CFR §180.399 (d)(1)

The time-limited tolerance for cottonseed, established under PP#2F4111 (61 FR 19845, 5/3/96), expired on March 15, 1997; therefore, this tolerance can not be reassessed. The Agency notes that the registrant filed a proposal (62 FR 3691, 1/24/97) for an extension of this time-limited tolerance which was denied.

Tolerances Listed Under 40 CFR §180.31

Temporary tolerances for tangelos and tangerines, established under PP#3G4210, expired in 1997; therefore, these tolerances can not be reassessed. The Agency notes that the registrant filed a petition proposal (PP#3G4210) for an extension of these temporary tolerances (62 FR 3691, 1/24/97) which was denied.

Tolerances Listed Under 40 CFR §185.3750

There are no processed commodities associated with ginseng (Table 1, OPPTS GLN 860.1000). Therefore, the established food additive tolerance for "ginseng, dried" should be revoked concomitant with the establishment a Section 408 tolerance of 4 ppm for the combined Iprodione residues of concern in/on "ginseng, root, dried". The tolerance for raisins should be changed to 15 ppm.

Tolerances Listed Under 40 CFR §186.3750

The established feed additive tolerances for peanut soapstock, grape dry pomace, and raisin waste should be revoked since these items have been removed from Table 1 (OPPTS GLN 860.1000) because they are not considered to be significant livestock feed items. The Agency has proposed the revocation of the established feed additive tolerance for peanut soapstock (60 FR 49142, 9/21/95). Current tolerance levels for rice hulls and bran are appropriate.

Pending Tolerance Petitions

PP#4F4281: Rhone-Poulenc has submitted this petition for the establishment of tolerances for the combined residues of Iprodione, its isomer, and one metabolite in/on canola (rape seed). This petition is currently in reject status because of deficiencies pertaining to storage stability and residue data.

Table 60. Tolerance Reassessment Summary for Iprodione.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.399 (a)			
Almonds, hulls	2.0	2.0	
Almonds, nutmeat	0.3	0.3	[*Almonds, nutmeats*]
Apricots	20.0	0.05[1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Beans, dry	2.0	2.0	
Beans, succulent	2.0	2.0	
Beans, dried, vine hay	90.0	Revoke	Provided labels are amended such that Iprodione use on cowpeas is prohibited, these tolerances should be revoked.
Beans, forage	90.0	Revoke	
Blueberries	15.0	15.0	
Boysenberries	15.0	Revoke	Iprodione residues on boysenberries and raspberries are covered by the established tolerance for [*Caneberry (blackberry and raspberry) subgroup*].
Raspberries	15.0	Revoke	
Broccoli	25.0	25.0	
Caneberries	25.0	25.0	[*Caneberry (blackberry and raspberry) subgroup*]
Carrots	5.0	5.0	
Cherries (sour)	20.0	0.05[1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Cherries (sweet)	20.0	0.05[1]	
Currants	15.0	15.0	The available blueberry data can be translated to currants.
Garlic	0.1	0.1	
Ginseng	2.0	Replace	The appropriate RAC for ginseng is dried root (Table 1, OPPTS GLN 860.1000). Concomitant with the revocation of tolerance for "ginseng", a Section 408 tolerance of 4.0 ppm on [*ginseng, root, dried*] should be established.
Grapes	60.0	10.0	

Table 60. ***(continued)*****.**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Kiwi fruit	10.0	10.0 [2]	[*Kiwifruits*]
Lettuce	25.0	25.0	
Nectarines	20.0	0.05 [1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Onions, dry bulb	0.5	0.5	[*Onions, bulb*]
Peaches	20.0	0.05	Reassessed tolerance at 0.05 ppm based on voluntary deletion of all post harvest uses and label amendments
Peanuts, nutmeat	0.5	0.5	
Peanut hay	150.0	Revoke	Label amendments to prohibit the feeding of peanut hay to livestock have been submitted.
Peanut forage	150.0	Revoke	These items are no longer considered significant livestock feed items (Table 1, OPPTS GLN 860.1000).
Peanut hulls	7.0		
Plums	20.0	0.05 [1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Potatoes	0.5	0.5	
Prunes	20.0	0.05 [1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Rice grain	10.0	10.0	[*Rice, grain*]
Rice straw	20.0	20.0	[*Rice, straw*]
Strawberries	15.0	0.05 [1]	Reassessed tolerance based on risk mitigation negotiations at time of issuance of RED.
Tolerances Listed Under 40 CFR §180.399 (b)			
Cattle, fat	0.5	0.5	
Cattle, kidney	3.0	3.0	
Cattle, liver	3.0	3.0	
Cattle, meat	0.5	0.5	
Cattle, meat byproducts (mbyp) (except kidney and liver)	0.5	3.0	
Eggs	1.5	1.5	
Goats, fat	0.5	0.5	
Goats, kidney	3.0	3.0	
Goats, liver	3.0	3.0	
Goats, meat	0.5	0.5	
Goats, mbyp (except kidney and liver)	0.5	3.0	
Hogs, fat	0.5	0.5	
Hogs, kidney	3.0	3.0	
Hogs, liver	3.0	3.0	
Hogs, meat	0.5	0.5	

Table 60. ***(continued)*****.**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Hogs, mbyp (except kidney and liver)	0.5	3.0	
Horses, fat	0.5	0.5	
Horses, kidney	3.0	3.0	
Horses, liver	3.0	3.0	
Horses, meat	0.5	0.5	
Horses, mbyp (except kidney and liver)	0.5	3.0	
Milk	0.5	0.5	
Poultry, fat	3.5	7.0	
Poultry, liver	5.0	7.0	
Poultry, meat	1.0	1.0	
Poultry mbyp (except liver)	1.0	7.0	
Sheep, fat	0.5	0.5	
Sheep, kidney	3.0	3.0	
Sheep, liver	3.0	3.0	
Sheep, meat	0.5	0.5	
Sheep, mbyp (except kidney and liver)	0.5	3.0	
Tolerances Listed Under 40 CFR §180.399 ©			
Chinese mustard	15.0	15.0	[*Mustard, Chinese*]
Tolerance Listed Under 40 CFR §180.399 (d)(1)			
Cottonseed	0.10	N/A, Expired	Tolerance expired in 1997. Therefore, it can not be reassessed at this time.
Tolerances Listed Under 40 CFR §180.31			
Tangelos	3.0	N/A, Expired	Tolerances expired in 1997 and therefore can not be reassessed at this time.
Tangerines	3.0	N/A, Expired	
Tolerances Listed Under 40 CFR §185.3750			
Ginseng, dried	4.0	Revoke	There are no processed commodities associated with ginseng (Table 1, OPPTS GLN 860.1000).
Raisins	300	15.0	
Tolerances Listed Under 40 CFR §186.3750			
Grapes, pomace, dry	225.0	Revoke	These items are no longer considered significant livestock feed items (Table 1, OPPTS GLN 860.1000).
Raisin waste	300.0	Revoke	
Rice bran	30.0	30.0	
Rice hulls	50.0	50.0	
Soapstock	10.0	Revoke	This item is no longer considered a significant livestock feed item (Table 1, OPPTS GLN 860.1000).

