United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA738-R-99-011
November 1999

Reregistration Eligibility Decision (RED)

FOLPET

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 folpet which includes the active ingredients folpet. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999 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 Moana Appleyard at (703)308-8175. Address any questions on required generic data to the Special Review and Reregistration Division representative Christina Scheltema (703)308-2201.

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 703-605-6000).

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 Citation of Data**. Complete and sign EPA form 8570-34 and 8570-35 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

FOLPET

List A

CASE 0630

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

FOLPET REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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Frank Hernandez	Economic Analysis Branch
Margaret Cogdell	Science Information and Analysis Branch

Environmental Fate and Effects Risk Assessment

Kevin Costello	Environmental Risk Branch 1
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James Hetrick	Fate and Monitoring Branch

Health Effects Risk Assessment

David Hrdy	Reregistration Branch 4
Thurston Morton	Reregistration Branch 4
Christine Olinger	Reregistration Branch 2
Jack Arthur	Registration Action Branch 3
Timothy Leighton	Reregistration Branch 4
Sanju Diwan	Reregistration Branch 4
Nicole Paquette	Reregistration Branch 2

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Cynthia Giles-Parker	Registration Division
Maria Rodriguez	Registration Division
Marshall Swindell	Antimicrobial Division
Wallace Powell	Antimicrobial Division

Risk Management

Christina Scheltema	Reregistration Branch III
Susan Jennings	Reregistration Branch III
Betty Shackleford	Reregistration Branch III

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWLOC	Drinking Water Level of Comparison
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
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
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.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Adverse Effect Level
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
Fg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OPP	Office of Pesticide Programs

GLOSSARY OF TERMS AND ABBREVIATIONS

Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose - Reference Dose Adjusted for FQPA Safety Factor
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Database
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
RTU	Ready to Use Pesticide
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24c of FIFRA)
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 of the pesticide folpet. The Agency has determined that folpet products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency has determined that all supported folpet products are eligible for reregistration under the conditions specified in this Reregistration Eligibility Decision document. Products containing folpet for use on avocados and in coatings and sealants are eligible for reregistration. The registrants are not supporting other folpet uses and have requested voluntary cancellation of agricultural, ornamental, and greenhouse registrations (EPA Registration numbers 66222-8 and 7401-231). These unsupported uses were suspended due to lack of supporting data and are ineligible for reregistration.

The registrant is supporting import tolerances for the following commodities which are being canceled in the US: apples, cranberries, cucumbers, grapes, lettuce, melons, onions, strawberries, and tomatoes. The tolerances are being converted to import tolerances for these commodities. A new import tolerance will be established for raisins because residue data show that folpet concentrates in raisins. For some commodities, the import tolerances will be lower than the old tolerance with a US registration because the import tolerances are based on different use information than was used previously.

The Agency has conducted both human health and ecological risk assessments for folpet. The human health risk assessment includes dietary, drinking water, residential, aggregate, and occupational exposure, as required by FQPA. The acute and chronic dietary risk for folpet are not of concern for food or water exposure. Aggregate risk from food, water, and residential exposure are not of concern. The cancer risk for folpet is not of concern for food, water, residential, or aggregate exposure. Occupational risks for folpet are of concern only for workers who add folpet to paints and stains during manufacturing. Ecological risks for folpet are not of concern at this time based on the limited use of folpet. Only the avocado use might result in releases of folpet to the environment.

To lessen the risks posed by folpet, EPA is requiring the following mitigation measures for folpet-containing products:

- Gloves and dust/mist respirator or equivalent engineering controls are required to lessen the risks to workers adding the wettable powder to paints and stains during the manufacturing process; and

- An Environmental Hazard warning is required to lessen risks to nontarget aquatic organisms. Specific label language is provided in Section V of the RED.

Before reregistering the products containing folpet, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for all end-use products. The Agency will reregister a product only after reviewing these data and the revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA. Products containing folpet and 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. 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 the submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "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 ingredients 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 human 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 Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. 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 and EPA initiated 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 use pesticides.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of folpet including the risk to infants and children from any potential dietary or drinking water exposure; occupational risks; risk to homeowners who apply folpet-containing paint and stain; and risks associated with releases of folpet to the environment. The document consists of six sections. Section I is the introduction. Section II describes folpet, 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 folpet. Section V discusses the reregistration requirements for folpet. Finally, Section VI contains the Appendices that support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available upon request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Folpet
- **Chemical Name:** *N*-[(trichloromethyl)thio]phthalimide
- **Chemical Family:** Dicarboximides or chlorinated organosulfur compounds
- **CAS Registry Number:** 133-07-3
- **OPP Chemical Code:** 081601
- **Empirical Formula:** $C_9H_4C1_3NO_2S$
- **Molecular Weight:** 296.6
- **Trade and Other Names:** Folpan®
- **Technical Registrant:** Makhteshim-Agan of North America, Inc.

B. Use Profile

The following is an overview of use information on folpet's currently registered uses. A table detailing the uses is attached as Appendix A.

Type of Pesticide: fungicide

Mode of Action: Broad spectrum contact protectant, which acts by denaturing fungal proteins when folpet reacts with thiol groups in proteins

US Use Sites:

Terrestrial Food/Feed Crops
avocados (Florida only), wood protection treatment to forest products

Terrestrial Non-Food
paints, caulking compounds, nonaqueous coatings, stains

Import Tolerances: apples, cranberries, cucumbers, grapes, lettuce, melons, onions, strawberries, tomatoes

Target Pests: avocado scab (sphaceloma); wood rot fungi; mold/mildew; spoilage fungi (coating compounds)

Formulation Types Registered:

Manufacturing Use Products

There are currently four folpet manufacturing-use products (MUPs) registered under OPP Chemical Code Number 081601. The registered folpet MUPs listed below in Table 1 are subject to this reregistration eligibility decision.

Table 1. Registered Folpet Manufacturing-Use Products

Formulation	EPA Reg. No.	Registrant
88% T	10182-294	Zeneca Ag Products
88% T	11678-18	Makhteshim-Agan North America

End Use Products

liquid - ready to use 0.3 to 0.7%
wettable powder 44 to 50%

Technical Grade

solid 88%

Method and Rates of Application:

Equipment - dip tank, airblast sprayer, by hand, pad, paint brush, paint roller, airless sprayer

Method - dip treatment, foliar treatment, high volume spray, paint additive; soak, spray, wood surface treatment

Rates- Avocados: 3 lbs a.i./acre at 14-day retreatment intervals, maximum of 7 applications (21 lbs ai/year), 7 month preharvest interval

Timing - pre-bloom (bud swell), late bloom, post bloom, foliar, during manufacture, when needed (for wood treatment)

C. Estimated Usage

This section summarizes the best information available for the pesticidal uses of folpet. 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 different sources.

Relatively minor non-agricultural use of folpet is reported. According to proprietary sources, folpet has a share of the biocide market for paint additives of less than 5 percent, and a share of the biocide market for wood preservatives of less than 1 percent.

Use on avocados is the only domestic food crop currently registered for folpet, and folpet is labeled for use in Florida only. The 1992 Census of Agriculture lists only Brevard and Dade counties as having commercial acreage in avocado production. The total 1992 avocado acreage for Brevard County was 5; the total 1992 avocado acreage for Dade County was 5829. There were 585 avocado orchards in Dade County. This yields an average avocado orchard size of approximately 10 acres. However, according to recent information from the Florida Agricultural Extension service, there is no significant use of folpet on Florida avocados. For the purposes of dietary risk assessment, the Agency assumes that 1% of all avocados are treated with folpet.

Support for registraton of folpet on all the other fruits and vegetables grown domestically was dropped by the registrant in 1987, and US registrations were voluntarily canceled for all US crops except for avocados. The registrant is currently supporting folpet tolerances for nine imported fruits and vegetables: apples, cranberries, cucumbers, grapes (table and wine), lettuce, melons, dry bulb onions, strawberries, and tomatoes. Less than 25% of the total US consumption of these crops is imported, according to public data from USDA. Data submitted by the registrant indicate that 1 percent or less of commodities with import tolerances consumed in the U.S. is expected to be treated with folpet.

D. Data Requirements

The 1987 Registration Standard for folpet required Part 158 generic data and product specific data. These data were required to support the uses listed in the Registration Standard. An additional data call in (DCI) was issued in January 1993. Appendix B summarizes all data requirements identified by the Agency for currently registered uses and the data submitted to support reregistration.

E. Regulatory History

Folpet is the common name of the pesticide chemical N-[(trichloromethyl)thio] phthalimide. This chemical was first registered in the US in 1948 as a fungicide, insecticide and miticide on roses and other ornamental plants. There have been over 200 products registered containing folpet. The majority of the products were canceled voluntarily in response to the Agency's 1987 Registration Standard because the registrants did not want to support continued registration of the products. Folpet is currently registered as a wood preservative, an additive to coatings and sealants (such as paint and caulk), a fungicide for Florida avocados, and as a manufacturing use product. As mentioned above, folpet is registered for other food uses overseas for which the Agency has established import tolerances, i.e., tolerances without a US registration.

Two folpet products were suspended in 1987 because the registrants did not submit the data required for the registration. After this suspension, use on avocados was the only remaining agricultural use for folpet. The technical registrant, Makhteshim-Agan, kept the suspended registration active to allow the accompanying tolerances for overseas commodities to continue. During this time, EPA and Makhteshim-Agan reached an agreement about the residue data required to support the import tolerances. Concurrently, the Agency also established a policy to clarify data requirements to support an import tolerance (i.e., a tolerance without a US registration)[1]. In 1999, the registrants requested voluntary cancellation of the suspended products, which is currently being processed. The proposed cancellation was published in the *Federal Register*[2] on August 4, 1999 for a 180 day comment period. The Agency's Reregistration Decision for folpet assumes that these uses will be canceled in the near future.

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[1] See Stasikowski M. Draft Import Tolerance Guidelines. December 8, 1998. USEPA, Office of Pesticide Programs, Health Effects Division.

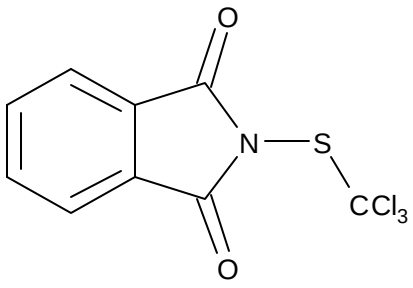
[2] Federal Register Vol. 64, No. 149, Wednesday, August 4, 1999. [OPP-66269; FRL 6092-6]

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

Folpet [*N*-[(trichloromethyl)thio]phthalimide] has an empirical formula of $C_9H_4Cl_3NO_2S$ and a molecular weight of 296.6. The chemical structure is given below:



Folpet

2. Identification of Active Ingredient

Pure folpet is a white crystalline solid with a melting point of 177° C. Technical folpet is an off-white to tan powder with a melting point of 169-177° C. Folpet has low solubility in water at room temperature (1 mg/L), has very low solubility in aliphatic hydrocarbon solvents, and has low solubility in aromatic, polar, oxygenated, and hydrocarbon solvents. Folpet is stable in dry conditions at ambient or elevated temperatures, but is not stable under alkaline conditions at high temperatures.

B. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for the active ingredient folpet (N-[(trichloromethyl)thio]phthalimide) for the purposes of making a reregistration eligibility decision. In conducting its assessment, the Agency evaluated the toxicological, residue chemistry, and exposure data bases for folpet and determined that the data are adequate to support a reregistration eligibility decision. The Agency assessed acute and chronic dietary risks, occupational risks, and risks to homeowners from the use of folpet. The Agency also evaluated aggregate risks associated with simultaneous residential and dietary exposures, including potential exposure from drinking water.

1. Toxicology Assessment

The toxicological data base on the active ingredient folpet is substantially complete and adequate to support a reregistration eligibility decision. The required Subdivision F Toxicology Guideline requirements specified in 40 CFR Part 158 for a food use chemical are complete for folpet technical. For a detailed discussion of the toxicology data supporting reregistration, see the Agency's Human Health Risk Assessment for folpet.

a. Hazard Profile for Folpet

Folpet is a member of the N-trihalomethylthio group of compounds which are highly reactive with biological tissues. The labile N-trichloromethylthio (S-CCl_3) side chain is the reactive portion of the molecule and degrades rapidly under neutral/alkaline conditions in the presence of tissue or blood thiols (such as cysteine and glutathione) to form a key short-lived intermediate, thiophosgene.

Thiophosgene is highly reactive and severely irritating to tissues. Thiophosgene causes irritation to mucus membranes and is a skin irritant and sensitizer. The thiophosgene moiety is most likely responsible for folpet's activity as a surface fungicide and is responsible for the predominant toxicity in mammals, although the rest of the molecule (i.e., phthalimide, phthalamic acid) may also contribute to folpet's toxicity.

Subchronic studies in rats demonstrated that the critical systemic toxic effect was acanthosis and hyperkeratosis and/or ulceration/erosion of the stomach following high oral doses of folpet. In a 21-day dermal toxicity study, rats treated with folpet at dose levels as low as 1 mg/kg developed treatment-related skin damage which consisted of acanthosis and exudate; the higher doses produced skin ulcers (MRID 40750802). In both the oral and dermal studies, rats showed a dose related decrease in body weight gain. The local irritating effect to mucus membranes may be responsible, in part, for secondary toxic effects such as decreased body weight gain in adult animals.

The Agency has reviewed the available developmental toxicity data for folpet (MRIDs 00132456; 00132457; 00160432; 00156636; 00151490). Folpet was tested in one strain of rat and two separate strains of rabbits. Folpet caused an increase in the incidence of hydrocephaly in fetuses with associated domed skull and irregularly-shaped fontanelles in New Zealand White rabbits in the presence of maternal toxicity. Both fetal and litter incidences of this malformation were increased. There was also evidence of fetal effects (delayed ossification of the sternebrae) in HY/CR rabbits at a lower dose than that causing maternal toxicity. Delayed ossification is not considered a permanent or life-threatening adverse effect. There is no indication of increased sensitivity in a prenatal developmental toxicity study in rats following *in utero* exposure or in either of the two-generation reproduction studies in rats (MRIDs 00151489; 40051401; 40135901).

Folpet is classified as a Group B2, probable human, carcinogen based on the increased incidences of adenomas and carcinomas in the duodenum of male and female mice in two strains (CD-1 and B6C3F1; MRIDs 00125718 and 00151075). The cancer potency value, or Q_1*, is 1.86 x 10^{-3} $(mg/kg/day)^{-1}$. The increase in the incidence of duodenal adenocarcinomas in the CD-1 mouse study occurred at relatively high doses. A similar response was observed in a 2-year feeding study with B6C3F1 mice. The highly reactive thiophosgene is most likely the metabolite responsible for duodenal tumor formation in mice. In rats, folpet was classified as a carcinogen in males only based on an increase in the incidences of C-cell adenomas and carcinomas of the thyroid as well as interstitial cell tumors of the testes (MRIDs 00151560, 00157493, 40682501, and 43640201). There was no evidence of duodenal tumors in the rat; however, there was a dose related increase in incidence and severity of hyperkeratosis of the esophagus and stomach which may be due to thiophosgene.

The Agency has conducted a preliminary review of mechanistic studies on folpet (MRIDs 44286302, 44286303, and 44316502). Both folpet and captan appear to exert toxicity via the reaction of thiophosgene with the gastrointestinal tract. A more thorough review has been conducted on the mechanistic studies submitted for the related fungicide, captan. For captan, the Agency has concluded that thiophosgene is most likely implicated in the duodenal tumors, although its exact mode of action is unclear and a genotoxic component cannot be ruled out.