[1] These tolerances are contingent upon submission of confirmatory field trial data based on risk mitigation and label changes.
[2] There are no U.S. registrations for Kiwi fruits as of 12/11/96; the currently established tolerance for kiwi fruit is an import tolerance.

4. Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for iprodione residues in/on various commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part 2, FAO CX/PR, 4/91*). The Codex MRLs are expressed in terms of iprodione *per se*. Harmonization of the Codex MRLs with the U.S. tolerances is not feasible at this time because of differences in the U.S. tolerance and Codex MRL expressions. Although incompatible, a numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 61.

Table 61. Codex MRLs and applicable U.S. tolerances.

Commodity, As Defined	MRL, mg/kg [1]	Step	Reassessed U.S. Tolerance, ppm
Almonds	0.2	5/8	0.3
Apple	10	CXL [2]	--
Barley	2	5/8	--
Beans (dry)	0.2	CXL [2]	2.0
Beans (dry)	0.1	5/8	2.0
Blackberries	30	5	25.0
Broccoli	25	5/8	25.0
Carrot	10	5	5.0
Cherries	10	5	0.05 (*)
Common bean (pods and/or immature seeds)	2	5	--
Cucumber	5	CXL [2]	--
Cucumber	2	5/8	--
Currants,Black, Red, White	5	CXL [2]	15.0
Garlic	0.1	CXL [2]	0.1
Grapes	10	CXL [3]	10.0
Kiwi fruits	5	CXL [3]	10.0
Lettuce, Head	10	CXL [3]	25.0
Lettuce, Leaf	25	5/8	25.0
Onion, Bulb	0.1	CXL [2]	0.5
Onion, Bulb	0.2	5/8(a)	0.5
Peach (post-harvest treatment)	10	CXL [2]	revoke
Peach	10	5/8(a)	0.05 (*)
Pear	10	CXL [2]	–
Peppers, Sweet	5	CXL [2]	–
Plums (including prunes)	10	CXL [2]	0.05 (*)
Pome fruits	5	5/8(a)	--
Rape seed	0.5	5/8	--
Raspberries, Red, Black	5	CXL [2]	25.0
Raspberries, Red, Black	30	5/8(a)	25.0
Rice, Husked	3	CXL	Rice grain, 10.0

Commodity, As Defined	MRL, mg/kg [1]	Step	Reassessed U.S. Tolerance, ppm
Rice, Husked	10	5	Rice grain, 10.0
Strawberry	10	CXL	0.05 (*)
Sugar beet	0.1 (*)	5/8(a)	--
Sunflower seed	0.5	5/8	--
Tomato	5	CXL [4]	--
Witloof chicory (sprouts)	1	CXL [3]	--

[1]An asterisk (*) signifies that the MRL was established at or about the limit of detection.
[2]Deletion was recommended (1994 JMPR). Where there are multiple entries for the same crop/group, the current MRL will be canceled upon replacement.
[3]Confirmed (1994 JMPR). [4]Withdrawal was recommended (1994 JMPR); on hold awaiting data from France.

5. Reference Dose (RfD)

The Agency's RfD/Peer Review Committee established a Reference Dose (RfD) of 0.06 mg/kg/day based on a NOEL of 6.1 mg/kg/day established in a combined chronic toxicity/carcinogenicity study (MRID 42637801; MRID 42787001) based on histopathological lesions in the male reproduction system and effects on the adrenal glands in males at 12.4 and in females at 16.5 mg/kg/day (LOEL). The NOEL was adjusted with an uncertainty factor of 300 (10X for inter-species extrapolation, 10X for intra-species variability, and 3X for FQPA considerations). The chronic FQPA RfD was determined to be 0.02 mg/kg/day.

6. Cancer Risk Assessment

The EPA Cancer Assessment Review Committee (CARC) in accordance with the EPA *Proposed Guidelines for Carcinogen Risk Assessment* (April 10, 1996), classified Iprodione as a "likely" (B2) human carcinogen based on the combined hepatocellular adenomas/ carcinomas in mice and testicular tumors in male rats with a linear low-dose extrapolation approach and a 3/4s interspecies scaling factor for human risk characterization. For the combined hepatocellular adenomas/ carcinomas, the Q_1*s are 8.7×10^{-3} for the male mouse and 5.07×10^{-3} for the female mouse. For the Leydig cell tumors in male rats, the Q_1* is 4.39×10^{-2} was established. The CARC determined that of these, the most potent Q_1* of 4.39×10^{-2} should be used for cancer risk assessments. Therefore, the Q_1* of 4.39×10^{-2} was used for estimating carcinogenic risk.

7. Endocrine Disruption

The available toxicology data for Iprodione suggest that it is associated with endocrine effects. However, the extent of these effects and the mode of action are not yet fully understood. The Agency continues to investigate this matter. A special rat developmental toxicity study with Iprodione showed decreased anogenital distance (AGD) at the mid and high dose level (120 and 250 mg/kg/day). However, there were only marginal differences in AGD between the dose levels. In addition, Iprodione is structurally related to Vinclozolin and Procymidone, which are associated with endocrine disruption.

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects.

8. Occupational Exposure

The Worker Protection Standard (WPS)

EPA's Worker Protection Standard for Agricultural Pesticides (WPS) affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. In general, WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. At this time all registered uses of iprodione are within the scope of the WPS.

a. Handler Exposure and Risk

For each end-use product, personal protective equipment and engineering control requirements for pesticide handlers are set during reregistration as follows:

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient specific (active ingredient specific) handler requirements for end-use products containing that active ingredient. If such risks are minimal, EPA may choose not to establish active ingredient specific handler requirements.

- EPA establishes handler PPE requirements for most end-use products, based on each product's acute toxicity characteristics.

- If active ingredient specific requirements have been established, they must be compared to the PPE specified for the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product. Engineering controls are considered more stringent than PPE requirements.

EPA is establishing active-ingredient specific requirements for some occupational handlers for iprodione. The cancer risks to handlers from combined dermal and inhalation

exposures exceeded 10^{-4} for most scenarios, although all exposures are less than 10^{-4} with additional personal protective equipment and/or engineering controls. The Agency has determined that risk to handlers resulting from short-term and intermediate-term exposures are acceptable, provided appropriate risk mitigation measures are taken for each formulation type.

Granular Formulations: The Agency has determined that cancer risks to handlers of granular formulations will be acceptable with addtional PPE and risk mitigation. Belly-grinder application risks are greater than 10^{-4} with maximum PPE, therefore, application using a belly grinder is ineligible for reregistration. Using push-type spreader application, loaders and applicators must wear chemical-resistant gloves.

Liquid Formulations: The Agency has determined that risks to handlers of liquid formulations will be adequately mitigated with the use of and personal protective equipment. In aerial/chemigation application, mixers and loaders must must wear double-layer clothes, chemical-resistant gloves and dust/mist respirators. In ground boom application, in orchard airblast sprayer application, and in professional application using a low-pressure/high-volume hand sprayer, mixers and loaders must wear chemical-resistant gloves. Applicators using a low-pressure/high-volume handsprayer must wear chemical-resistant gloves. In high-pressure hand wand application, mixers, loaders, and applicators must wear double-layer clothes and chemical-resistant gloves. In low-pressure hand wand application, mixers, loaders, and applicators must wear chemical-resistant gloves. In backpack sprayer application, mixers, loaders, and applicators must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirators.

Wettable Powder Formulations: The Agency has determined that risks to handlers of wettable-powder formulations will be adequately mitigated with the use of engineering controls and personal protective equipment. In aerial/chemigation application (all agricultural uses), mixers and loaders must use water-soluble bags. In ground boom application, mixers and loaders must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirators. In orchard airblast application, and in professional application to turf using a low-pressure/high-volume hand sprayer, mixers and loaders must wear chemical-resistant gloves.

Dry Flowable Formulations: The Agency has determined that risks to handlers of dry-flowable formulations will be adequately mitigated with the use of personal protective equipment. In chemigation application to turf, mixers and loaders must must wear double-layer clothes, chemical-resistant gloves, and dust/mist respirator. In ground boom application, mixers and loaders must wear double-layer clothes and chemical-resistant gloves.

b. Post-Application Exposure and Risk

Restricted-entry intervals, early-entry PPE, and "double" notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REIs) for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. In addition, the WPS retains two types of REIs established

by the Agency before the promulgation of the WPS: (1) product-specific REIs established on the basis of adequate data, and (2) interim REIs that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces.

"Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement was imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

During the reregistration process, EPA establishes REI's, early-entry PPE, and double notification requirements based on consideration of all available relevant information about the active ingredient, including acute toxicity, other adverse effects, epidemiological information, and post-application data. EPA is establishing a 48-hour REI for iprodione use on grapes and ornamental uses, and a 24-hour REI for all other iprodione uses. The following early-entry PPE for all in-scope WPS uses of products containing iprodione: coveralls, chemical-resistant gloves, socks, and shoes. EPA has determined that double notification is not required.

The post-application exposure and risk assessment indicates that risks, specifically cancer-risks, to post-application (reentry) workers should be acceptable provided entry is postponed until at least 48-hours for grapes and ornamentals, and 24-hours for all other iprodione uses. The Agency also determined that early-entry personal protective equipment consisting of coveralls, chemical-resistant gloves, and socks plus shoes would be adequately protective, if workers must enter during the restricted-entry interval as permitted under the Worker Protection Standard.

c. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing iprodione. For the specific labeling statements, refer to Section V of this document.

9. Ecological Effects Risk Management

In general, the risk assessment shows various levels of concern (LOC) regarding avian risk and mammalian risk from broadcast applications of granular and nongranular products used on turf, ornamental trees and ornamental plants. In addition, most agricultural uses present acute and chronic risks of varying levels to endangered and nonendangered aquatic organisms, with turf and rice demonstrating the higher risks. In general, the risks to invertebrates are greater than the risks to fish. The turf and rice uses present high acute risks for nonvascular aquatic plants. To reduce risks to nontarget organisms, the Agency will limit

the maximum number of applications on turf, lawn, golf course, ornamental trees, and ornamental plants from “unlimited” to 6 per year; at a maximum annual active ingredient application of 24 lbs.. In addition, include label warnings requiring a vegetative buffer strip of at least 25-feet for application of iprodione adjacent to water bodies such as lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, and commercial fish ponds, except for golf courses. For use on golf courses, the following statement will be included on the label: “for golf courses only, do not apply to turf cut higher than 1" on golf holes where water bodies are present.” Include label warnings to prevent application of iprodione when wind direction is toward aquatic area; Also, use of iprodione for herbaceous ornamental seed treatment is ineligible for reregistration, thus reducing all risk quotients for seed treatments below levels of concern; and, for rice use only, continue to include endangered species restrictions in the state of Arkansas (for the fat pocketbook pearly mussel and its habitat).

10. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

11. Endangered Species Program

The Agency has developed a program (the “Endangered Species Protection Program”) to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in Federal Register Notice 54 FR 27984-28008 (July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register Notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product-use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of iprodione for the above eligible uses has been reviewed and determined to be substantially complete. For confirmatory purposes, the following information will need to be submitted:

- *Pre and/or Post-Natal Exposure Study*
  [GLN 83-3(a); OPPTS 870.3700]
  The 1998 Hazard Identification Review Committee (HIARC) determined that there are outstanding questions with regard to postnatal exposure that remain to be addressed in light of the observed effects of iprodione on the testes and its proposed mode of action (disruption of testosterone biosynthesis). Iprodione has been shown to alter anogenital distances in male fetuses following exposure during late gestation and there is evidence of toxicity to the male reproductive organs in chronic rat studies. Also, no data are available on the effects of iprodione on sperm count, motility or morphology in rats or other species. Therefore, the HIARC concluded that an assessment of effects on the male reproductive system following pre/post-natal exposure is required.