Folpet induces a wide range of genotoxic events *in vitro* including gene mutations/DNA damage in bacteria and mammalian cells, chromosomal aberrations in mammalian cells and mitotic recombination in yeast. Although folpet was active in both the presence and absence of S9 activation, the response was generally more pronounced without S9 activation (MRIDs 00148625; 00132582; 00143567; 00149489; 00149567; 00160445; 42122014; 00153085; 00162394; 00160435).

An oral metabolism study was conducted in Sprague Dawley rats. Folpet was readily and extensively absorbed and rapidly excreted in the urine. There was no accumulation of folpet detected during the 5 days after dosing. The major fecal metabolite was phthalamic acid (MRIDs 42122017 and 42122016).

In a comparative metabolic fate and biochemical effects study, both rats and mice each received a single oral gavage dose of ^{14}C-labeled folpet (MRID 42122016). Two hours after dosing, the majority of the radioactivity in the contents of the gastrointestinal tract at the high dose was in the stomach as unchanged folpet. No breakdown of the compound by cleavage of the trichloromethylthio side chain (where the ^{14}C label was positioned) was apparent in either the rat or mouse. The contents of sections of the intestinal tract contained primarily reaction products of thiophosgene. Unchanged folpet was present in the cecum of mice, but not rats, at the highest dose indicating that this dose was close to the animal's maximum capacity to degrade folpet. The pulse dose passed through the gastrointestinal tract of the mouse more rapidly than did the dose in rats. The metabolites identified in the contents of the intestine and in the walls were glutathione conjugates of thiophosgene, partially degraded derivatives of the conjugate, thiazolidine and a disulfonic acid. Radioactivity was rapidly excreted by all routes with most of the dose of ^{14}C eliminated within 24 hours.

A dermal absorption study in rats indicates folpet is minimally absorbed. An absorption of 2.7% over 72 hours exposure was determined for folpet. Repeated dermal application of folpet caused hyperkeratosis, acanthosis, exudates and ulcers; however, the systemic effects were limited to reduced body weight gain in males and females, which indicates that folpet is not absorbed through the skin in significant amounts. There were no sex related differences in the severity of effects observed (MRID 42122018).

b. Hazard Profile for Folpet Metabolites and Degradates

The following environmental degradates of folpet have been detected: phthalic acid (PAI), phthalimide (PI), and phthalamic acid (PAM). Phthalimide and pthalic acid are also animal and plant metabolites. In addition, a fish bioconcentration study shows that the phthalic anhydride accumulates and concentrates in fish (MRID 42122029). No human health toxicology data are available for these degradates or metabolites. However, the Agency has determined that none of these environmental degradates or metabolites are expected to be of human toxicological concern.

c. Acute Toxicity of Folpet

The acute toxicology database on folpet is adequate and will support the reregistration eligibility decision. Table 2 summarizes the acute toxicity values and categories for folpet technical.

Table 2. Acute Toxicity of Folpet

Test	Results	Toxicity	MRID
Oral LD_{50} - Rat	43.8 g/kg(M); 19.5 g/kg(F)	IV	00144057
Dermal LD_{50} - Rabbit	>5.0 g/kg	IV	00141728
Inhalation LC_{50} - Rat	0.34mg/L(M);1.00mg/L(F);0.48mg/L(M+F)	II	40592301
Eye Irritation - Rabbit	intermediate irritation	II	00160444
Dermal Irritation - Rabbit	no irritation	IV	00160430
Dermal Sensitization - Guinea Pig	sensitizing	N/A	00160431

d. FQPA Considerations for Folpet

The Food Quality Protection Act of 1996 (FQPA) directs the Agency to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue in setting and reassessing tolerances. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and

completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such a margin will be safe for infants and children."

In determining whether an FQPA safety factor is appropriate for assessing risks to infants and children, EPA considers all available reliable data and makes a decision using a weight-of-evidence approach. This approach takes into account the completeness and adequacy of the toxicity and exposure databases, the nature and severity of the effects observed in pre- and post-natal studies in two species, and other information, such as epidemiological data. Based on these considerations, the Agency concluded that the FQPA safety factor for folpet should be reduced to 3X. Although there was no evidence of increased susceptibility in rat developmental and reproduction studies nor in the developmental study with the HY/CR rabbit strain, the Agency recommenced a 3X safety factory because increased susceptibility was observed in the developmental study with the New Zealand strain of rabbits. The FQPA safety factor is to be applied to the population subgroup of females 13-50 for those scenarios in which the appropriate endpoint for risk assessment is developmental toxicity.

To address the apparent increased susceptibility in the rabbit, the Agency is requiring that a developmental toxicity study be conducted in New Zealand white rabbits, with dosing of test animals on days 6 through 18, the major organogenesis period for the rabbit. In the existing studies, the researchers failed to dose the animals in a manner adequate to cover the major organogenesis period of the rabbit.

As mentioned above, the Agency also considers the completeness and adequacy of the exposure database for a chemical when determining whether an FQPA uncertainty factor should be applied. For folpet, the dietary exposure assessments are partially refined using anticipated residue data and percent crop treated information which results in more realistic estimates of dietary exposure. Modeling data are used for the ground and surface source drinking water exposure assessments for folpet, resulting in estimates considered to be reasonable but conservative upper-bound concentrations. When potential for residential exposure to infants and children exists during application of products containing folpet; conservative methods are used for exposure assessment. Postapplication residential exposure to folpet is not expected. Therefore, the exposure assessments for folpet do not indicate a greater concern for potential risk to infants and children than for other population groups.

The FQPA Safety Factor will be applied to acute dietary risk assessments for females age 13-50 years only because the endpoint of concern is developmental malformations (hydrocephaly). An appropriate endpoint attributable to a single dose was not identified for the general population, including infants and children. The FQPA Safety Factor will not be applied for chronic dietary risk assessment since the chronic toxicological endpoint is based on non-developmental effects (hyper-keratosis/acanthosis and ulceration/erosion of the non-glandular stomach) observed in a long-term study. The FQPA Safety Factor will be applied to residential risk assessments since there is potential

for exposure to females age 13-50 years based on the use pattern (indoor and outdoor paints, stains, and wood treatment products).

e. Endpoint Selection for Risk Assessment

The Agency has evaluated the toxicological database for folpet and selected toxicological endpoints that are appropriate for acute and chronic dietary, as well as occupational and residential (dermal and inhalation) risk assessments. In the process of selecting toxicological endpoints for risk assessment, the Agency has also evaluated the use pattern and exposure profile for folpet. The risk assessment endpoints for folpet are summarized in Table 3 below.

Once the appropriate toxicological endpoints are selected for risk assessment, the uncertainty associated with the study results and the endpoints selected is determined. The No Observed Adverse Effect Levels (NOAELs), Lowest Observed Adverse Effect Levels (LOAELs), and Uncertainty Factors are used to establish the "allowable" acute and chronic exposures to a pesticide. The Agency refers to this "allowable" exposure as the reference dose (RfD) or, when an FQPA safety factor is used, Population Adjusted Dose (PAD). These established doses are set as the target dietary exposure that should not ordinarily be exceeded. The percentages of acute and chronic RfD or PAD are the used as a measure of risk. A dose resulting in less than 100% of the RfD or PAD is usually not of concern. For occupational and residential exposure, a dose resulting in a Margin of Exposure (MOE) less than the uncertainty factor is of concern. For example, an MOE of 150 would be of concern if the uncertainty factor is 300 but would not be of concern if the uncertainty factor is 100.

Table 3. Doses and Endpoints Selected for Folpet Human Health Risk Assessments

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
	Acute PAD=0.03; Acute RfD = 0.1 mg/kg/day		
Acute Dietary Female 13-50 years only	NOAEL=10 UF = 100, with 3x for FQPA	Increased number of fetuses and litters with hydrocephaly and related skull malformations at 20 mg/kg	Developmental Toxicity Study in Rabbits
Chronic PAD = Chronic RfD = 0.09 mg/kg/day			
Chronic Dietary US Population	NOAEL=9 UF = 100	Hyperkeratosis/acanthosis and ulceration/erosion of non glandular stomach epithelium in both sexes at 35 mg/kg	Chronic Toxicity in Rats
Carcinogenicity (Dietary)	N/A	Q_1*= 1.86 x 10^{-3} $(mg/kg/day)^{-1}$ based on incidence of duodenal tumors	Chronic/Carcinogenicity Study in Mice
Short- and Intermediate Term (Dermal)	Oral NOAEL=10 UF = 100 with 3x for FQPA	Increased number of fetuses and litters with hydrocephaly and related skull malformations at 20 mg/kg	Developmental Toxicity Study in Rabbits
Short - and Intermediate-Term (Inhalation)	Oral NOAEL=10 UF = 100 with 3x for FQPA	Increased number of fetuses and litters with hydrocephaly and related skull malformations at 20 mg/kg	Developmental Toxicity Study in Rabbits
Long-Term (Dermal)	Oral NOAEL = 9 UF= 100	Hyperkeratosis/acanthosis and ulceration/erosion of non glandular stomach epithelium in both sexes at 35mg/kg	Chronic Toxicity in Rats
Long-Term (Inhalation)	The use pattern and exposure scenario does not indicate a need for long term risk assessment except for the paint manufacturing scenario, which uses oral NOAEL of 9 mg/kg/day from chronic rat study		

UF, uncertainty factor, 10x for intraspecies variability, 10x for interspecies extrapolation; 3x FQPA safety factor is applied only to females 13-50. Acute PAD applies only to females 13-50 because developmental toxicity is the only acute effect of concern for folpet.

Correction for dermal route necessary (2.7% dermal absorption factor)

A factor of 100% is used to convert inhalation exposures to oral equivalent doses.

i. Acute Dietary

The Agency is using the NOAEL of 10 mg/kg/day from the oral developmental toxicity study with New Zealand rabbits for evaluating the acute dietary risk. The following uncertainty factors are applied to acute endpoints for risk assessment: interspecies variability (10X) and intraspecies variability (10X). Accordingly, the acute dietary Reference Dose RfD for folpet is 0.1 mg/kg/day. The Acute Population Adjusted Dose (PAD) for folpet is 0.03 to include the FQPA Safety Factor. This Acute PAD applies only to females age 13-50 because developmental toxicity is the only acute effect of concern for folpet as described in the study below.

Folpet (88.6%) was administered by gavage to New Zealand White rabbits (20 females/group) at doses of 0, 10, 20 or 60 mg/kg/day during gestations days 6 through 28 (MRID 00160432). There was little or no effect of treatment on body weight gain at various intervals throughout gestation. Food consumption was below the control values during the latter portion of the study in the 20 and 60 mg/kg/day groups. One fetus from the 20 mg/kg/day dose and three fetuses from two litters of the 60 mg/kg/day had "domed head," which was considered to have been treatment related and correlated with the incidence of hydrocephalus. The historical control fetal and litter incidences of this external malformation were reported to be 5/2,160 (0.2%) and 5/285 (1.8%), respectively. The percent values in the current study were 4.1 for fetuses and 16.7 for litters at 60 mg/kg/day. Soft tissue examination revealed that one fetus from the 20 mg/kg/day dose group and 4 fetuses from the 60 mg/kg/day dose group had hydrocephalus (20 mg/kg/day, one fetus also had a cleft palate). Historical control fetal and litter data for hydrocephalus were 3/2,160 (0.1%) and 3/285 (1.0%), respectively. The percent values in the current study were 5.5 for fetuses and 25.0 for litters. Enlarged or irregularly-shaped fontanelles were present in all hydrocephalic fetuses. The maternal NOAEL was 10 mg/kg/day. The maternal LOAEL was 20 mg/kg/day based on a decrease in food consumption. The developmental NOAEL was 10 mg/kg/day. The developmental LOAEL was 20 mg/kg/day based on a dose-related increase in hydrocephalus and related skull malformations (MRID 00160432, also see 00151490). Similar effects were seen in another developmental toxicity study in New Zealand White rabbits. However, a NOAEL/LOAEL could not be established in this second study because only a single dose (60 mg/kg/day) was tested (MRID 00151490).

ii. Chronic Dietary

The Agency is using the NOAEL of 9 mg/kg/day from a two-year feeding study in rats for assessing the chronic noncancer dietary risk. The following uncertainty factors are applied to the chronic endpoint for risk assessment: interspecies variability (10X) and intraspecies variability (10X). Accordingly, the chronic dietary Reference Dose is 0.09 mg/kg/day. The FQPA Safety Factor applied to females 13-50 years for the acute dietary risk assessment is not applied for the chronic dietary risk assessment because the FQPA factor is based on developmental effects which are presumed to occur from a single dose and are not relevant to the chronic endpoint described below.

Folpet (89.5%) was administered by dietary admix to Sprague Dawley rats (60/sex/group with 10/sex/group sacrificed after 52 weeks) at doses of 0, 200, 800 or 3,200 ppm (approximately 0, 9, 35 or 145 mg/kg/day for males and 0, 11, 45 and 180 mg/kg/day for females) for up to 104 weeks. There were no effects on survival, body weights/gains, food consumption, hematology parameters, clinical chemistry values, urinalysis parameters or ophthalmic findings. Various non-neoplastic parameters had higher incidences in treated animals than in controls (out of 60/sex/group, 0, 200, 800 and 3,200 ppm). These effects included hyperkeratosis/acanthosis, submucosal edema and submucosal inflammation of the stomach; ulceration/erosion of non-glandular stomach; spongiosis hepatis; focal hepatic necrosis; and ovarian medullary tubule hyperplasia. Neoplastic incidences included: thyroid C-cell hyperplasia, thyroid C-cell adenoma, C-cell carcinoma, combined thyroid C-

cell adenomas and carcinomas, testicular interstitial cell hyperplasia, and testicular interstitial cell tumor. For chronic toxicity, the NOAEL was 200 ppm (9 mg/kg/day) and the LOAEL was 800 ppm (35 mg/kg/day) based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females (MRID 00151560).

The Agency evaluated the carcinogenicity studies in rats and mice to determine the carcinogenic potential of folpet. A carcinogenicity study in CD-1 mice showed a statistically significant, dose-related increase in the incidence of duodenal adenocarcinomas with an increase of about 50% at the highest dose tested (1429 mg/kg/day) that was not observed in any controls (MRID 00125718). A similar response was observed in a 2-year feeding study with B6C3F1 mice in which animals were exposed to up to 1000 mg/kg/day; the incidence was about 50% at this dose and was not observed in controls (MRID 00151075). The Agency has concluded that folpet is carcinogenic in rats and mice and has classified it as a Group B2, probable human carcinogen, based on the increased incidences of duodenal adenomas and carcinomas in males and females of two strains of mice. For human cancer risk assessment, a linear low-dose extrapolation approach is used.

Folpet (93%) was administered in the diet of CD-1 mice (80/sex/treated group and 52/sex plus 52/sex from a concurrent study in the control group) at levels of 0, 1,000, 5,000 or 12,000 ppm for 112 weeks for males and 113 weeks for females (MRID 00125718). The highest dose tested (12,000 ppm) was considered adequate to assess the carcinogenic potential in mice. Body weights of males and females at all dose levels were statistically significantly less than respective control values during the first two weeks of the study. Throughout the study, there were lower body weights (both sexes) in the 5,000 and 12,000 ppm groups compared with the respective controls. Body weight gains of treated mice varied from controls. Food consumption was statistically lower (g/mouse/day) for both sexes throughout most of the first half of the study. Food consumption in the higher two doses had increased after about week 20 of the study. There were changes in hematology which indicated macrocytic anemia for the 12,000 ppm males. Regarding spontaneous neoplasms of the small intestine, surveyed literature showed 1/202 mice with such a lesion and historical control data from the Registrant yielded values of 4/146 in the duodenum, 3/146 in the jejunum and 0/146 in the ileum. Folpet, at 5,000 and 12,000 ppm, was shown to cause a statistically significant increase in the incidence of duodenal adenocarcinomas in both sexes. For chronic toxicity the NOAEL was 1,000 ppm (93 and 95.5 mg/kg/day for males and females, respectively) and the LOAEL was 5,000 ppm (502 and 515 mg/kg/day for males and females, respectively) based on a decrease in body weight/gains (MRID 00125718).

A carcinogenicity study in B6C3F1 mice (52/sex/group) was conducted with folpet (89.0%) administered in the diet at doses of 0, 1,000, 5,000 (reduced to 3,500 ppm weeks 22-104) or 10,000 ppm (reduced to 7,000 ppm weeks 22-104). There was a statistically significant trend for an increase in the incidence of malignant lymphomas in treated females only (about 50% of the premature deaths). Esophageal and stomach hyperkeratosis (slight/moderate) appeared in statistically significant higher incidences in males and females (final sacrifice) at the 3,500 and 7,000 ppm doses compared with the

respective controls (74-100% compared with 0% for controls and 10-25% at 1,000 ppm). The highest dose tested (7,000 ppm) in this study was considered adequate to assess the carcinogenic potential in mice. The chronic toxicity NOAEL was not established because effects were noted at 1,000 ppm, the lowest dose tested. The chronic toxicity LOAEL was 1,000 ppm (107 and 118 mg/kg/day for males and females, respectively) based on increased incidences of hyperplasia of the duodenum and hyperkeratosis of the esophagus and stomach (MRID 00151075).

Folpet (89.5%) was administered by dietary admix to Sprague Dawley rats (60/sex/group with 10/sex/group sacrificed after 52 weeks) at doses of 0, 200, 800 or 3,200 ppm (approximately 0, 9, 35 or 145 mg/kg/day for males and 0, 11, 45 and 180 mg/kg/day for females) for up to 104 weeks. There were no effects on survival, body weights/gains, food consumption, hematology parameters, clinical chemistry values, urinalysis parameters or ophthalmic findings. For chronic toxicity, the NOAEL was 200 ppm (9 mg/kg/day) and the LOAEL was 800 ppm (35 mg/kg/day) based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females. Folpet was classified as a carcinogen in males only based on an increase in the incidences of C-cell adenomas and carcinomas of the thyroid as well as interstitial cell tumors of the testes. The highest dose tested in this study (3,200 ppm) was considered adequate to assess the carcinogenic potential of Folpet in rats (MRID 00151560).

In another chronic toxicity study in Fischer 344 rats (20/sex/dose), Folpet (91.1%) was administered by dietary admix at doses of 0, 250, 1,500 or 5,000 ppm (equal to 0, 12, 81 or 291 mg/kg/day in males and 0, 15, 100 or 351 mg/kg/day in females) for 24 months. There was no evidence of carcinogenicity in this study. The following parameters were effected: a decrease in body weight gain for both sexes at 5,000 ppm; a decrease in food consumption for both sexes at 5,000 ppm; a decrease in water consumption at 5,000 ppm (10-20% throughout the study) especially during week one (30%) for both sexes; esophageal effects (increase in the incidence and severity of diffuse hyperkeratosis) in both sexes at 5,000 ppm; and an increase in the incidence and severity of diffuse hyperkeratosis of the nonglandular epithelium of the stomach of both sexes at 1,500 and 5,000 ppm. For chronic toxicity the NOAEL was 250 ppm (12 and 15 mg/kg/day, males and females, respectively). and the LOAEL was 1,500 ppm (81 and 100 mg/kg/day, males and females, respectively) based on an increase in incidence and severity of hyperkeratosis of the esophagus and nonglandular epithelium of the stomach (MRID 43640201).

In a carcinogenicity study in Fischer 344 rats (60/sex/group), Folpet (89.5-91.1%) was administered as a dietary admix at doses of 0, 500, 1,000 or 2,000 ppm (approximately 0, 25, 50 or 100 mg/kg/day) for 24 months. The Agency concluded that 2,000 ppm caused an increase over control values in thyroid C-cell adenomas and mammary benign fibroepithelial tumors in females only. The highest dose tested (2,000 ppm) in this study was considered adequate to assess the carcinogenic potential in rats. For chronic toxicity the NOAEL was 500 ppm (25 mg/kg/day) and the LOAEL was 1,000 ppm (50 mg/kg/day) based on an increased incidence of hyperkeratosis of the nonglandular mucosa of the stomach in both sexes (at 2,000 ppm or 100 mg/kg/day, there was an increase in the

incidence of hyperkeratosis in the esophagus of males and females as well as basophilic cell type foci in the liver of males only at these doses) (MRID 00157493, 40682501).

iii. Route to Route Extrapolation

To evaluate dermal risks, a dermal absorption factor of 2.7% is used to convert dermal exposures to oral equivalent doses, which are then compared with a NOAEL from an oral study. A factor of 100% is used to convert inhalation exposures to oral equivalent doses.

iv. Short and Intermediate Term Dermal

The Agency is also using the NOAEL from the New Zealand White rabbit study to serve as the basis for evaluation of short and intermediate term occupational and residential risks. This study showed a NOAEL of 10 mg/kg based on the increased in number of fetuses and litters with hydrocephalus with associated skull malformations (irregular shaped interparietal fontanelles and domed head) at the developmental LOAEL of 20 mg/kg/day. The Agency selected the oral NOAEL because of the lack of an appropriate dermal toxicity study. In a dermal toxicity study (MRID 40750802), rats were dermally treated with folpet at 0, 1, 10 and 30 mg/kg for a total of 21 applications over a 4-week period. All folpet treated rats developed pronounced dermal irritation in a dose-related manner. Systemic toxicity was defined as decreased body weight gain in male and female rats in rats given 10 and 30 mg/kg, but the critical effect could not be unequivocally separated from a response to severe skin damage.

v. Long Term Dermal

The use pattern and exposure scenario do not indicate a need for long-term risk assessment except for the paint manufacturing scenario. Folpet is only used in a small fraction of paints and stains. The Agency is using a NOAEL of 9 mg/kg/day from a chronic dietary study in rats for risk assessment for long-term dermal exposures. The chronic rat study is the same study used to establish the chronic RfD and is described in section ii, Chronic Dietary (MRID 00151560).

vi. Short and Intermediate Term Inhalation

The Agency is using the 10 mg/kg/day NOAEL from the New Zealand rabbit oral developmental toxicity study to serve as the basis for evaluation of short and intermediate term occupational and residential inhalation risks (MRID 00160432). As mentioned previously, a factor of 100% is used to convert inhalation exposures to oral equivalent doses.

vii. Long Term Inhalation

The use pattern and exposure scenario do not indicate a need for long term risk assessment

except for the paint manufacturing scenario. The Agency is using the oral NOAEL of 9 mg/kg/day from the chronic rat study for this single long term inhalation risk assessment (MRID 00151560).

f. Endocrine Disruptor Effects

FQPA requires EPA 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..." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disruptor Screening Program was published in the *Federal Register* of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of folpet and end-use products for endocrine effects may be required.

2. Exposure Assessment

a. Summary of Registered Uses

Folpet formulated as a wettable powder (Folpet 50 WP) is applied to avocados with airblast sprayers. Single application rates for avocados vary from 1.5 to 3.0 pounds active ingredient per acre (lb ai/A) or 3 to 6 lbs formulated product (50% ai). Folpet application to avocados begins at bud swell and continues through late bloom. Folpet can be applied up to seven times a season at 2-week retreatment intervals with a seasonal maximum of 21 lb ai/A or 42 lbs formulated product. A 7-month preharvest interval (PHI) is specified along with a 24-hour restricted-entry interval (REI).

Folpet, formulated as a solid powder, is added to paint, stains, and caulking compounds in manufacturing settings using a variety of techniques, such as open pouring and pump-metering. Folpet-containing paint is subsequently applied with handheld painting equipment (e.g., paint brush, roller, compressed-air sprayer, or airless sprayer).

Folpet, formulated as a ready-to-use house/deck stain, is applied with handheld painting equipment (e.g., paint brush, roller, compressed air sprayer, or airless sprayer). At this time, products containing folpet are available for use both occupationally and by the homeowner.

b. Dietary Exposure (Food Sources)

As mentioned previously, folpet is registered in the U.S. for use on Florida avocados. Folpet also has a number of tolerances to allow apples, cranberries, cucumbers, grapes, lettuce, melons, onions, strawberries, and tomatoes which have been treated with folpet outside the US to be imported.

In addition, a new tolerance will be established for imported raisins because folpet residues concentrate in raisins. These commodities must therefore also be considered in the evaluation of dietary exposure in the US. The dietary exposure analysis for folpet considers folpet residues in/on the following commodities and dietary consumption of avocados, apples, cranberries, cucumbers, grapes, lettuce, melons, onions, raisins, strawberries, and tomatoes.

Results of the residue chemistry data for folpet are summarized below. The residue chemistry database for folpet is substantially complete, and the data are adequate to assess dietary exposure and reassess tolerances. However, additional storage stability data are required to confirm the Agency's analysis. Once these data are received, the Agency will re-evaluate the affected tolerances.

i. Residue Chemistry Data

Nature of the Residue

Plants. The qualitative nature of the residue of folpet in plants is adequately understood based upon acceptable avocado, grape, and wheat metabolism studies. The Agency has concluded that the residue of concern in plants is folpet *per se*. The metabolites phthalimide and phthalic acid are not of toxicological concern and will not be regulated.

Animals. For purposes of reregistration, ruminant and poultry metabolism studies are not required because there are no animal feed items associated with avocados, which is the only food/feed use currently being supported in the U.S. A ruminant oral metabolism study was submitted to support the import tolerance on apples. A ruminant feeding study is still required to determine the magnitude of the residue in livestock receiving folpet residues in feed (apple pomace) and to determine if meat/milk tolerances are necessary. Also, an analytical method will be required for any residues of concern that are identified in the ruminant feeding study. Wet apple pomace may be used as an animal feed in countries which export livestock commodities into the U.S. and where folpet is used on apples.

The nature of the residue in livestock (GLN 860.1300) is adequately understood. Following dosing of ^{14}C-trichloromethyl-labeled-folpet, most of the radioactivity was excreted in urine (5–10%), feces (35-42 %), and as expired CO_2. Small amounts of radioactivity were found in tissue and milk samples. Significant amounts were found in liver, kidney, muscle, and milk. Analysis of the radioactivity showed it to be associated with natural products. No folpet *per se* was found except in the feces, which demonstrates extensive metabolism. Following dosing of ^{14}C-benzene-labeled folpet, most of the radioactivity was excreted in urine and feces. Small amounts of radioactivity were found in tissue and milk samples. Significant amounts were found in liver and kidney. Analysis of radioactivity in tissue and milk samples showed the presence of phthalamic acid and phthalimide.

The results of the ruminant metabolism study suggest that folpet is degraded by loss of the one carbon trichloromethyl moiety. This part of the molecule becomes extensively metabolized and the

radiolabeled carbon becomes incorporated into thiazolidine and natural products. The remaining phenyl labeled part of the molecule is mostly metabolized to phthalimide and phthalamic acid.

Magnitude of the Residue

Plants. The registrant conducted a single residue study in Dade County, Florida, which is representative of avocado growing regions in Florida. Five foliar applications of folpet (50 WP) at 3 lb ai/acre/application were applied to avocados. Following the final application, triplicate samples of avocados were collected at 1, 3, 7, 14, and 28 days post treatment. Folpet residues at day 1 were 0.101 - 0.183 ppm and declined to <0.05 - 0.066 ppm by day 28. The maximum folpet residue (0.356 ppm) was found in the day 3 sample.

Adequate crop field trial data have been submitted in support of import tolerances for onions, cranberries, grapes, lettuce, strawberries, apples, and tomatoes. Additional storage stability data are required to support import tolerances for melons and cucumbers.

Animals. No animal feed items are currently associated with avocados, the only use of folpet registered in the U.S. However, livestock feeding studies are required as a result of the import tolerance on apples. The livestock metabolism study is summarized above; a feeding study is still required. No metabolites of concern were identified in the ruminant metabolism study.

Processed food/feed. Reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled as there are no processed commodities associated with avocados. Adequate processing data have been submitted to support import tolerances on apples, grapes, and tomatoes. Although concentration of folpet residues was observed in wet apple pomace, a tolerance is not required because it is unlikely that apples imported into the U.S. will be processed and wet apple pomace is not imported into the U.S.

Storage Stability Data. Requirements for storage stability data are outstanding. Results of previously submitted storage stability data on residues of folpet in avocados have been variable. Analyses of fortified avocados stored at -10^{o} C showed an initial decline in folpet residues after 14 days; however, folpet residues appeared stable after 60 days of storage. The registrant must conduct a 14- day refrigeration storage stability study to support the residue values in the field trial study. These data are confirmatory.

Sufficient storage stability information has been submitted to support the import tolerances on onions, cranberries, apples, grapes, lettuce, and tomatoes. Additional storage stability data are required for melons and cucumbers.

Residue Analytical Method and Multiresidue Method: An adequate GC analytical method is available for enforcing tolerances of folpet in/on plant commodities and is listed as Method I

in PAM, Vol. II. This method is for the analysis of captan, folpet, and difolatan in plants. However, the enforcement methodologies described in PAM, Vol. II for folpet (Methods IIa, IIb, and A) are based on colorimetric detection of folpet residues, and are no longer considered suitable for tolerance enforcement.

Two new enforcement GC/ECD methods, one for oily crops (Method 568W-1) and the other for non-oily crops (Method FP/15/91), have undergone successful method validation by the Agency using avocados, lettuce, onions, and tomatoes. These methods are available for enforcement purposes. The adequacy of HPLC method WLS/018 for data gathering purposes can not be assessed until additional validation data are submitted. The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix I) indicates that folpet is completely recovered using FDA Multiresidue Protocols D and E (nonfatty) (PAM I Sections 232.4 and 211.1) and is partially recovered using FDA Multiresidue Protocol E (fatty) (PAM I Sections 212.1).

ii. Acute Dietary Risk Assessment

The Agency conducted an acute probabilistic dietary (food) exposure analysis using the Dietary Exposure Evaluation Model (DEEM^{TM}). The acute analysis evaluates the dietary exposure based on individual consumption data from USDA's 1989-1992 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII). Residue inputs to the model are based on field trials. No data from USDA's Pesticide Data Program (PDP) are available for folpet. Acute dietary exposure is compared to the acute population adjusted dose (acute PAD) to derive a percent acute PAD. The percent acute PAD is below the Agency's level of concern (< 100% acute PAD at the 99.9th percentile) for females age 13-50, the only population group of concern for the developmental toxicity endpoint. The results of this analysis indicate that the acute dietary risk associated with the uses of folpet which are supported for reregistration is below the Agency's level of concern (Table 4).

Table 4. Summary of Acute Dietary Risk Assessment for Folpet

Population Subgroup	95th Percentile Exposure (% acute PAD)	99th Percentile Exposure (% acute PAD)	99.9th Percentile Exposure (% acute PAD)
Females(13-50 years)	0.000038 (0.13%)	0.001532 (5.11%)	0.007578 (25.26%)

* Acute population adjusted dose (PAD) is 0.03 mg/kg/day.

iii. Chronic (Non-Cancer) Dietary Risk Assessment

The Agency conducted a chronic dietary exposure analysis using DEEM^{TM}. The chronic analysis evaluated the dietary exposure based on individual consumption data from USDA's 1989-1992 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII). Average field trial and percent crop treated information along with processing factors from submitted studies were used to

estimate the anticipated residue contribution for the general U.S. population and 22 subgroups. Exposure was then compared to the chronic RfD.

The results of the chronic (non-cancer) analysis indicate that the chronic (non-cancer) dietary risk estimates associated with the folpet uses supported through reregistration are below the HED's level of concern (<100% RfD) for the U.S. Population.. These results are presented in Table 5.

Table 5. Chronic (Non-Cancer) Dietary Exposure Results for Folpet (Chronic RfD = 0.09 mg/kg/day).