- *UV/Visible Absorption for the Pure Active Ingredient*
  [OPPTS 830.7050]
  There is currently no core data for UV/visible absorption for the iprodione PAI.

- *Density for the Technical Grade Active Ingredient*
  [GLN 63-7; OPPTS 830.7300];
  There is currently no core data for density for the iprodione TGAI.

- *Residue Analytical Methods*
  [GLN 171-4(d); OPPTS 860.1340]

  The Agency will consider alternative methods developed for residue confirmation as the enforcement methods; the registrant will develop and validate (including the appropriate independent laboratory validations) and LC/MS method of analysis for parent, RP46190 and RP30228 in crop commodities.

- *Product Chemistry Reports*
  [GLN 61/62; OPPTS 830.1550, 830.1600, 830.1670, 830.1700, 830.1750, and 830.1800];
  Product chemistry reports need to be submitted to fulfill product chemistry data requirements for the revised manufacturing process.

- *Aerobic Soil Metabolism [GLN 162-1]; Leach/Adsorp/Desorption [GLN 163-1]*

All environmental fate data requirements for iprodione are satisfied, except that information on the toxic degradate 3,5-dichloroaniline (RP32596) is required. 3,5-dichloroaniline was observed at high concentrations in the laboratory experiments, but was not monitored in the field. Its persistence and mobility are not well understood at this time. Additional aerobic metabolism and batch equilibrium studies are needed to help characterize the fate of this toxic degradate and to better estimate its expected environmental concentrations in both surface water and ground water.

- *Confined Rotational Crop Study*
  [GLN 165-1; OPPTS 860.1850];
  There is currently no core data for the confined rotational crop study. The Agency previously advised that depending on crops and plantback intervals chosen, residues in rotational crops would be expected to increase dietary exposure to iprodione residues. Also, during a recent review of a petition for use on cotton, the Agency required that rotations be restricted to those crops for which primary iprodione tolerances were already established. This study would confirm these data.

- *Estimation of Dermal/Inhalation Exposure*
  [GLN 231; OPPTS 875.1100 [GLN 232; OPPTS 875.1300];
  There are currently data gaps for two handler scenarios under occupational and residential exposure. There are no chemical-specific or Pesticide Handler's Exposure Database (PHED) baseline data for applying iprodione with a low pressure/high volume hand gun to turf grass, and there are no chemical-specific or PHED data for mixing/loading/applying iprodione as a dip treatment.

- *Aquatic Plant Growth Study [GLN 122-2]*
  The guideline requirement for aquatic plant growth is currently only partially fulfilled. The results of the Tier II water studies indicate that the requirement for a study conducted with the vascular plant, *Lemna gibba*, is still outstanding. As the label has application rates up to 22 lbs. active ingredient, the registrant must either test Lemna up to this rate (or the limit of solubility), or establish an EC_{50} value for this plant. The studies conducted with *Navicula* and *Anabaena* do not need to be repeated, as tests with these aquatic plants are not required to support the uses of fungicides.

- *Crop Field Trial Studies (strawberries, stone fruit)*
  [GLN 171-4 (k); OPPTS 860.1500]
  These confirmatory studies are required based on the risk mitigation measures involving new pre-harvest intervals for strawberries and stone fruit. This information will give the Agency true residue more accurate estimates for subsequent monte carlo and DEEM analyses. The registrant must also submit a formal report on the Novigen Monte Carlo Analsysis submitted September 1998.

- *Surface Water Monitoring Study (Special Study)*

This confirmatory study is required to replace existing modeled surface-water monitoring data with more accurate data, and to enhance known surface water monitoring data. If, with the submission of this data, the drinking water level of concern for iprodione is exceeded, the Agency will require further mitigation measures. This surface water monitoring study is considered a non-guideline, or "special study," and as such will be forwarded to the registrant in a separate Data Call-In after review and clearance by the Office of Management and Budget (OMB).

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"*This pesticide is toxic to invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.*."

"This product is not registered for use at residential sites."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "*This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).*"

(b) "*This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).*"

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has

been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

a. PPE and Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain iprodione:

- **!** Revise the product labeling to adopt the handler personal protective equipment/engineering control requirements set forth in this section.
- **!** Remove any conflicting PPE requirements on the current labeling.

For **multiple-active-ingredient** end-use products that contain iprodione:

- **!** Compare the handler personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.

- **!** Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7.)

b. Products Intended Primarily for Occupational Use

(1) Active-Ingredient Specific Engineering Control Requirements

EPA is establishing active-ingredient specific engineering controls for some occupational uses of iprodione end-use products.

For wettable powder formulations:

"For aerial/chemigation application, mixers and loaders are required to use water-soluble bags. The water-soluble bags must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240)."

(2) Active-Ingredient Specific Personal Protective Equipment Requirements

EPA is establishing active-ingredient specific personal protective equipment requirements for all occupational uses of iprodione end-use products.

For liquid formulations:

"*For aerial/chemigation application, mixers and loaders must wear:*
-- double-layer clothes,
-- chemical-resistant gloves,*
-- socks plus shoes, and
-- dust/mist respirator."

"*For ground-boom application, in orchard airblast sprayer application, and in professional application to turf using a low-pressure/high-volume hand sprayer, mixers and loaders must wear:*
-- long-sleeved shirt and long pants,
-- chemical-resistant gloves, and*
-- socks plus shoes."

"*For low-pressure/high-volume handsprayer application, applicators must wear:*
-- long-sleeved shirt and long pants,
-- chemical-resistant gloves, and*
-- socks plus shoes."

"*For low-pressure hand wand application, mixers, loaders, and applicators must wear:*
– long-sleeved shirt and long-pants,
– chemical-resistant gloves, and*
– shoes plus socks."

"*For high-pressure hand wand anad backpack sprayer application, mixers and loaders, and applicators must wear:*
-- double-layer clothes,
-- chemical-resistant gloves,*
-- socks plus shoes, and
-- dust/mist respirator."