Subgroups	Chronic (Non-Cancer) Exposure (average field trial residue)
U.S. Population (48 states)	<1 % (0.000053 mg/kg body wt/day)
Children (1-6 yrs)	<1 % (0.000081 mg/kg body wt/day)
Children (7-12 yrs)	<1 % (0.000071 mg/kg body wt/day)
Females (13-50 nursing)	<1 % (0.000084 mg/kg body wt/day)

iv. Dietary Cancer Risk Assessment

Based on a Q_1* of 0.00186 $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be 1.2 x 10^{-6}, contributed by all the published uses of folpet at tolerance levels. Incorporating processing factors from submitted studies and percent crop treated data with average field trail residues, risk was calculated to be 9.8 x 10^{-8}. The upper bound cancer risk is less than the Agency's level of concern of 1 x 10^{-6} for dietary cancer risk. However, if new uses are added in the future, the carcinogenic dietary risk from folpet treated commodities will require reevaluation.

v. Dietary Exposure (Drinking Water Source)

When the Agency begins to conduct a drinking water analysis, a Tier I screening model or Tier II refined screening model is used to provide conservative estimates of concentrations of pesticides in surface or ground water. These model estimates are then compared against "DWLOC" (Drinking Water Level Of Concentration Level) values.

A DWLOC is the concentration of a pesticide in drinking water that is acceptable as an upper limit in light of total aggregate exposure to the pesticide in food, water, and through home uses. A DWLOC will vary depending on the toxic endpoint, and with drinking water consumption patterns and body weights. Different subpopulations will have different DWLOCs.

The Agency uses the DWLOC values as a surrogate measure of risk. Because current screening models for drinking water are very conservative, the Agency does not use concentration estimates from these models to quantify risk as %RfD, %PAD, or MOE. The Agency will instead compare these model estimates to DWLOC values. If the model estimate is less than the DWLOC, there is no drinking water

concern. If model estimates are greater than the DWLOC, refined estimates of drinking water concentrations are needed. The Agency tries to use any available ground and surface water monitoring data. This comparison provides a semi-quantitative risk assessment for drinking water until monitoring data can be obtained.

The potential for folpet contamination of ground and surface water is expected to be minimal. Folpet use is currently limited to two counties in Florida and additionally folpet degrades rapidly in the aquatic environment. No ground or surface water monitoring data are available, so models were used to predict environmental concentrations of folpet. The SCI-GROW model predicts that groundwater is not likely to exceed 0.06 ppb (µg/L). The Generic Expected Environmental Concentration (GENEEC) model predicts that surface water concentrations resulting from use on avocados will range from 156 ppb at peak exposure to 2 - 3 ppb at 56 days (Table 26). Currently, Agency drinking water SOPs divide this 56 day number by a factor of 3 prior to comparison with the $DWLOC_{chronic}$ and $DWLOC_{cancer}$. The GENEEC model estimated maximum concentration is compared directly to the $DWLOC_{acute}$.

vi. DWLOCs for Acute Exposure

Acute DWLOCs for folpet were calculated based on the acute dietary (food) exposure and default body weights and water consumption figures. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/L (child). To calculate the acute DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the following equation:

$$DWLOC_{acute} = \frac{[\text{acute water exposure (mg/kg/day)} \times \text{body weight (kg)}]}{[\text{consumption (L)} \times 10^{-3}\ \text{mg/µg}]}$$

Where acute water exposure (mg/kg/day) = [acute PAD (mg/kg/day) - acute food (mg/kg/day)].

As shown in Table 6, the drinking water estimated concentrations in ground water (0.06 µg/L or ppb) and surface water (159 µg/L or ppb) are below the Agency's $DWLOC_{acute}$ (673 µg/L or ppb) for folpet for females 13-50. The Agency concludes that based on the available information, modeled residues in drinking water do not indicate an unacceptable contribution to acute dietary exposure at this time.

Table 6. Drinking Water Levels of Comparison for Acute Dietary Exposure

Population Subgroup	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{acute}$ (µg/L)	GENEEC (µg/L)	SCI-GROW (µg/L)
Females 13-50	0.007578	0.022422	673	159	0.06

The acute PAD is 0.03 mg/kg/day.

vii. DWLOCs for Chronic (Non-Cancer) Exposure

Chronic drinking water levels of comparison (DWLOCs) were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. To calculate the $DWLOC_{chronic}$, the chronic dietary food exposure was subtracted from the chronic PAD using the formula given above for the acute DWLOC, substituting the chronic PAD for the acute PAD.

$$DWLOC_{chronic} = \frac{[\text{chronic water exposure (mg/kg/day)} \times \text{(body weight)}]}{[\text{consumption (L)} \times 10^{-3}\ \text{mg/}\mu\text{g}]}$$

where chronic water exposure (mg/kg/day) = [chronic PAD - (chronic food (mg/kg/day)]

As shown in Table 7, the drinking water estimated concentrations in ground water (0.06 µg/L) and surface water (3 µg/L) are all below the Agency's $DWLOC_{chronic}$ for folpet for all population subgroups. Based on the available information, residues of folpet in drinking water do not result in an unacceptable contribution to chronic dietary exposure at this time.

Table 7. Drinking Water Levels of Comparison for Chronic Dietary Exposure

Population Subgroup	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (µg/L)	GENEEC (µg/L)	SCI-GROW (µg/L)
US Population	0.00005	0.08995	3148	1	0.06
Children 1-6 (Highest Exposure)	0.00008	0.08992	899	1	0.06

*The chronic PAD is 0.09 mg/kg/day.

viii. DWLOCs for Chronic (Cancer) Endpoint

Cancer DWLOCs were calculated based on the cancer dietary (food) exposure and default body weight and water consumption figures as follows:

$$DWLOC_{cancer} = \frac{[1 \times 10^{-6} - \text{food risk}_{cancer}] \times 70\text{kg/2L} \times 10^{3}\ \mu\text{g/mg}}{Q_1^*\ (\text{mg/kg/day})^{-1}}$$

$$DWLOC_{cancer} = \frac{[1 \times 10^{-6} - 9.8 \times 10^{-8}] \times 70\text{kg/2L} \times 10^{3}\ \mu\text{g/mg}}{1.86 \times 10^{-3}\ (\text{mg/kg/day})^{-1}} = 17\ \mu\text{g/L or ppb}$$

The resulting 17 ppb drinking level of comparison ($DWLOC_{cancer}$) is greater than the model drinking number values generated for chronic scenarios for both ground and surface water (0.06 and 1 ppb, respectively.) Based on the conservative nature of available information, modeled residues in drinking water do not indicate an unacceptable contribution to dietary cancer risk at this time.

c. Occupational Exposure

There is a potential for both agricultural and industrial workers to be exposed to folpet. Agricultural workers may be exposed to folpet from application and postapplication activities associated with use of folpet on avocados in Florida. Industrial workers may be exposed from addition of folpet to paints, stains, and other products during manufacturing. Occupational exposure may also occur during application of folpet-containing paints and sprays. Exposure duration is unlikely to exceed several months for any of the occupational scenarios except to workers adding folpet to paints as an in-can preservative.

Occupational exposure to folpet residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying as well as during postapplication activities such as harvesting avocados. The Agency identified seven handler scenarios for folpet that warranted assessment.

Postapplication exposure to folpet is limited to the avocado use. Postapplication exposures from painting/staining uses in occupational and/or residential settings are expected to be minimal because (1) folpet was not detected in a chemical-specific post application exposure monitoring study and (2) folpet has an extremely low vapor pressure of 1.6×10^{-7} mmHg at 25EC. Therefore, the Agency did not conduct a postapplication exposure assessment for painting or staining exposure scenarios.

i. Occupational Handler Exposure Scenarios

Seven handler scenarios were identified for folpet use including: (*Scenario 1*) adding powder to paint during the manufacturing process, (*Scenario 2*) loading wettable powder for airblast applications to avocados, (*Scenario 3*) applying sprays using an airblast sprayer to avocados, (*Scenario 4*) applying folpet-containing paint with a paint brush, (*Scenario 5*) applying folpet-containing house stain using an airless sprayer, (*Scenario 6*) applying folpet-containing paint with a paint roller, and (*Scenario 7*) applying a ready-to-use formulation as an on-site wood dip treatment. No data are available to assess *Scenarios 6 and 7*. Data for the other painting scenarios are sufficient surrogates to estimate worst case exposure for the paint roller scenario (*Scenario 6*) and the on-site wood dip treatment (*Scenario 7*).

These occupational scenarios reflect a broad range of application equipment, application methods, and use sites. The scenarios were classified as short-term (1-7 days) and intermediate-term (1 week to several months) based on the frequency of exposure. Application of folpet-containing paints and stains is not considered to be long-term exposure because only a small fraction of paints and stains contain folpet. Long-term exposure (greater than 6 months duration) is only expected for the addition of folpet to paints and stains as an in-can preservative. The estimated exposures in this assessment considered baseline protection (long pants, long-sleeved shirt, shoes, socks, no gloves, and an open cab tractor), as well as additional personal protective equipment (PPE), which also includes chemical resistant gloves and a dust/mist respirator.

ii. Occupational Handler Data Sources and Assumptions

An exposure assessment for each folpet use scenario was developed using chemical-specific data and surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a software system consisting of two parts -- a database containing measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. PHED was developed by Health Canada, the American Crop Protection Association, and EPA and was initially released for public use in 1992. PHED is a generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling and applying pesticides. The database currently contains data for over 2000 monitored exposure events. The Agency considers use of surrogate or generic data appropriate because the physical parameters of the handling and application process (e.g., the type of formulation used, the method of application, and the type of clothing worn), rather than the chemical properties of the pesticide, determine the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than are normally available from a single exposure study.

The Agency's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, without using chemical-resistant gloves or a respirator. If the level of concern is met or exceeded, then increasing levels of risk mitigation, such as PPE and engineering controls, are used to recalculate the MOEs until exposure is sufficiently reduced to achieve an MOE that is not of concern.

Folpet-specific passive dosimetry exposure monitoring studies were also used in the occupational exposure assessment. The first study (MRID 41411801) monitored exposures resulting from the use of a paint brush; the second study (MRID 41411802) monitored exposures resulting from the use of an airless sprayer for house stain. In the paintbrush study, folpet-containing paint was applied by non-professional painters using 2 and 4-inch paint brushes to interior bathroom walls. The one percent by weight folpet was packaged as a ready-to-use product. In the sprayer study, folpet-containing stain was applied to the exterior of a house using a commercial airless sprayer from five gallon ready-to-use containers.

Paint Brush Study. This study monitored 15 exposure replicates of non-professional painters painting interior bathroom walls. Painting was conducted with 2 and 4-inch paint brushes. The paint contained folpet at a concentration of one percent by weight. Technical grade folpet was added to the paint by the researchers prior to the study to ensure stability. Because folpet containing paint is packaged as a ready-to-use product, the absence of monitoring the act of mixing folpet into the paint is acceptable. The painters applied the paint at a rate of 500 to 550 ft^2 per gallon and applied approximately one-half gallon of paint per replicate. Application duration ranged from 34 to 94 minutes per replicate. The amount of active ingredient (a.i.) handled per replicate ranged from 0.0253 to 0.051 lb a.i. (MRID 41411801).

Dermal exposure was monitored with multi-layered patches simulating normal work clothing (i.e., long pants and long sleeved shirt) and the hands were monitored with cotton gloves over latex gloves. Inhalation monitoring was performed using personal air monitoring pumps with polyurethane foam filters.

Although the study is acceptable, the Agency identified a number of deficiencies: paint rollers should have been used in the study instead of paint brushes for potentially higher exposure results; an insufficient number of replicates were used in the laboratory and field recovery experiments for the cotton gloves and the foam filters; and a range of fortification levels for the field recovery experiments would have been more appropriate.

Airless Sprayer Study. This study monitored 15 exposure replicates of workers using a commercial airless sprayer. The stain used in the study, packaged in ready-to-use 5 gallon containers, contained 0.5 percent folpet by weight. The amount of a.i. used per replicate was calculated by using the percent folpet and assuming a stain density of 0.8 g/mL or 0.1667 lbs a.i. per replicate (i.e., 5-gallon stain bucket). Folpet was used at a rate of 750 to 1,250 ft^2 per 5-gallons. Application duration ranged from 11 to 27 minutes per replicate (MRID 41411802).

Dermal exposure was monitored with multi-layered patches simulating normal work clothing (i.e., long pants and long sleeved shirt) and the hands were monitored with cotton gloves over latex gloves. Inhalation monitoring was performed using personal air monitoring pumps with polyurethane foam filters. The patch and glove residue values were corrected for field recoveries.

Although the study is acceptable, the Agency identified a number of deficiencies in the study: an insufficient number of replicates were used in the laboratory and field recovery experiments for the cotton gloves and the foam filters; and a range of fortification levels for the field recovery experiments would have been more appropriate.

Other Assumptions. The following assumptions were used in the occupational exposure and risk assessment as appropriate:

- The Agency uses 60 kg as the average body weight of an adult handler for the short-term and intermediate-term dermal and inhalation exposure and 70 kg as the average body weight for the cancer assessments. The Agency typically uses a 60 kg body weight for adult females is used when developmental toxicity is the risk assessment endpoint.

- 10 Acres of avocados are treated per day.

- 4,000 Gallons of paint are treated per day during the manufacturing process.

C PHED surrogate information for wettable powder is used to estimate exposure to the solid powder used in the paint manufacturing process. PHED is also used for estimating exposure to folpet for the avocado use.

C A painter could paint up to 5 gallons of paint with a brush at residential site and stain up to 2 houses in a day. A typical house dimension is assumed to be 30 ft x 40 ft x 20 ft (2,400 ft^2 living area or 2,800 ft^2 outdoor surface area to be treated).

C For *Scenario 4*, application with a paint brush, the maximum application rate for paint and stain products (0.088 lb a.i./gal) is used for the short and intermediate term assessments. A typical rate of 0.044 lb a.i./gal is used in the cancer assessment.

C The exposure data presented in *Scenario 5* for airless sprayers is assumed to be higher than that for compressed-air type paint/stain sprayers. Therefore, the airless sprayer is a reasonable worse-case representative for all other types of paint/stain sprayers.

iii. Occupational Handler Risk Characterization

The same toxicological endpoint was selected for risk assessment for short- and intermediate-term dermal and inhalation exposures (i.e., NOAEL of 10 mg/kg/day from an oral developmental toxicity study discussed earlier). Because the endpoints are derived from oral studies, the absorbed daily dose for each route of exposure is converted to an equivalent oral dose using a dermal absorption rate of 2.7 percent or an inhalation absorption rate of 100 percent, according to the following formula:

$$Absorbed\ Daily\ Dose\left(\frac{mg}{Kg/Day}\right) = Daily\ Exposure\left(\frac{mg}{Day}\right) \times \left(\frac{1}{Body\ Weight\ (Kg)}\right) \times Percent\ Absorption$$

The absorbed daily dose of folpet for short-term and intermediate-term exposures is calculated using a 60 kg body weight representing adults females because a developmental toxicity endpoint is used for risk assessment.

Worker MOEs are derived from a comparison of the total oral equivalent dose (corrected for inhalation and dermal absorption) with the NOAEL of 10 mg/kg/day for short- and intermediate-term duration, according to the following formula:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Absorbed\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Folpet is classified as a Group B2, probable human, carcinogen with a cancer potency value (Q_1^*)

from a 2 year feeding study in mice of 1.86 x 10^{-3} $(mg/kg/day)^{-1}$. Estimated worker cancer risk is calculated using the following formula:

$$Estimated\ Risk = LADD\ (mg/kg/day) * Q_1^*\ (mg/kg/day)^{-1}$$

where Lifetime Average Daily Dose, or LADD is calculated as

*LADD (mg/kg/day) = Daily Total Dose (mg/kg/day) * (days worked/365 days/yr) * (35 years worked/70 yr lifetime).*

Worker MOEs greater than 100 are not of concern. Worker cancer risks less than 1 x 10^{-6} are not of concern. The Agency policy for worker risk states that risks shall be as close to negligible (1 X 10^{-6}) as possible. Worker risks in the range of 10^{-4} are acceptable when risks have been mitigated to the maximum extent feasible with practical measures and when benefits outweigh the risks.