"*For other handling activities and in case of a spill or other emergency exposure, handlers must wear:*
-- coveralls over long-sleeved shirt and long pants,
-- chemical-resistant gloves,*
-- chemical-resistant footwear, and
-- chemical-resistant apron when cleaning equipment."

*For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.

For wettable powder formulations:

For ground-boom application, mixers and loaders must wear:
– double-layer clothes,
– chemical-resistant gloves,*
– socks plus shoes, and
– dust/mist respirator."

For orchard airblast application, and in professional application to turf using a low-pressure/high-volume hand sprayer, mixers and loaders must wear:
– double-layer clothes,
– chemical-resistant gloves, and*
– socks plus shoes."

*For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.

For dry flowable formulations:

"*For chemigation application, mixers and loaders must wear:*
-- double-layer clothes,
-- chemical-resistant gloves,*
-- socks plus shoes, and
-- dust/mist respirator."

"*For ground-boom application, mixers, loaders, and applicators must wear:*
– double-layer clothes,
– chemical-resistant gloves, and*
– shoes plus socks."

*For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.

For granular formulations:

"*For push-type spreader application, mixers, loaders, and applicators must wear:*
– long-sleeved shirt and long pants,
– chemical-resistant gloves, and*
– shoes plus socks."

*For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.

c. Determining PPE Labeling Requirements for End-use Products Containing This Active Ingredient

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

d. Products intended for Residential Use

Rhone-Poulenc has voluntarily requested to cancel all residential uses of iprodione .

e. Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

f. Entry Restrictions

For **sole-active-ingredient** end-use products that contain iprodione:

- Revise the product labeling to adopt the entry restrictions set forth in this section.
- Remove any conflicting entry restrictions on the current labeling.

For **multiple-active-ingredient** end-use products that contain iprodione:

- Compare the entry restrictions set forth in this section to the entry restrictions on the current labeling.
- Retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

g. Products Intended Primarily for Occupational Use

(1) WPS Uses

(a) Restricted-entry interval

A 48-hour restricted-entry interval (REI) is required for iprodione grape and ornamental uses. A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all other iprodione end-use products.

(b) Early-entry personal protective equipment (PPE)

The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves,
-- shoes plus socks, and
-- dust/mist respirator.

(c) Placement in labeling

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

Other Labeling Requirements

Application Restrictions

"*Do not apply this product in a way that will contact workers or other persons, either directly or indirectly or through drift. Only protected handlers may be in the area during application.*"

"If applying this product adjacent to a water body such as a lake, reservoir, river, permanent stream, marsh or natural pond, estuary, or commercial fish pond, there must be at least a 25-foot vegetative buffer strip between the water body and the point of application. Do not apply this product when the wind direction is toward aquatic area."

"*This chemical can contaminate surface water through aerial and ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.*"

"This pesticide is toxic to invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

For Turf Use Only: May apply up to but no more than 24 pounds a.i. annually, with a maximum application rate of 8 lbs. a.i.. Product may be applied up to 6 times per year. There must be at least a 30-day interval between applicatons.
"*For Rice Use Only: Do not apply in areas where catfish and crayfish are commercially cultivated.*"

"This product is not registered for use at residential sites."

For granular formulation:

"This pesticide is toxic to invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Cover, incorporate, or clean up spills. Do not contaminate water when disposing of equipment washwater or rinsate."
Endangered Species:

For Rice Use Only: **ENDANGERED SPECIES RESTRICTIONS IN THE STATE OF ARKANSAS**

The use of Iprodione on rice is restricted to protect the endangered fat pocketbook pearly mussel (*Potamilus capax*) and its habitat. Use is prohibited in the following areas of Arkansas.

Mississippi County: Within the basin that drains directly into the Right Hand Chute of Little River, south of Big Lake National Wildlife Refuge.

Poinsett County: Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway. Use is also prohibited west of Rt. 140 and north of Rt. 63 at the siphon near Marked Tree. Except that the prohibited area does not include the area bounded by Arkansas Highway 373 on the west, Highway 63 on the east and Highway 14 on the south.

Cross, St. Francis and Lee Counties: Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway as far south as the confluence of L'Anguille River (Lee County).

User Safety Requirements

1. Registrants: place the following statement on the labeling if coveralls are required for pesticide handlers on the end-use product label:

"*Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.*"

2. Registrants always place the following statement on the end-use product labeling:

"*Follow manufacturer's instructions for cleaning/maintaining PPE. If not such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.*"

User Safety Recommendations

- "*Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.*"
- "*Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.*"
- "*Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.*"

h. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.
The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

It is recommended that the applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

> [This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE: The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE:

- **!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
- **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.
- **!** Maintenance of Nozzles - periodic inspection and subsequent replacement of nozzles to ensure proper chemical application is recommended.

BOOM LENGTH: For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT: Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for

aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT: When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND: Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY: When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS: Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS: The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

Table 62. Required Labeling Changes

Description	Required Labeling	Placement on Label
Manufacturing use		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group. Environmental Hazards Statement	"Only for formulation into a/an [fill in blank with insecticide, herbicide, or the applicable term which describes the type of pesticide use(s) for the following use(s) [fill blank only with those uses that are being supported by the MP registrant..]"	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
	"This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
	"This product is not registered for use at residential sites. "	
	"This pesticide is toxic to invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment authority. For guidance contact your State Water Board or Regional Office of the EPA."	
Products Intended Primarily for Occupational Use (WPS and non-WPS)		
Worker Protection Requirements for Products Subject to WPS	Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.	Use Restriction section in Directions for Use
Engineering Control Requirements	All wettable powder applications that contain directions that would allow aerial or chemigation application must be formulated in water-soluble packaging the outside of which contains a pictogram depicting that users should not cut, ripped, or torn.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
General Personal Protective Equipment (PPE) Requirements	Default PPE is established on the basis of acute toxicity category of the end-use products in accordance with PR Notice 93-7. The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE requirements for liquid formulations	"Mixers, loaders, others exposed to the concentrate, cleaners/repairers of equipment, and applicators applying as a seed soak, seed treatment, or dip treatment must wear: -- long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- chemical-resistant apron, and -- chemical-resistant footwear plus socks."	Precautionary Labeling Under Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement on Label
PPE requirements for liquid formulations (continued)	"Applicators using handheld equipment must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- chemical-resistant footwear plus socks, -- chemical-resistant headgear for overhead exposures, and -- a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicator using aircraft or mechanical ground equipment (groundboom, airblast, etc.), and flaggers for aerial applications must wear: -- long-sleeve shirt and long pants, and -- shoes plus socks. Applicators using truck-mounted equipment with a handgun at the end of a hose (i.e., for commercial turfgrass or ornamental applications) and all other handlers not specified above must wear: -- long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- shoes plus socks." *For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE requirements for products formulated as wettable powders or dry flowables	"Mixers, loaders, others exposed to the concentrate, cleaners/repairers of equipment, and applicators applying as a seed soak, seed treatment, or dip treatment must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- chemical-resistant footwear plus socks, -- chemical-resistant apron, and -- a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicators using handheld equipment must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- chemical-resistant footwear plus socks, -- chemical-resistant headgear for overhead exposures, and -- a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicator using aircraft or mechanical ground equipment (groundboom, airblast, etc.), and flaggers for aerial applications must wear: -- long-sleeve shirt and long pants, and -- shoes plus socks."	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE requirements for products formulated as wettable powders or dry flowables (continued)	Applicators using truck-mounted equipment with a handgun at the end of a hose (i.e., for commercial turfgrass or ornamental applications) and all other handlers not specified above must wear: -- long-sleeve shirt and long pants, -- chemical-resistant gloves*, -- shoes plus socks." *For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals Under