A summary of the short- and intermediate-term, and chronic MOEs, and lifetime cancer risk estimates are given in Table 8. Risk values are given for baseline and baseline with additional mitigation. Baseline represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor used in airblast application. Additional PPE includes chemical resistant gloves and a dust/mist respirator (5-fold protection factor).

Occupational exposures reflecting baseline protective clothing (i.e., long pants, long sleeved shirt, no gloves, and open systems) result in MOEs and cancer risks that do not exceed the Agency's level of concern for all scenarios but one. For this one scenario (*Scenario 1*), loading a powder formulation to paint at the manufacturing process, additional PPE (i.e., use of chemical resistant gloves and a dust/mist respirator or in-lieu of PPE, the use of engineering controls) are required to mitigate exposure/risk. Provided that folpet exposures are mitigated for the above specified exposure scenario with PPE (or engineering controls), MOEs and cancer risk for total exposure/risk do not exceed the Agency's level of concern.

Table 8. Summary of Occupational Risks for Folpet

Exposure Scenario	Exposure Duration	Margin of Exposure (MOE)			Cancer Risk at Baseline***
		Baseline* MOE	Additional PPE **	Acceptable Value	
Scenario 1: Manufacture of Paints and Stains	Short and Intermediate Term	17	130	100	9.1×10^{-5}
	Chronic	15	120	100	4.5×10^{-5}
Scenario 2: M/L for Avocados	Short and Intermediate Term	140	>100	100	1 to 2.2×10^{-6}
Scenario 3: Applicator for Avocados	Short and Intermediate Term	1400 to 3300	N/A	100	1.1 to 1.9×10^{-7}
Scenarios 4-7: Application of Paints and Stains	Short and Intermediate Term	212 to 260	N/A	100	4.3 to 5.6×10^{-6}
Postapplication Scenario: Avocado Harvesters (1 day REI)	Short Term	100	N/A	100	6.5×10^{-6}

* Baseline reflects use of long-sleeved shirt, long pants, shoes, and socks.
** PPE includes baseline plus chemical resistant gloves and a dust/mist respirator.
*** Cancer risk at baseline are considered acceptable, so cancer risks with PPE are not presented here, although risks with PPE are $< 1 \times 10^{-6}$.

iv. Incident Reports

No serious illnesses associated with folpet exposure have been reported in the data sources available to the Agency. The scientific literature suggests folpet may contribute to allergic contact dermatitis and irritant effects to the skin. The Agency has reviewed the OPP Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) data bases for reported incident information for folpet. Of the 11 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995), 3 involved use of folpet alone, and it was determined to be responsible for the health effects. Eye and skin irritation were the only reported effects. Based on these few reports, under some circumstances exposure to folpet can lead to skin and eye irritation, such as skin rashes and conjunctivitis.

v. Occupational Postapplication Exposure

The Agency has assessed postapplication exposures for both the avocado and paint uses of folpet. For paints, postapplication inhalation exposures are expected to be substantially lower than those experienced by occupational handlers. Monitoring in the 14 days following application of folpet-containing paint in a residential setting showed negligible exposure potential (MRID 41411801). Moreover, the

vapor pressure of folpet is negligible, $1.6x10^{-7}$ mmHg at 25E C. Although no post-application monitoring data are available for the use of folpet-containing stains and wood treatment products, negligible exposure potential is expected. The worst case exposure potential, which is experienced by commercial painters using folpet-containing paints and stains, results in acceptable risk (MOEs >100).

Post-Application Exposures to Workers in Folpet-treated Avocado Orchards. EPA has some chemical-specific data upon which to assess the exposure of workers entering avocado orchards to perform tasks, such as harvesting, following applications of folpet. Dislodgeable foliar residue (DFR) studies and concurrent worker exposure studies were conducted for folpet in avocado orchards (MRIDs 42122019 and 42122020). However, the study is based on a single application of folpet even though 7 applications are permitted annually at a minimum interval of 14 days separating each application. The worker portion of the study had the following deficiencies: the quantification limit was not provided or described; the study did not indicate the number of field fortifications per monitoring period; and workers wore an *optional* outer garment over the tee-shirt dosimeter, specific clothing attire and material type was not reported. Therefore, the available data do not represent a worst-case characterization of exposures to workers.

For both the DFR study and the worker exposure study, approximately 3.0 lbs a.i./acre of folpet 50WP, the maximum labeled rate (e.g., 47.6% a.i., formulated as a wettable powder), was applied to avocado trees once using an airblast spray system (MRIDs 42122019 and 42122020). Four different sprayers placed on trailers were each hitched to 4 different tractors in order to spray 47.5 acres of avocado trees (i.e., the total acres for the three different sites) located at Goulds, Florida. Applications were made on November 4, 1989. Rainfall was measured as a "trace" amount on November 6, 0.24 inches on November 8, and intermittently throughout the study (trace to 0.44 inches per event).

Dislodgeable Foliar Residue (DFR) Study. For the DFR study, six samples (e.g., each sample consisting of 50 leaf discs measuring 10 cm^2) were taken at each sampling interval from each site. Three of the samples were used for measuring folpet dislodgeable foliar residues, and three samples were used for measuring total residues. The leaf disc samples were collected from the trees at the height of six feet. The DFR discs were dislodged using a detergent solution (an aqueous dilution of Aerosol OT-75). Foliage samples were collected at 0, 1, 3, 7, 9, 13, 21, 28, and 35 days after treatment (DAT).

Avocado Harvester Study. For the worker exposure study, thirty workers were monitored while harvesting avocados from trees that had been treated once with folpet. Ten volunteers worked in each grove. Thus, the study contained a total of 10 replicate measurements for calculating folpet inhalation and dermal exposure at three sampling intervals. The sampling interval was different at each site.

Two harvesting techniques were monitored in this study. The first harvesting exposure scenario involved workers who used a machine similar to a "cherry picker". In this type of harvesting, a worker stands on a platform which is raised and lowered by the "cherry picker" so that a worker can pick avocados at different heights of the tree. The platform contains a bucket where the avocados are stored.

When the bucket becomes full, the "cherry picker" lowers the platform so that the worker can empty the bucket of avocados into a set of wooden crates placed in a tractor drawn trailer. The second harvesting scenario involves workers picking avocados from the ground or picking up avocados dropped on the ground by workers in the harvesting machine, and then driving the trucks containing the crates of avocados.

TransferCoefficient. The average dissipation of folpet residues on avocado was calculated using measured DFR data from 3 sites, correcting the data for a field recovery of 63.5 percent, and averaging the results of the three sites together. Table 6 also provides an MOE assessment based on an average transfer coefficient (Tc) of 30,015 cm^2/hr. The average transfer coefficient is based on the average exposure of cherry picker harvesters at three different sites, which ranges from 13,359 to 42,237 cm^2/hr.

The transfer coefficient for the cherry picker harvesters were used in the risk assessment instead of the harvesters working on the ground or tractors because the cherry picker scenario represents a reasonable worst case exposure. The transfer coefficients are calculated as follows:

$$\textit{Transfer Coefficient } (cm^2/hr) = \frac{\textit{Total Dermal Residue } (\mu g/day)}{\textit{Time}(4\ hr/day) \times \textit{DFR } (\mu g/cm^2)}$$

vi. Postapplication Risk Estimates

As previously mentioned, the toxicology endpoint for short and intermediate term exposures is the NOAEL of 10 mg/kg/day from an oral developmental toxicity study. Because the endpoint is derived from an oral study, the absorbed daily dose for each route of exposure is converted to an equivalent oral dose using a dermal absorption rate of 2.7 percent or an inhalation absorption rate of 100 percent. Potential average daily exposure (ADE) is calculated as follows:

$$\textit{Potential ADE} = \frac{\textit{DFR } (\mu g/cm^2) \times \textit{Transfer Coefficient } (10{,}000\ cm^2/hr) \times \textit{Work Day } (8\ hr)}{\textit{Unit Adjustment from } \mu g \textit{ to mg } (1{,}000\ \mu g)}$$

The ADE is corrected for percent absorption to convert it to average daily dose, which is then used to calculate post-application MOEs using the following formula:

$$MOE = \textit{NOAEL (mg/kg/day)/Dose (mg/kg/day)}$$

Postapplication cancer risks were calculated using the following formulas:

$$\textit{Estimated Risk} = \textit{LADD (mg/kg/day)} * \textit{folpet } Q_1 \textit{ of } 1.86^{-3}\ \textit{(mg/kg/day)}^{-1}$$

where *LADD (mg/kg/day) = Daily Absorbed Dermal Dose (mg/kg/day) * (30 days worked/365 days/yr) * (35 years worked/70 year lifetime).*

The risk assessment indicates that the MOEs for short- and intermediate-term exposures exceed 100 on day 1 after treatment. Cancer risks are 6.9 x 10^{-6} on the day of treatment after sprays have dried and still exceed 1.0 X 10^{-6} on day 40 following treatment. EPA believes this represents a potential underestimate of post-application risks to avocado workers following folpet applications because of the data deficiencies noted above.

Table 9. Summary of Avocado Worker Post-Application Exposure and Risk

Days After Treatment	Best Fit Average DFR (Fg/cm^2)[a]	Daily Dermal Exposure (mg/day)[b]	Daily Absorbed Dermal Dose (mg/kg/day)	Dermal MOE	Dermal LADD (mg/kg/day)	Cancer Risk
0	0.97	232.9	0.105	95	3.7E-3	6.9E-6
1	0.93	223.3	0.100	100	3.5E-3	6.5E-6

[a] The average dislodgeable foliar residues from the avocado study MRID No. 421220-19, DFR (Fg/cm^2) were derived by converting the measured DFR data (averaged DFR data from the three sites and corrected for a field recovery of 63.5%) into lognormal then running a linear regression equation to estimate the dissipation over time.

[b] Exposure (mg/day) = [(Best Fit Average DFR x Average Tc (30,015 cm^2/hr)) / 1,000 Fg/mg unit conversion] x 8 hrs/day.

The postapplication data used in this assessment are based on a single application of folpet, while the folpet label permits as many as 7 applications per year, with a minimum interval of 14 days separating each application. Therefore, actual exposure and risk to workers is likely to be higher than the values presented in Table 9 above.

d. Residential Exposure

There are four major folpet exposure scenarios for homeowner handlers using folpet containing paints and stains labeled for pesticidal use: (*Scenario 4*) applying ready-to-use formulation with a paint brush, *(Scenario 5*) applying ready-to-use stain formulation with an airless sprayer, (*Scenario 6*) applying ready-to-use formulation with a paint roller, and *(Scenario 7*) applying ready-to-use formulation as an on-site wood dip treatment. In addition, homeowners may also handle paint and stain products to which folpet has been added, but not labeled. There are three major folpet exposure scenarios for homeowners using folpet- containing products not labeled for pesticide use: (*Scenario 4*) applying paint with a brush, (*Scenario 5*) applying stain with an airless sprayer, and (*Scenario 6*) applying paint with a roller.

i. Residential Handler Exposure Scenarios, Data Sources, and Assumptions

The Agency conducted residential handler exposure assessments for painting/staining use scenarios. Residential handler exposures are based on homeowners wearing long pants, long sleeved shirt, and no gloves or respirator. The residential assessment is based on data from two folpet-specific passive

dosimetry monitoring studies using either a paintbrush (MRID 41411801) or an airless sprayer (MRID 41411802). In the paintbrush study, a folpet-containing paint was applied by non-professional painters using 2 and 4-inch paint brushes to interior bathroom walls. The 1 percent by weight folpet was packaged as a ready-to-use product. In the airless sprayer study, a folpet-containing stain was applied to the exterior of a house using a commercial airless sprayer from 5 gallon ready-to-use containers.

Assumptions: The Agency made assumptions regarding body weight, toxicology endpoints, application rate, area treated, and frequency and duration of exposure similar to those used in the occupational exposure and risk assessment. The Agency also made the following assumptions regarding residential exposure:

- Area treated in each scenario: 2 gallons of paint for a homeowner, a homeowner would treat one typical house with stain. A typical house dimension is assumed to be 30 ft x 40 ft x 20 ft (2,400 ft^2 living area or 2,800 ft^2 outdoor surface area to be treated).

- The airless sprayer is a reasonable worse-case representative for all other types of paint/stain sprayers. Also, the maximum application rate for ready to use stain products is used and is expressed in lb a.i./ft^2 covered. This product is expected to be used primarily for residential application and not for large scale commercial structures.

- The number of treatment days per year for the cancer assessment are assumed to be as follows: 4 days of painting for homeowners and 1 day for staining for homeowners (house treatment once per year).

These residential exposure scenarios reflect a broad range of application equipment, application methods, and use sites. The exposure scenarios were classified as short- and intermediate-term based primarily on the frequency of exposure. A long-term exposure duration is not expected because homeowners are not expected to use paint for more than 6 months.

ii. Residential Handler Risk Characterization

MOEs and cancer risks are calculated in the same manner as occupational handlers. However, for homeowners MOEs greater than 300 are not of concern. This reflects the application of the 3X FQPA safety factor to homeowners. Cancer risks for homeowners less than 10^{-6} are not of concern.

A summary of the short-term hazard and risk estimates for residential handlers is presented in Table 10. The estimates for short-term dermal and inhalation hazards and risks are combined because dermal and inhalation endpoint effects are the same. Exposures were estimated assuming that residents would stain the house once a year, apply folpet-containing paint 4 times per year, and paint up to 2 gallons per use. Residential exposures result in MOEs and cancer risks that are below the Agency's level of concern.

iii. Residential Postapplication Exposures and Risks

As stated previously, postapplication exposures are considered to be negligible for persons in or near areas where (1) folpet ready-to-use products are being or have recently been applied with brushes, rollers, or sprayers, or as a dip; and (2) paints containing folpet are being or have recently been applied. Therefore, postapplication exposure and risk estimates are not presented here. Residential postapplication exposures and risks are also not of concern.

e. Summary of Occupational Risk Estimates

i. Short- and Intermediate-term Dermal Risk

The calculations of short-term and intermediate-term dermal risk indicate that the MOE is less than 100 with baseline PPE for Scenario 1, adding the wettable powder formulation to paint at the manufacturing process. However, the MOE is greater than 100 with the addition of chemical resistant gloves. Therefore, chemical-resistant gloves are required for workers adding folpet to paints during manufacture.

ii. Short and Intermediate Term Inhalation Risk

Inhalation exposure is expected only for workers adding wettable powder to paint during the manufacturing process (*scenario 1*). The calculation of short- and intermediate term inhalation risk for this scenario gives an MOE of 40 with baseline PPE and an MOE of 200 with the addition of a dust/mist respirator. Therefore, a dust/mist respirator is required for workers adding folpet to paints during manufacture. Inhalation exposure and risk are expected to be negligible for all other occupational exposure scenarios.

iii. Total Noncancer Risk from Handler Exposure

The calculations of total short-term and intermediate-term risk indicate that the MOEs are more than 100 with additional PPE (chemical resistant gloves and dust/mist respirator) for *Scenario 1,* adding wettable powder formulation to paint during the manufacturing process. Total risk reflects risk from combined inhalation and dermal exposure.

iv. Cancer Risk From Handler Exposure

Cancer risk estimates are between 1×10^{-4} and 1×10^{-5} at baseline for *Scenario 1,* adding wettable powder to paint during manufacturing. However, with mitigation (chemical-resistant gloves and dust/mist respirator) risk for *Scenario 1* is 4.5×10^{-5}.

Table 10. Short-, Intermediate-, and Chronic Term Dermal Risks

Exposure Scenario (Scenario #)	Baseline Absorbed Daily Dermal Dose (mg/kg/day)[a]	Baseline Dermal MOE[b]	Risk Mitigation Measures		
			Additional PPE		
			PPE Dermal Unit Exposure (mg/lb a.i.)[c]	PPE Absorbed Daily Dermal Dose (mg/kg/day)[a]	PPE Dermal MOE[b]
Mixer/Loader Risk					
Scenario 1: Adding Wettable Powder to Paint at the Manufacturing Process	0.59	17	0.17	0.027	370
		Chronic 15			Chronic 330
Scenario 2: Mixing/Loading Wettable Powder for Airblast Application	Typical Rate, 0.025	400	N/A	N/A	N/A
	Maximum Rate, 0.050	200		N/A	N/A
Applicator Risk					
Scenario 3: Applying Sprays with an Airblast Sprayer	Typical Rate, 0.002	5,000	N/A	N/A	N/A
	Maximum Rate, 0.005	2,000		N/A	N/A
Scenario 4: Applying Ready-to-use Formulation or Paint Product with a Paint Brush	(H) 0.014	710	N/A	N/A	N/A
	(O) 0.036	280		N/A	N/A
Scenario 5: Applying Ready-to-use Stain Formulation with an Airless Sprayer	(H) 0.015	670	N/A	N/A	N/A
	(O) 0.029	350		N/A	N/A
Scenario 6: Applying Ready-to-use Formulation or Paint Product w/ Paint Roller	No data	No data	No data	No data	No data
Scenario 7: Applying Ready-to-use Formulation as On-site Wood Dip Treatment	No data	No data	No data	No data	No data

[a] Absorbed Daily Dermal Dose (mg/kg/day) = [Dermal Exposure (mg/day) * Dermal Absorption Rate (2.7%)] / Body Weight (60 kg).

[b] Dermal MOE = Subchronic NOAEL (10 mg/kg/day) / Absorbed Daily Dermal Dose (mg/kg/day). Scenario 1: Chronic NOAEL (9 mg/kg/day) / Absorbed Daily Dermal Dose (mg/kg/day). A MOE of 100 is required for occupational and 300 for homeowners (i.e., residential).

[c] Additional PPE for *Scenario 1*: Single layer of clothing and chemical resistant gloves.

Table 11. Total Risks (Inhalation plus Dermal Exposure)

Exposure Scenario (Scenario #)	Baseline Daily Dose (mg/kg/day)[a]			Baseline Total MOE[d]	Risk Mitigation[e]			
	Absorbed Dermal[a]	Inhalation [b]	Total[c]		PPE Absorbed Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Total Dose (mg/kg/day)	Total MOE
Mixer/Loader Risk								
Scenario 1: Adding Wettable Powder to Paint at the Manufacturing Process	0.59	0.25	0.84	12 Chronic 11	0.027	0.050 (dust/mist)	0.077	130 Chronic 120
Scenario 2: Mixing/Loading Wettable Powder for Airblast Application	Typ. Rate, 0.025	0.011	0.036	280	N/A	N/A	N/A	N/A
	Max. Rate, 0.050	0.022	0.072	140	N/A	N/A	N/A	N/A
Applicator Risk								
Scenario 3: Applying Sprays w/ Airblast	Typ. Rate, 0.002	0.001	0.003	3,300	N/A	N/A	N/A	N/A
	Max. Rate, 0.005	0.002	0.007	1,400	N/A	N/A	N/A	N/A
Scenario 4: Applying Ready-to-use Formulation or Paint w/ Paint Brush	(H) 0.014	0.0008	0.015	700	N/A	N/A	N/A	N/A
	(O) 0.036	0.002	0.038	260	N/A	N/A	N/A	N/A
Scenario 5: Applying Ready-to-use Stain Formulation with an Airless Sprayer (5)	(H) 0.015	0.012	0.027	407	N/A	N/A	N/A	N/A
	(O) 0.029	0.023	0.052	212	N/A	N/A	N/A	N/A
Scenario 6: Applying Ready-to-use Formulation or Paint w/ Paint Roller	No data	No data	No data	No data	No data	No data	No data	No data
Scenario 7: Applying Ready-to-use as an On-site Wood Dip Treatment	No data	No data	No data	No data	No data	No data	No data	No data

N/A Not applicable, previous MOE greater than 100.

(H) Homeowner; (O) Occupational

[a] Baseline Abs. Daily Dermal Dose (mg/kg/day) = [Unit exposure (mg/lb ai) * Appl. rate (lb ai/acre or lb ai/gal or lb ai/ft2) * Acres or gallons or square ft treated * Dermal Abs. (2.7%)] / 60 kg Body weight. Values from Table 2.

[b] Baseline Daily Inh. Dose (mg/kg/day) = [Unit exposure (mg/lb ai) * Appl. rate (lb a.i./acre or lb ai/gal or lb ai/ft2) * Acres or gallons or square feet treated] / 60 kg BWt

[c] Baseline Total Dose (mg/kg/day) = Baseline Absorbed Daily Dermal Dose (mg/kg/day) + Baseline Daily Inhalation Dose (mg/kg/day)

[d] Baseline Total MOE = Subchronic Dermal NOAEL (10 mg/kg/day) / Baseline Total Dose (mg/kg/day); Scenario 1: Chronic NOAEL (9 mg/kg/day) / Absorbed Daily Dermal Dose (mg/kg/day). A MOE of 100 is required for occupational and 300 for homeowners (i.e., residential).

[e] Risk Mitigation: Scenario 1: Single layer of clothing and chemical resistant gloves, and a dust/mist respirator.

Table 12. Combined Dermal and Inhalation Cancer Risk

Exposure Scenario (Scenario #)	Baseline Daily Dose (mg/kg/day)			Treatments per year[d]	Baseline (Total)		Risk Mitigation		
	Dermal[a]	Inhalation[b]	Total[c]		LADD (mg/kg/day)[e]	Risk[f]	PPE (Total) Dose, mg/kg/day[g]	PPE (Total) LADD, mg/kg/day[h]	PPE Total Risk[i]
Mixer/Loader Cancer Risk									
Scenario 1: Adding WP to Paint at Manufacturing Process	0.50	0.21	0.71	50	0.049	9.1E-5	N/A	N/A	N/A
				250	0.24	4.5E-4	0.069	0.024	4.5E-5
Scenario 2: Mixing/Loading Wettable Powder for Airblast	Typ.: 0.022	0.009	0.031	14	0.0006	1.1E-6	N/A	N/A	N/A
	Max.: 0.044	0.019	0.063		0.0012	2.2E-6	N/A	N/A	N/A
Applicator Cancer Risk									
Scenario 3: Applying Liquid w/ Airblast Sprayer	Typ.: 0.002	0.001	0.003	14	0.00006	1.1E-7	N/A	N/A	N/A
	Max.: 0.004	0.002	0.006		0.0001	1.9E-7	N/A	N/A	N/A
Scenario 4: Applying RTU or Paint w/ a Paint Brush	(H) 0.012	0.001	0.013	4	0.00007	1.3E-7	N/A	N/A	N/A
	(O) 0.031	0.002	0.033	50	0.0023	4.3E-6	N/A	N/A	N/A
Scenario 5: Applying RTU Stain w/ Airless Sprayer	(H) 0.012	0.010	0.022	1	0.00003	5.6E-8	N/A	N/A	N/A
	(O) 0.025	0.020	0.045	50	0.003	5.6E-6	N/A	N/A	N/A
Scen.6: RTU or Paint w/ Roller	No data	No data	No data	No data	No data	No data	No data	No data	No data
Scenario 7: Applying RTU as On-site Wood Dip Treatment	No data	No data	No data	No data	No data	No data	No data	No data	No data

[a] Baseline Abs.Daily Dermal Dose (mg/kg/day) = [Baseline Derml Exp., mg/day * Dermal Abs. 2.7%]/BWt,70 kg. Derml doses differ from Table A-2 due to different BWt

[b] Baseline Daily Inh. Dose (mg/kg/day) = Baseline Inh. Exposure (mg/day) / BWt (70 kg). Note: Inh. doses differ from values in Table A-3 because of the use of different BWt.

[c] Baseline Daily Total Dose (mg/kg/day) = Baseline Abs. Daily Dermal Dose (mg/kg/day) + Baseline Inh. Dose (mg/kg/day).

[d] Number of Treatments per year are based on professional judgement.

[e] Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (number of days per year worked / 365 days per year) * (35 years worked / 70 years lifetime).

[f] Baseline Risk = Baseline LADD (mg/kg/day) * (Q_1^*). Where Q_1^* = 1.86E-3 $(mg/kg/day)^{-1}$

[g] PPE Total Dose(mg/kg/day) = PPE Abs. Dermal (mg/kg/day) + Baseline Inh. Dose (mg/kg/day), Where add'l PPE is for Scen. 1:Single layer clothing w/ chem. resist. gloves

[h] PPE LADD (mg/kg/day) = PPE Total Daily Dermal Dose (mg/kg/day) * (days/yr worked / 365 day/yr) * (35 years worked / 70 years lifetime).

[I] PPE Risk = PPE LADD (mg/kg/day) * (Q_1^*). Where Q_1^* = 1.86E-3 $(mg/kg/day)^{-1}$

f. Aggregate Risk

In establishing or reassessing tolerances, the Food Quality Protection Act (FQPA) requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mode of toxicity. The Act further directs the Agency to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residue.

Folpet and captan both generate the very short-lived but reactive intermediate thiophosgene. Other chemicals may share thiophosgene as a common intermediate. The generation of thiophosgene may need to be considered in an aggregate assessment. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier where appropriate.

In examining aggregate risk, FQPA also directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure can include pesticide residues in drinking water, exposure from pesticides uses in and around the home, and exposure in non-residential settings, such as parks and schools. For folpet, EPA has included exposure from food, water, and residential exposure in the aggregate risk assessment, as appropriate.

i. Acute Aggregate Risk

Acute aggregate risk estimates for folpet do not exceed the Agency's level of concern. The aggregate acute dietary risk estimates include exposure to folpet residues in food and water. Exposure (food only) to combined residues of folpet based on a refined analysis using field trial data and percent of crop treated, represents 25% of the acute PAD for females 13-50, the population subgroup of concern for acute effects. Using conservative screening-level models, the estimated maximum peak concentrations of folpet in ground water is 0.06 ppb and in surface water is 159 ppb. This estimated peak concentration is less than the Agency’s Drinking Water Level of Comparison (DWLOC) for exposure to folpet in drinking water as a contribution to aggregate acute dietary risk. Based on the available information, the Agency concludes with reasonable certainty that no harm to any population will result from acute aggregate dietary exposure to folpet.

ii. Short- and Intermediate-Term Aggregate Risks

Short and intermediate term aggregate risk estimates for folpet do not exceed the Agency's level of concern. Short and intermediate term aggregate risk estimates considered only two potential homeowner exposure scenarios: application of Ready-to-Use paint or stain with either a paint brush or an

airless sprayer. The highest exposure, from the airless sprayer, represents a short-term MOE of 407 when dermal and inhalation exposures are added. The chronic dietary exposure from folpet represents less than 1% of the chronic PAD. This leaves a short-term DWLOC of 90 ppb available for water. The modeled 56-day GENEEC value is 1 ppb, and the modeled concentration of folpet in groundwater is 0.06 ppb. Because the short-term DWLOC is greater than the modeled concentrations of folpet in surface or groundwater, the short-term aggregate risk is not of concern. Therefore, the registered uses of folpet do not exceed the Agency's level of concern when short-term residential exposures are added to the chronic dietary exposure from currently registered food uses.

iii. Chronic (Non-Cancer) Aggregate Risk

Chronic (non-cancer) aggregate risk estimates for folpet do not exceed the Agency's level of concern. The aggregate chronic dietary risk estimates include exposure to folpet residues in food and water. No chronic residential use scenarios were identified. Exposure to folpet residues in food, based on a assessment using average field trail residues and percent of crop treated data, represents less than 1% of the chronic PAD for the most highly exposed population subgroup (non nursing infants less than 1). Exposure to all other groups represents less than 1% of the chronic PAD. Using conservative screening-level models, the estimated concentration of folpet in ground water is 6 ppb and in surface water is 1 ppb. This estimated average concentration is less than the Agency's drinking water level of comparison for exposure to folpet in drinking water as a contribution to aggregate chronic dietary risk. Based on the available information, the Agency concludes with reasonable certainty that no harm to any population will result from chronic dietary exposure to folpet.

iv. Cancer Aggregate Risk

Cancer aggregate risk estimates for folpet do not exceed the Agency's level of concern. Lifetime exposure estimates for dietary food, water, and residential exposure scenarios were combined to provide estimates of aggregate risk. The dietary food and water exposure numbers are considered conservative. The dietary portion is refined through percent crop treated and field trial residues. The residential exposure number was derived from a chemical-specific monitoring study submitted by the registrant. The modeled concentration of folpet in ground water is 6 ppb and in surface water is 1 ppb. This estimated average concentration is less than the Agency's $DWLOC_{cancer}$ for exposure to folpet in drinking water as a contribution to aggregate chronic dietary risk. Aggregate lifetime exposure from food, water, and residential use does not pose a cancer risk of concern to the Agency.

v. Cancer Aggregate Risk for Captan and Folpet

Captan and folpet share a common metabolite, thiophosgene, which is believed to be responsible for the carcinogenic effects of these compounds. Thiophosgene is a highly reactive, short-lived species. Studies indicate that thiophosgene causes local irritation of the site with which it comes in contact, and is believed to cause tumors through the irritation of the duodenum. Because they are so short-lived,

thiophosgene residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the rate of formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst case estimate. For captan, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 1.3×10^{-7}. For folpet, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 9.8×10^{-8} . If these two risks are added together the total risk is 2.3×10^{-7} The aggregate cancer Drinking Water Level of Comparison ($DWLOC_{cancer}$) based on this total cancer risk estimate is 11 ppb, using the captan Q_1^* of 2.4×10^{-3} . The estimated environmental concentration (EECs) for folpet are 1 ppb for surface water and less than 1 ppb for ground water. The EECs for captan are 4 ppb for surface water and less than 1 ppb for ground water. The largest EEC of 4 ppb is less than the DWLOC, the Agency's level of concern. This aggregate assessment is for dietary exposure only. The tumor of concern occurs in the GI tract (duodenum/jejunum-ileum) as a result of oral dosing. The relevance of dermal exposure to a GI tract tumor is unknown at this time. Thus, the Agency concludes that an aggregate cancer risk estimate considering dietary exposure (food and water) only for captan and folpet based on their common metabolite thiophosgene is appropriate.

e. Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act 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. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

At this time, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments; however, there are pesticides for which the common

mechanism issues can be resolved. For example, 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).

In the case of folpet, the Agency is aware of a proposed common mechanism of carcinogenicity with captan, via the common metabolite thiophosgene. This thiophosgene moiety is thought to be responsible for many of the toxic effects observed with both compounds. However, thiophosgene is a highly reactive moiety whose residues are not found because it is transient and not readily measurable. Without measurable residues of the thiophosgene common metabolite, it is difficult at this time to relate exposures of folpet to those of captan because the rate of thiophosgene formation may be different for each compound. Other chemicals may also share a common mode of toxicity with thiophosgene or have thiophosgene as a reactive intermediate. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. In the meantime, the Agency has determined that it should proceed with reregistration and reassessment of folpet tolerances independent of a cumulative risk assessment.