Description	Required Labeling	Placement on Label
PPE Requirements for Granular Formulations	"Loaders, applicators, and other handlers must wear: -- long-sleeved shirt and long pants, and -- shoes plus socks. In addition, applicators using push-type spreaders must wear chemical-resistant gloves*." *For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE
User Safety Requirements for all products that specify coveralls in the PPE	"Discard clothing or other materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE
Engineering Controls	"Engineering Controls"	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements
	"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	
Engineering Controls for formulations with water-soluble packaging	The following Engineering Control statements are required in addition to those specified above: "Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets are permitted to wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and chemical-resistant apron, provided the other required PPE is immediately available in case the bag is opened."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements
User Safety Requirements	"User Safety Recommendations"	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following "Engineering Controls"
	"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."	
	"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."	
	"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	
Environmental Hazards, Ground and Surface Water Statements	"This chemical can contaminate surface water through aerial and ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."	Precautionary Statements Environmental Hazards
	"This pesticide is toxic to invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."	
Restricted-Entry Interval for WPS Uses	The restricted-entry interval for grapes and ornamental uses is 48-hours. The restricted-entry interval for all other WPS uses is 24-hours.	Directions for Use Agricultural Use Requirements Box

Description	Required Labeling	Placement on Label
Early-Entry PPE for WPS Uses	The PPE required for early entry is: --coveralls, --chemical-resistant gloves*, --shoes plus socks, *For the glove statement, use the statement established for iprodione through the instructions in Supplement Three of PR Notice 93-7.	Directions for Use Agricultural Use Requirements Box as specified by Supplement Three of PR Notice 93-7.
Entry restrictions for non-WPS uses that are applied as sprays	"Do not enter or allow others to enter the treated area until sprays have dried."	**If no WPS uses are on the label --** Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label --** Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.
Entry restrictions for non-WPS uses that are applied as granulars.	"Do not enter or allow others to enter the treated area until dusts have settled."	**If no WPS uses are on the label --** Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label --** Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.
General Application Restrictions	"Use of this product at residential sites is prohibited."	General Precautions and Restrictions section in Directions for Use
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or indirectly or through drift. Only protected handlers may be in the area during application."	General Precautions and Restrictions section in Directions for Use
General Application Restrictions	"Except for use on golf courses, if applying this product adjacent to a water body such as a lake, reservoir, river, permanent stream, marsh or natural pond, estuary, or commercial fish pond, there must be at least a 25-foot vegetative buffer strip between the water body and the point of application."	General Precautions and Restrictions section in Directions for Use
	For golf courses only, do not apply to turf cut higher than 1" on golf holes where water bodies are present."	
	"Do not apply this product when the wind direction is toward aquatic area."	
	"For Rice Use Only: Do not apply in areas where catfish and crayfish are commercially cultivated."	
General Application Restrictions	<u>For granular formulation:</u> "Do not apply this product using "belly grinder" or other handheld application equipment." "This pesticide is toxic to invertebrates. Do not apply directly to water or to areas where surface water is present or	General Precautions and Restrictions section in Directions for Use

Description	Required Labeling	Placement on Label
	to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Cover, incorporate, or clean up spills. Do not contaminate water when disposing of equipment washwater or rinsate."	
General Application Restrictions	Endangered Species:	General Precautions and Restrictions section in Directions for Use
	For Rice Use Only: **ENDANGERED SPECIES RESTRICTIONS IN THE STATE OF ARKANSAS**	
	The use of Iprodione on rice is restricted to protect the endangered fat pocketbook pearly mussel (*Potamilus capax*) and its habitat. Use is prohibited in the following areas of Arkansas.	
	Mississippi County: Within the basin that drains directly into the Right Hand Chute of Little River, south of Big Lake National Wildlife Refuge.	
	Poinsett County: Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway. Use is also prohibited west of Rt. 140 and north of Rt. 63 at the siphon near Marked Tree. Except that the prohibited area does not include the area bounded by Arkansas Highway 373 on the west, Highway 63 on the east and Highway 14 on the south.	
	Cross, St. Francis and Lee Counties: Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway as far south as the confluence of L'Anguille River (Lee County).	
Application Restrictions for Products with Directions for Applications to Turf	Directions for application to turf must be amended to specify a maximum annual application rate of 24 lbs. ai per acre with a maximum of 6 applications.	Directions For Application section in Directions for Use
Application Restrictions for Products with Directions for Applications to Lawn	Directions for application to lawn must be amended to specify a maximum annual application rate of 24 lbs. ai per acre with a maximum of 6 applications.	Directions For Application section in Directions for Use
Application Restrictions for Products with Directions for Applications to Golf Courses	Directions for application to golf courses must be amended to specify a maximum annual application rate of 24 lbs. ai per acre with a maximum of 6 applications.	Directions For Application section in Directions for Use
Application Restrictions for Products with Directions for Applications to Ornamental Trees and Plants	Directions for application to ornamental trees and plants must be amended to specify a maximum annual application rate of 24 lbs. ai per acre with a maximum of 6 applications.	Directions For Application section in Directions for Use
Application Restrictions for Products with Directions for Applications Table Grapes	Directions for application to table grapes must be amended to specify a maximum seasonal application rate one application per season at early- to mid-bloom.	Directions For Application section in Directions for Use
Pre-Harvest Intervals (PHI) for products with Directions for Application on Strawberry	Directions for application to strawberries must be amended to specify a pre-harvest interval (PHI) of up to but not after first flower. Suggested language: "This product may not be applied after first flower."	Directions For Application section in Directions for Use
Pre-Harvest Intervals (PHI) for products with Directions for Application on Stone fruits (Apricots, Cherries, Nectarines, Plums, Peaches)	Directions for application to stone fruits (apricots, cherries, nectarines, plums, peaches) must be amended to specify a pre-harvest interval (PHI) of up to but not after petal fall. Suggested language: "This product may not be applied after petal fall."	Directions For Application section in Directions for Use