C. Environmental Assessment

The environmental assessment for folpet consists of five sections: Ecological Toxicity, Environmental Fate and Transport, Water Resources Assessment, Ecological Exposure and Risk Assessment, and Environmental Risk Characterization. The first and third sections report the ecological toxicity data from laboratory studies, estimate the ecological exposure and assess the effects to nontarget terrestrial and aquatic organisms. The second section depicts the environmental fate and transport data from field and laboratory studies and analyzes the impact to water resources. The section on environmental risk characterization integrates the exposure and effects assessments to determine the extent and potential for risk to the environment.

1. Ecological Toxicity Data

The Agency has sufficient data to assess the acute and chronic hazard of folpet to nontarget species for reregistering the existing folpet uses on avocados and in paint. However, additional data would be required if folpet were registered for new food uses or for if the geographic area for use on avocados were to expand.

The Ecological Effects Database for folpet is substantially complete for the current use pattern. There is a data gap for Guideline 850.4400, *Daphnia* chronic (life cycle) toxicity testing. These data are considered to be confirmatory and are not expected to alter the conclusions of the risk assessment. As

mentioned above, the Agency would require additional data with any expansion of folpet use; these data would include the following: (1) Guideline 850.5400, Tier 2 toxicity testing on 5 species of algae; (2) Guideline 850.1075, testing of the PAI degradate on bluegill sunfish; and (3) Guideline 850.1010, testing of the 50% WP formulation on *Daphnia magna*.

a. Toxicity to Terrestrial Animals

i. Birds, Acute and Subacute

To establish the toxicity of folpet to birds, the following tests were required and performed using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (mallard duck or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (mallard duck); and one species of upland game bird (bobwhite quail). Test results indicate that the folpet test material ranges from slightly toxic to practically non-toxic. The Acute and Subacute Toxicity data requirements (Guidelines 71-1(a), 71-1(b), 71-2(a), and 71-2(b), are fulfilled for reregistration (MRIDs 00112793, 00112794, 00112795, and 00160000). No additional acute or subacute toxicity data for birds are required. Study results are summarized in Tables 13 and 14 below.

Table 13. Avian Acute Oral Toxicity Findings

Species	% a.i.	LD_{50} mg/kg	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement*
Northern bobwhite quail	92.5	>2510	00112793	practically nontoxic	Yes
Mallard duck	92.4	>2000	00160000	practically nontoxic	Yes
Japanese quail	87.5	2440	00137698	practically nontoxic	No (Supplemental*)
Green finch	87.5	1340	00137698	practically nontoxic	No (Supplemental*)

*Supplemental Study provided useful information but Guideline was not satisfied.

Table 14. Avian Subacute Dietary Toxicity Findings

Species	% a.i.	LC_{50} ppm	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Northern bobwhite quail	92.5	>5000	0012794	practically nontoxic	Yes
Mallard duck	92.5	>5000	0012795	practically nontoxic	Yes

ii. Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly, or continuously, through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. The folpet end use label allows multiple applications per growing season, therefore avian reproduction studies were required. The avian reproduction studies indicate that exposure up to 1000 ppm in the diet does not appear to affect reproduction. Folpet residues at the maximum label application rate for avocados in Florida are not expected to exceed 800 ppm on foliage. The guideline requirements are fulfilled for the current folpet registrations (MRID 00098004, 00098005).

iii. Mammals

Data from available mammalian studies which are used for human health risk assessment were used to estimate the toxicity of folpet to wild mammals. Wild mammal testing is required on a case-by-case basis, depending on the results of such lower tier studies as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

An acute oral toxicity study in rats shows that folpet is practically non-toxic (MRID 001434057). The rat acute oral LD_{50} for folpet is 19,500 mg/kg. Chronic effects data are addressed in a two-year chronic feeding study in rats (MRID 00151560). The NOEL in the rat chronic study was 200 ppm; the LOEL was 800 ppm. Effects included hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach. However, exposure of nontarget animals for 2 years is unlikely in actual field exposure scenarios. Therefore, wild mammal toxicity testing is not required.

iv. Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. The acute LD50 in honeybees is 12.1 µg/bee. This is sufficient information to characterize folpet as relatively nontoxic to honeybees. The guideline requirement is fulfilled (MRIDs 00113613 and 05001991).

b. Toxicity to Aquatic Animals

i. Freshwater Fish

(1) Acute Toxicity

To establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Table15. Freshwater Fish Acute Toxicity Findings

Species	% a.i.	96-hr. LC_{50} (ppb a.i.)	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Bluegill sunfish (warmwater)	90.3	47	40818804	very highly toxic	Yes
Bluegill sunfish	88	72	40094602	very highly toxic	Supplemental*
Rainbow trout (coldwater)	90.3	15	40818803	very highly toxic	Yes
Rainbow trout	88	52.1	40098001	very highly toxic	Supplemental*
Brown trout	88	29	40098001	very highly toxic	Supplemental*
Brown trout	88	66	40094602	very highly toxic	Supplemental*
Channel catfish	88	108	40094602.	highly toxic	Supplemental*
Coho salmon	88	106	40094602	highly toxic	Supplemental*
Lake trout	88	24	40098001	very highly toxic	Supplemental*
Lake trout	88	87	40094602	very highly toxic	Supplemental*
Smallmouth bass	88	91	40094602	very highly toxic	Supplemental*
Yellow perch	88	177	40094602	highly toxic	Supplemental*

*Supplemental study provided useful information but guideline was not satisfied.

The results of the 96-hour acute toxicity studies in both cold and warm water species indicate that folpet is highly toxic to very highly toxic to fish. The guideline requirements are fulfilled for testing with technical material (MRIDs 40818803 and 41818804). The results of the 96-hour acute toxicity studies indicate that folpet end-use formulations are highly toxic to very highly toxic to fish. This is supported by 10 studies using an 88% formulation that shows a range of LC50 values from 24 to 177 ppb.

Additionally, when the technical LC_{50} is less than or equal to either the maximum expected environmental concentration or the estimated environmental concentration when the end-use pesticide is used according to the label, then acute formulated product testing with a typical end-use product is required. The folpet LC50 of 15 ppb in rainbow trout is less than the estimated environmental concentration of 159 µg/L, which triggers the requirement for testing with a typical end use product. For folpet, various formulations have been tested.

One of the formulations tested, Fungitrol 11-50, 44% a.i., is not a typical end use product (TEP) for use on avocados. Data from two other formulations, 50 and 75% wettable powder (50 and 75WP), indicate that the wettable powder end use products are less toxic than the technical grade material but are still very highly toxic to fish. The three supplemental wettable powder studies taken together satisfy the guideline requirement for TEP testing with freshwater fish.

Table 16. Freshwater Fish Acute Toxicity Findings

Species	Formulation	96-hr. LC_{50} (ppb a.i.)	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Bluegill sunfish	50 WP	675	40818804	highly toxic	Yes*
Bluegill sunfish	Fungitrol 11-50 (44% a.i.)	117	00074010	highly toxic	No (Supplemental)
Rainbow trout	75 WP	170	40818803	highly toxic	Yes*
Rainbow trout	50 WP	185	40098001	highly toxic	Yes*
Rainbow trout	Fungitrol 11-50 (44% a.i.)	71	00074009	very highly toxic	No (Supplemental)

* The three wettable powder studies together satisfy the guideline requirement for a typical end use product. Other supplemental studies provided useful information although the guideline was not satisfied.

Degradate testing can be required when the parent compound is short-lived and the major degradate(s) are believed to be stable and exist at concentrations greater than 10% of applied parent. Folpet is short lived, with a half life of 2.5 days based on the results of the aerobic soil metabolism study. Degradates include phthalimide (PI), phthalic acid (PAI), and phthalamic acid (PAM). Of these, PI and PAI are the are major degradates; however, none of the degradates are of toxicological concern although PI is slightly toxic to freshwater fish.

The following data were submitted on PI. The results of the 96-hour acute toxicity studies indicate that the folpet degradation product PI is slightly toxic to freshwater fish. The guideline requirement for PI is fulfilled (MRID 42122002, 42122004).

Table 17. Freshwater Fish Acute Toxicity Findings for Folpet Degradates

Species	% a.i.	96-hr. LC_{50} (ppm a.i.)	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Bluegill sunfish	98% PI	38	42122004	slightly toxic	Yes
Rainbow trout	98% PI	49	42122002	slightly toxic	Yes

(2) Chronic Toxicity

Data from fish early life-stage tests are required when the product is expected to be transported to water from the intended use sites, when the fish acute LC_{50} values are less than 1 mg/L, and when the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} values. The study results indicate that growth and survival of the fathead minnow are affected between 8.81 and 17.7 ppb. The study NOEL was 8.81 ppb. The guideline requirement is fulfilled (MRID 43786301).

A fish full life-cycle study is designed to evaluate risk from chronic pesticide exposure to fish reproduction and other life stages. This study is required when the end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site if the estimated environmental concentration is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test. The 56 day anticipated EECs for folpet in water, following single or repeat terrestrial applications of the product to avocado at the maximum label rates, are 1.22 and 2.85 ppb, respectively. This represents 18.4 and 32.3% of the NOEL reported in the fish early life cycle study. However, the Agency believes that the limited use of folpet on avocados in a regionally defined area in Dade and Brevard Counties, Florida, will not result in residue levels in excess of 10% of the NOEL for the fish early life study. No further testing is required to support the current use pattern.

ii. Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Table 18 lists the results of toxicity tests of folpet on freshwater invertebrates.

Table 18. Acute Toxicity of Folpet to Aquatic Invertebrates

Species	Formulation	48-hr. EC_{50} (ppb)	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	90.3	20	40844491	very highly toxic	Yes
Daphnia magna	88.6	>1500	00070507	moderately toxic	Supplemental*
Daphnia magna	87.5	85 (24 hr.)	00137697	very highly toxic	Supplemental*
Gammarus fasciatus	Tech	2500 (96 hour)	40094602	moderately toxic	Supplemental*

*Supplemental Study provided useful information but Guideline was not satisfied.

The results of the 48-hour acute toxicity studies indicate that folpet ranged from moderately toxic to very highly toxic to freshwater invertebrates. The guideline requirements are fulfilled for testing with technical material (MRID 40844491).

Acute toxicity testing with a typical end use product (TEP) is triggered when the LC_{50} is less than or equal to either the maximum expected environmental concentration or the estimated environmental concentration when the end-use pesticide is used according to the label. Any use resulting in an acute aquatic risk quotient equal to or greater that 1.0 triggers the requirement. For folpet, the 48 hour EC50 is 20 ppb, which is lower than the estimated EEC of 159 ppb. Therefore, acute invertebrate toxicity testing with the typical end use product is required.

A formulation with 44% active ingredient was tested on aquatic invertebrates. The results of the 96-hour acute toxicity study in *Daphnia magna* indicates that the 44% formulation is highly toxic to freshwater invertebrates, with a 96-hour LC_{50} of 600 ppb (MRID 0007408). Although the 44% formulation is not a typical end-use product for folpet on avocados. This data satisfies the requirement for Guideline 72-2B (OPPTS Guideline 850.1010), the toxicity of a typical end use product to freshwater invertebrates, for the purposes of the RED due to the limited use. However, additional data would be required if any additional uses are requested for folpet.

The Agency may require degradate testing when the parent compound is short-lived and the major degradate(s) are believed to be stable and exist at concentrations greater than 10%. Two of the major degradates, phthalimide (PI) and phthalic acid (PAI), meet these criteria. A 48-hour acute toxicity study in *Daphnia magna* using PI showed an LC50 of 39 ppm (MRID 42122005) characterizing the PI degradate as practically non-toxic to *Daphnia magna*. The guideline requirement for PI is fulfilled (MRID 42122005). No further testing on PAI is required at this time due to folpet's limited use. Additional data would be required with any expansion of folpet use.

Aquatic invertebrate life-cycle testing is required since folpet is applied repeatedly by air blast and may contaminate waterways via drift. A life cycle study in *Daphnia magna* showed a NOEL greater than 1.88 ppm (MRID 42122013); effects included reduced length and number of young produced. The results of this flow-through study are inconclusive because measured concentrations at all test levels varied substantially during the test. Therefore, the actual chronic levels to which the test organisms were exposed are unknown. The Agency considers this study unacceptable. Guideline 72-4B (OPPTS Guideline 850.4400), Chronic Daphnia Toxicity, is a data gap. These data are considered to be confirmatory and are not expected to alter the conclusions of the RED.

iii. Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is expected to reach the estuarine environment in significant concentrations. The current location of the avocado growing region in Florida is unlikely to present a nontarget exposure scenario for estuarine and marine organisms. Therefore, these data are not required to maintain the current folpet registration. Some estuarine and marine toxicity data have been submitted; these data are presented in the supporting Environmental Fate and Effects Division RED chapter.

c. Toxicity to Plants

i Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is not required for folpet. There are neither phytotoxicity label statements or reports of nontarget phytotoxic effects, so there is no reason to test the toxicity of folpet on terrestrial plants.

ii. Aquatic Plant Growth

The Agency would typically require aquatic plant testing for folpet since it has outdoor non-residential terrestrial uses and it may move off-site during application by drift (e.g., it has aerial and air blast applications). The typical application scenario for applying folpet to avocados is by airblast. There is also a study demonstrating phytotoxic effects of folpet on a species of alga (*Scenedesmus subspicatus*). The results of this toxicity test indicate that this particular algae species experienced a 50% inhibition in growth at less than 1 ppm; the EC_{50} in the study was 0.1 ppm (MRID 00137693). However, the Agency is not requiring further testing on either the parent folpet or its degradates at this time due to folpet's limited use. Additional data would be required with any expansion of folpet use. The required data would include OPPTS Guideline 850.5400 (OPP Guideline 123-2), Tier 2 aquatic plant growth, which would further characterize the toxicity of folpet to aquatic plants in the case of expanded use. Testing would be required on five aquatic species: *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flosaquae,* and a freshwater diatom).

2. Environmental Fate and Transport Data

The environmental fate and transport databases are adequate to support reregistration of folpet. To summarize, folpet dissipation appears to be dependent on abiotic hydrolysis and microbial-mediated degradation. Folpet degrades rapidly (half life, $t_{1/2}$, of 2.6 hours to 2 days) in aquatic and terrestrial environments, and its degradates contain either the trichloromethyl moiety of folpet or the phenyl-ring of folpet (i.e., phthalimide (PI), phthalamic acid (PAM), or phthalic acid (PAI)).

a. Degradation

i. Hydrolysis

Radiolabeled folpet, at 1 to 1.2 ppm, has a half-life of 2.6 hours in pH 5 buffer, 1.1 hours in pH 7 buffer, and 67 seconds in pH 9 buffer (MRID 40818801). Hydrolysis products were PI, PAM, and PAI.