Description	Required Labeling	Placement on Label
Spray Drift Label Requirements for Product with Aerial Applications	"**Spray Drift Labeling**	Directions for Use
	Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.	
	The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.	
	1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.	
	2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.	
	Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.	
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**INFORMATION ON DROPLET SIZE** The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions below).	Directions for Use
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**CONTROLLING DROPLET SIZE**	Directions for Use
	! Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.	
	! Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.	
	! Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.	
	! Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.	
	! Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.	
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**BOOM LENGTH** For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.	Directions for Use

Description	Required Labeling	Placement on Label
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**APPLICATION HEIGHT** Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.	Directions for Use
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**SWATH ADJUSTMENT** When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)	Directions for Use
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**WIND** Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.	Directions for Use
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**TEMPERATURE AND HUMIDITY** When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.	Directions for Use
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**TEMPERATURE INVERSIONS** Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use

C. Existing Stocks

The Agency has determined that registrants may distribute and sell iprodione products bearing old labels/labeling for 12 months from the date of the approval of the new labels/labeling. The new labels/labeling for risk mitigation as outlined in this document, which Rhone-Poulenc has already submitted,will be approved following the 60-comment period for this RED (which begins with publication of the Federal Register (FR) Notice of Availabiltiy), and following the Agency's review of all those comments received. Based on the comments received, the Agency may modify or amend risk mitigation, the approved labels/labeling, and/or the existing stock provision.

Persons other than the registrant may distribute or sell products with old labels/labeling until such stocks are exhausted. Registrants and persons other than registrants remain obligated to meet pre-existing Agency-imposed label changes and existing stocks requirements applicable to products they sell or distribute. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

VI. APPENDICES

Appendix A. Table of Use Patterns Subject to Reregistration

Due to the length of Appendix A (over 100 pages), Appendix A is not included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case DEET covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to DEET in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Iprodione

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	41790801
61-2A	Start. Mat. & Mnfg. Process	ALL	41790801
61-2B	Formation of Impurities	ALL	41790801
62-1	Preliminary Analysis	ALL	41855501
62-2	Certification of limits	ALL	42698201, 41855501
62-3	Analytical Method	ALL	42698201, 41855501
63-2	Color	ALL	41855501, 41855502
63-3	Physical State	ALL	41855501, 41855502
63-4	Odor	ALL	41855501, 41855502
63-5	Melting Point	ALL	41570801, 41855501, 41855502
63-7	Density	ALL	41517601
63-8	Solubility	ALL	41230502, 41855502
63-9	Vapor Pressure	ALL	41230502, 41230503
63-11	Octanol/Water Partition	ALL	42533601
63-13	Stability	ALL	41958501
63-14	Oxidizing/Reducing Action	ALL	41836402
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C,D	41604101
71-2A	Avian Dietary - Quail	A,B,C,D	41604102
71-2B	Avian Dietary - Duck	A,B,C,D	41604103
71-4A	Avian Reproduction - Quail	A,B,C,D	99126
71-4B	Avian Reproduction - Duck	A,B,C,D	86840
72-1A	Fish Toxicity Bluegill	A,B,C,D	162224, 41604104, 41604105
72-1B	Fish Toxicity Bluegill - TEP	A,B,C,D	40489203
72-2B	Invertebrate Toxicity - TEP	A,B,C,D	41642001, 40489206
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C,D	42892001, 40489205

Data Supporting Guideline Requirements for the Reregistration of Iprodione

REQUIREMENT		USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C,D	42892001, 40489202
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C,D	40489204, 42169301
72-4A	Early Life Stage Fish	A,B,C,D	40550801
72-4B	Life Cycle Invertebrate	A,B,C,D	40489201, 40832201
72-7B	Actual field-aquatic organism	A,B,C,D	41983601
122-2	Aquatic Plant Growth	A,B,C,D	43575601, 42892001, 41604107
123-1A	Seed Germination/Seedling Emergence	A,B,C,D	43575601, 41604109, 41604107
141-1	Honey Bee Acute Contact	A,B,C,D	44262021
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A,B,C,D,H,I	41514302, 42306301
81-2	Acute Dermal Toxicity - Rabbit/Rat	A,B,C,D,H,I	40567601
81-3	Acute Inhalation Toxicity - Rat	A,B,C,D,H,I	42946101
81-4	Primary Eye Irritation - Rabbit	A,B,C,D,H,I	41867301
81-5	Primary Dermal Irritation - Rabbit	A,B,C,D,H,I	41867302
81-6	Dermal Sensitization - Guinea Pig	A,B,C,D,H,I	40567602, 42524601
82-1A	90-Day Feeding - Rodent	A,B,C,D,H,I	42960701
82-1B	90-Day Feeding - Non-rodent	A,B,C,D,H,I	157377, 157378, 144391, 42211101
82-2	21-Day Dermal - Rabbit/Rat	A,B,C,D,H,I	42023201, 42468401
83-1A	Chronic Feeding Toxicity - Rodent	A,B,C,D,H,I	42637801
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B,C,D,H,I	41327001, 144391, 42211101
83-2A	Oncogenicity - Rat	A,B,C,D,H,I	70963, 42787001, 42637801, 71997, 128931, 164249
83-2B	Oncogenicity - Mouse	A,B,C,D,H,I	42825001, 42825002
83-3B	Developmental Toxicity - Rabbit	A,B,C,D,H,I	155469, 162984, 44365001, 40514901
83-4	2-Generation Reproduction - Rat	A,B,C,D,H,I	162983, 41871601
84-2A	Gene Mutation (Ames Test)	A,B,C,D,H,I	41604106, 148206
84-2B	Structural Chromosomal Aberration	A,B,C,D,H,I	148207, 43535001

Data Supporting Guideline Requirements for the Reregistration of Iprodione

REQUIREMENT		USE PATTERN	CITATION(S)
84-4	Other Genotoxic Effects	A,B,C,D,H,I	148209, 148208
85-1	General Metabolism	A,B,C,D,H,I	41346701, 42984101, 43484901
85-2	Dermal Penetration	A,B,C,D,H,I	4355003
ENVIRONMENTAL FATE			
160-5	Chemical Identity	A,B,C,D,H,I	41790801
161-1	Hydrolysis	A,B,C,D,H,I	41885401
161-2	Photodegradation - Water	A,B,C,D,H,I	41861901, 42201301
161-3	Photodegradation - Soil	A,B,C,D,H,I	43362001, 42897101
162-1	Aerobic Soil Metabolism	A,B,C,D,H,I	44590501, 43091002
162-4	Aerobic Aquatic Metabolism	A,B,C,D,H,I	42503801, 41927601
163-1	Leaching/Adsorption/Desorption	A,B,C,D,H,I	43349202, 43349201
164-1	Terrestrial Field Dissipation	A,B,C,D,H,I	41877401
165-1	Confined Rotational Crop	A,B,C,D,H,I	43596201
165-2	Field Rotational Crop	A,B,C,D,H,I	43718201
165-3	Accumulation - Irrigated Crop	A,B,C,D,H,I	162218
165-4	Bioaccumulation in Fish	A,B,C,D	43091001
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A,B,D,H	92083074
171-4B	Nature of Residue - Livestock	A,B,D,H	130833, 130835
171-4C	Residue Analytical Method - Plants	A,B,D,H	43526801
171-4D	Residue Analytical Method - Animal	A,B,D,H	43958202, 41878001
171-4E	Storage Stability	A,B,D,H	43702501, 43273401
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	A,B,D,H	43958201
171-4K	Crop Field Trials (almond)	A	150019
171-4K	Crop Field Trials (beans, dried)	A	43255701, 43222501
171-4K	Crop Field Trials (beans, succulent)	A	43295101, 43245801
171-4K	Crop Field Trials (caneberries)	A	43262501

Data Supporting Guideline Requirements for the Reregistration of Iprodione

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K	Crop Field Trials (carrot)	A	164882
171-4K	Crop Field Trials (grapes)	A	43034101, 43034102
171-4K	Crop Field Trials (kiwi fruit)	A	42506601, 42132801
171-4K	Crop Field Trials (small fruit and Berries)	A	43222502
171-4K	Crop Field Trials (stone fruit group)	A	44576601, 44441701

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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MRID **CITATION**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form (Insert A)
Attachment 3	-	Requirements Status And Registrant's Response Form (Insert B)
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion

of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert A). If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data

concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form (Insert A), and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert B). Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form (Insert B) and option 6b and 7 on the Data Call-In Response Form(Insert A). If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in

advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form (Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not

be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to

the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a

study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form (Insert B). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also

submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form (Insert B) indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,

b. fulfill the commitment to develop and submit the data as required by this Notice; or,

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency.

Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

IPRODIONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Iprodione.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Iprodione. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Iprodione. Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Iprodione are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Iprodione are needed. These data are needed to fully complete the reregistration of all eligible Iprodione products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dennis Deziel at (703) 308-8173.

All responsades to this Notice for the generic data requirements should be submitted to:

Dennis Deziel, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Iprodione

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to

the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A.	Terrestrial food
B.	Terrestrial feed
C.	Terrestrial non-food
D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified

TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

***See: guideline comment**

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of

your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert A). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall

an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your

registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, **all of the following three criteria must be clearly met**:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency

for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it

must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution

of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study

in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

IPRODIONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Iprodione.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Iprodione. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Iprodione Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Iprodione are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Iprodione are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Iprodione products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184 .

All responses to this Notice for the Product Specific data requirements should be submitted to:

Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Iprodione**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Sample Response Form for the Product Specific Data Call-In(Form A)

This page has been inserted as a place marker and is replaced by an electronically generated PDCI sample Part A form page number 1 in the actual Printed version of the Red document.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also

submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Sample Requirements Status and Registrant's Response Form for the Product Specific Data Call-In(Form B)

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EPA'S BATCHING OF IPRODIONE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing iprodione as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty products were found which contain Iprodione as an active ingredient. These products have been placed into three batches and a "no batch" category in accordance with the expected acute toxicity of the active and inert ingredients. Products in batch 1a and 1b may share all acute data except eye irritation and dermal sensitization. Products in batch 2 may be supported by category III/IV acute oral, acute dermal and acute inhalation data performed with the technical. The products in batch 3 may be supported by acute data on the source products in accordance with the Agency policy on the acute toxicity data requirements for granular pesticide products including fertilizer pesticide products.

The following “no batch” products may cite acute data as follows:

- EPA Reg. No. 264-558 may be supported by batch 1a for all acutes except dermal sensitization and/or batch 1b for all acutes except eye irritation.

- EPA Reg. No. 538-182 may be supported by acute toxicity data on the source product in accordance with the Agency policy on the acute toxicity data requirements for granular pesticide products including fertilizer pesticide products.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1a	264-453	50.0	Solid
	264-481	50.0	Solid
	264-532	50.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1b	264-524	50.0	Solid
	264-527	50.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	264-482	41.6	Liquid
	264-520	41.6	Liquid
	264-562	41.6	Liquid
	264-563	41.6	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	538-194	1.02	Solid
	538-217	1.02	Solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	264-452	95	Solid
	264-480	24	Liquid
	264-483	30	Liquid
	264-558	50.0	Solid
	264-571	14	Liquid
	538-159	1.30	Solid
	538-182	1.59	Solid
	538-183	19.65	Liquid
	2792-64	33.33	Solid

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Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:
   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 487-4650. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.