The trichloromethyl moiety of folpet appears to hydrolyze rapidly in pH 5, 7, and 9 buffer solutions (MRID 42451401). Potential hydrolysis products of the trichloromethy moiety of folpet are

trichloromethyl mercaptan, thiophosgene, CO_2, H_2S, and COS. The hydrolysis data requirement (Guideline 161-1) is fulfilled for reregistration. No additional hydrolysis data are required at this time.

ii. Photodegradation in Water

Radiolabeled folpet, at 0.96 ppm, in pH 3 buffer degraded in less than 8 hours at rates similar to the dark controls when irradiated with UV light for 8 hours. Phthalimide was detected in irradiated and dark controls. These data show that folpet degradation in water is governed by hydrolysis and does not appear to be dependent on photodegradative processes. The data requirement for photodegradation in water (Guideline 161-2) is fulfilled for reregistration. No additional photolysis in water data are needed at this time.

iii. Photodegradation on Soil

Existing data show that radiolabeled folpet had longer half-lives in irradiated treatments (17 and 68 days) when compared with dark controls (7.3 and 42.8 days) (MRID 42122026). These data suggest that photodegradation on soil is not a major route of dissipation for folpet. However, the existing data do not meet FIFRA guideline requirements. This study cannot be upgraded because of inherent technical difficulties associated with material balance and degradate identification. Additionally, the study results on the persistence of folpet in soil under irradiated conditions contradict the low folpet persistence observed in the aerobic soil metabolism study (MRID 42122022) and field dissipation studies (MRIDs 4212207 and 42122028). The photodegradation on soil study does not need to be repeated to support folpet use on avocados because the data suggest that photodegradation on soil is not an important route of dissipation for folpet. Further, the localized use of folpet on avocados in Florida limits the need for extensive environmental fate data.

iv. Photodegradation in Air

The data requirement for a photodegradation in air study (Guideline 161-4) is waived. Folpet has a low vapor pressure ($<1 \times 10^{-5}$ mmHg) obviating the need for these data.

v. Aerobic Soil Metabolism

Radiolabeled folpet, 10 µg/g, has a first-order half-life of 75.4 days in Georgia sandy loam soil (MRID 42122022). Since the degradation pattern for folpet is biphasic, the registrant estimated two half-lives to reflect distinct differences in degradation rates. The estimated half-life of folpet is 4.3 days from 0 to 14 days post-treatment and 164.5 days from 14 to 365 days post-treatment. The Agency estimated an integrated first-order half-life of 2.55 days from non-transformed data using non-linear regression. The integrated first-order half-life provides the most reliable description of folpet degradation without censoring the original data. Non-volatile soil degradates of folpet were PI and PAI. The Agency calculated first-order half-life of PI is 17.2 days. The major volatile degradate (cumulative concentration 69.8%) was

CO_2.

In another older aerobic soil metabolism study, carbonyl-labeled folpet at 5.92 ppm had a half-life of 2.4 days in a sandy loam soil (MRID 00160422, 42122022). Formation of radiolabeled carbon dioxide was rapid; 74% of applied radioactivity was measured as $^{14}CO_2$ at 7 days post-treatment.

The data requirement for aerobic soil metabolism (Guideline 162-1) is fulfilled. No additional aerobic soil metabolism data are required at this time.

vi. Anaerobic Soil Metabolism

Radiolabeled folpet, at 10 ppm, has an estimated anaerobic soil half-life of 14.6 days in anoxic Georgia sandy loam soil (MRID 42122023). Non-volatile degradates of folpet are PI and PAI. The major volatile degradate was CO_2.

In an earlier anaerobic soil metabolism study, researchers found carbonyl-labeled folpet at 5.33 ppm had a half-life < 7 days in anaerobic loamy sand (MRIDs 0160422 through 0160428). PAI and PAM had a combined maximum concentration of 44.6% of applied folpet at 112 day post-treatment and declined to 18 % of applied folpet at 365 days post-treatment. Carbon dioxide was a major volatile degradate (80% of applied radioactivity).

The data requirement for anaerobic soil metabolism (Guideline 162-1) is fulfilled. No additional data are required at this time.

vii. Aerobic and Anaerobic Aquatic Metabolism

Aerobic and anaerobic aquatic metabolism data are not needed because folpet is not directly applied to aquatic environments. Because all wood and paint preservative uses are restricted to terrestrial environments, the Agency believes that direct impacts to aquatic environments are not likely. The Aerobic and Anaerobic Aquatic Metabolism (162-3 and 162-4) data requirements are waived for current uses of folpet. No additional data are required at this time.

b. Mobility

i. Leaching and Adsorption/Desorption

Studies submitted to the Agency indicate that folpet residues are mobile, as indicated by low soil/water partitioning coefficients. The Freundlich adsorption coefficients for folpet range from 0.13 to 0.22 mL/g, and desorption coefficients ranged from 0.04 to 0.12 mL/g. Corresponding K_{oc} values ranged from 7.47 to 21.87 mL/g.

The un-aged batch equilibrium data are non-upgradable, supplemental, studies because of problems with identification of specific folpet residues, sterilization of soil, and discrepancies between adsorption and desorption coefficients (MRID 42122025). Since radiolabeled residues were not identified and folpet hydrolyzes rapidly in water, the Freundlich partitioning coefficients are only representative of total folpet residues (parent and degradates) and not folpet alone. Further, the use of sterile soils is discouraged because it can alter the physicochemical properties of soils which may alter the batch equilibrium coefficients.

The aged residues mobility portion of the batch equilibrium/soil column study do not fulfill the data requirement for Guideline 163-1. Aged soil column data are unacceptable because of inadequate identification of residues, inadequate residue aging period, and low material balances. Low material balances prevent confirmation of experimental and analytical methodologies. Because folpet has a relatively short half-life in soil, a 30 day pre-incubation period is too long to assess mobility of folpet degradates (*e.g.*, PI and PAI).

Although the studies have numerous scientific deficiencies which limit data interpretation, the Agency believes that additional batch equilibrium studies (Guideline 163-1) are not needed since folpet residues (including folpet, phthalimide, phthalimic acid, phthalic acid) have a low soil water partitioning coefficients, indicating high mobility. The Agency assumes that all folpet residues are highly mobile in terrestrial and aquatic environments.

The batch equilibrium/soil column leaching (Guideline 163-1) data are adequate for reregistration of the avocado use of folpet. Batch equilibrium data on soil cannot be used to support paint uses of folpet. Partitioning of folpet from paint coatings is expected to be different than soil/water partitioning.

ii. Volatility

The Laboratory Volatility (163-2) data requirement is waived because folpet has a low vapor pressure ($<1 \times 10^{-5}$ mmHg). However, folpet has a relatively high estimated Henry's Constant (2.96×10^{-3} atm m^3/mole) (Thomas, 1990). Although the estimated Henry's Constant for folpet is relatively high and suggests volatilization may be a potential dissipation pathway from water, the rapid hydrolysis of folpet is expected to limit volatilization. Potential degradates of the trichloromethyl moiety of folpet (*e.g.*, thiophosgene) are expected to be highly volatile (estimated vapor pressure is 29.7 mmHg and estimated Henry's constant is 0.00586 atm-m^3/mole) in terrestrial and aquatic environments. However, the Agency believes that thiophosgene is not likely to enter the environment via volatilization because it is expected to react rapidly with compounds containing hydroxy, amino, and sulfhydryl groups.

iii. Bioaccumulation in Fish

Radiolabeled folpet residues, at 10 µg/mL, has bioconcentration factors (BCFs) in bluegill sunfish of 19X in fillet, 61X in whole fish, and 81X in viscera (MRID 42122029 and 42122030). Accumulated

residues are rapidly eliminated (greater than 93%) over a 7 day depuration period. PAI and phthalic anhydride are major metabolites (i.e., greater than10% of accumulated residues) in fish fillet and viscera. (Phthalic anhydride was not identified in other fate studies, and is not of toxicological concern to the Agency.) Folpet, PI, and PAM are minor constituents (less than 10% of accumulated residues) in fish tissues.

Bioconcentration factors for folpet are based solely on total radiolabeled residues and not specific folpet residues. Further analysis of radiolabeled residues in both water and fish tissues indicates that folpet was not stable during study. More importantly, PAI is a major degradate in the aquarium water as well as in fish fillets and viscera. These data suggest that folpet should not bioconcentrate in fish because it rapidly hydrolyzes in water. Independent laboratory environmental fate data substantiate that folpet does not persist in soil and aquatic environments. Also, the data suggest that phthalic acid should not accumulate in fish tissues. The data requirement for the bioaccumulation in fish study (Guideline165-4) is fulfilled. No additional data are needed at this time.

iv. Field Dissipation

Supplemental terrestrial field dissipation studies on citrus in Florida provide limited confirmation on the routes of dissipation for folpet (MRIDs 42122027 and 42122028). Folpet, at 18 lbs a.i./A, has a 50% dissipation time of less than 1 week when applied to oranges in central Florida. Although the field dissipation (Guideline 164-1) data requirement is not fulfilled, additional field studies are not needed because of limited folpet use.

v. Spray Drift

Droplet size spectrum (Guideline 201-1) and drift field evaluation (Guideline 202-1) studies were required due to airblast application to orchards, which raise a concern for potential risk to nontarget aquatic organisms. However, to satisfy these requirements the registrant in conjunction with registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency a series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. The Agency plans to complete its evaluation of these studies in the near future. In the interim and for the RED, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The rates are 1% of the applied spray volume from ground applications and 5% from aerial and orchard air blast applications at 100 feet downwind. After its review of the new studies, the Agency will determine whether a reassessment of the potential risks to nontarget organisms is warranted.

3. Water Resources Assessment

The Agency has conducted a Tier I water resources assessment for folpet. This assessment is limited because of deficiencies with the environmental fate data. Monitoring data are not available at present, thus this assessment of potential ground and surface water exposure is based on screening models. Tier 1 surface water modeling indicates maximum acute concentrations of folpet of 159 µg/L. The modeled maximum 56 day average annual chronic concentration of folpet is 2.6 µg/L. Tier 1 surface water modeling the maximum acute and chronic concentration for PI is 219 µg/L.

Because folpet exhibits a clear biphasic degradation pattern in an aerobic soil metabolism study (MRID 42122010), the Agency estimated a new half-life of 2.55 days using an integrated first-order degradation model fit to non-transformed data. This half-life provides a better description of folpet degradation without censoring data.

The potential for folpet contamination in ground and surface waters is expected to be limited because of the environmental fate behavior of folpet, limited use area, and foliar dissipation. Since folpet degrades rapidly in aquatic and terrestrial environments, folpet is not expected to pose a threat to ground and surface waters. Additionally, most folpet use on avocados occurs in single county in Florida which has extensive areas of surface water (*e.g.*, Everglades) and shallow ground water levels. Based on geographic site analysis, the registrant stated the folpet use area is approximately 3 miles from the Everglades. This information suggests that direct folpet movement into the Everglades would be dependent on long-range spray drift. Since folpet is a foliar-applied fungicide and hence is likely to have indirect impact to terrestrial environments, there is limited potential for ground water contamination because of foliar interception and dissipation processes. It is reasonable to assume that foliar interception will reduce the environmental loading of folpet. The magnitude of the load reduction cannot be quantified at this time.

Based on limited environmental fate data, phenyl ring degradates of folpet have sufficient mobility and persistence for potential movement in ground and surface waters. The rapid hydrolysis of the trichloromethyl moiety of folpet is expected to limit persistence in ground and surface waters. A possible degradate of the trichloromethyl moiety is thiophosgene. The fate of thiophosgene appears to be dependent on volatilization. However, thiophosgene was not detected as a volatile component in any of the submitted laboratory studies. Therefore, based on data submitted to the Agency, the amount of thiophosgene formed by folpet degradation cannot be quantified. For this reason, and because the Agency currently has no methods for estimating exposure to vapor-phase residues, the risk posed by folpet-derived thiophosgene to non-target organisms cannot be calculated.

The registrant states that thiophosgene is not likely to enter the environment via volatilization because it will instantaneously react with most compounds containing -OH, -NH_2, and -SH groups. To document this claim, the registrant provided literature citations on the reactivity of thiophosgene with ammonia, amines, thiols, epoxides, ketones, and phenols. Degradation products include ammonium thiocyanate, thioureas, thiocarbonates, HCl, H_2O, and CO_2. Furthermore, thiophosgene has an estimated

vapor pressure of 29.7 mmHg and an estimated Henry's constant of 0.00586 atm-m^3/mole.

In summary, thiophosgene is not expected to be a drinking water concern, due to dissipation either by volatilization or reaction with compounds on leaf surfaces or in the soil. Thiophosgene can degrade to form ammonium thiocyanate, a potentially toxic degradate. However, the extent to which this compound is formed by degradation of thiophosgene cannot be quantified, since the amount of thiophosgene formed in the environment is not known, and because ammonium thiocyanate is only one of several possible degradates of thiophosgene.

a. Ground Water

No ground water monitoring data are available for folpet. Therefore, potential maximum folpet concentrations in groundwater were estimated using the SCI-GROW screening level model. The SCI-GROW model predicts that groundwater concentrations of total folpet residues (folpet + PI) of 5.8 ppb.

Results from SCI-GROW are based on the fate properties of the pesticide, 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 groundwater is particularly vulnerable to contamination. However, a considerable portion of any use area will have groundwater 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. If the risk associated with this estimate is exceeded, either at the acute or chronic endpoints, refinement of the exposure estimate will be necessary to better characterize actual exposures.

Input for the screen included the maximum application rate of 21 lbs a.i./A/year for folpet, and calculated maximum application rate of 11.55 lbs a.i./A/ year for PI. The application rate for PI is a source of significant uncertainty in this assessment. This rate was derived by multiplying the maximum annual rate of 21 lb a.i./A of folpet by 0.55, the maximum amount of PI detected in any laboratory study as a percentage of applied folpet. The Agency used an aerobic soil metabolism half life of 2.5 days for parent folpet (17.2 days for PI), and a median K_{oc} for folpet of 17 mL/g (7.1 mL/g for PI).

Table 19. Estimated Folpet Residues in Groundwater

Compound	Groundwater Concentration (ppb folpet equivalents)
Folpet	0.06
PI	5.7
Total Folpet Residues (Folpet + PI)	5.8

The potential for folpet contamination of groundwater is expected to be limited because of the

environmental fate of folpet, the limited use area, and foliar dissipation. Folpet degrades rapidly in aquatic and terrestrial environments, and so is not expected to pose a threat to ground water. Folpet use is also currently limited to a single county in Florida. Also, folpet is a foliarly applied fungicide, so the environmental loading should be reduced by foliar interception and dissipation.

b. Surface Water

Tier 1 surface water modeling indicates the maximum acute concentration of folpet is not likely to exceed 159 µg/L. The GENEEC model predicts a 56 day average annual chronic concentration of folpet of 2.6 µg/L. Tier 1 surface water modeling predicts that the maximum acute and chronic concentrations are PI equal to 219 µg/L.

The following data were used for input into the GENEEC modeling for folpet:

Parameter	Value	Reference
soil K_{oc}	7.4 mL/g	MRIDs 42122022
Aerobic soil half-life	2.55 days	MRID 42122021
Aerobic aquatic half-life	Stable	Assumption
Photolysis Half-life (pH 7)	Stable	MRIDs 42122021
Hydrolysis (pH 7)	0.05 days	MRID 40818801
Water Solubility	1.3 mg/L	Assumption

Table 20. GENEEC EECs (µg/L) for Folpet Use on Avocados

Annual Application Rate (lbs a.i./A)	Peak	4 Days	21 Days	56 Days
3 (single application)	91	23	4	2
21 (seven applications)	159	40	8	3

GENEEC EECs are based on either a single application of 3.0 lbs a.i./A or seven applications of 3.0 lbs a.i./A at 14-day application intervals (Folpet 50 W label, EPA Reg. No. 66222-7).

The surface water assessment for PI is based on the following assumptions: (1) the K_{oc} and solubility of PI are equivalent to parent folpet; (2) the aerobic soil metabolism half-life was estimated from the aerobic soil metabolism data (MRID 42122021); (3) the batch equilibrium coefficient for folpet was used as a surrogate value; and 4) the application rate of PI is assumed to be 55% of the folpet application rate based on mass conversion efficiency in the aerobic soil metabolism study (MRID 42122021).

The following data were used for input into the GENEEC modeling for PI:

Parameter	Value	Reference
Soil K_{oc}	7.4 mL/g	MRID 42122025
Aerobic soil half-life	17.2 days	MRID 42122022
Aerobic aquatic half-life	Stable	Assumption
Photolysis Half-life (pH 7)	Stable	Assumption
Hydrolysis (pH 7)	Stable	Assumption
Water Solubility	1.3 mg/l	Assumption

Table 21. GENEEC EECs (µg/L) for PI Use on Avocados.

Annual Application Rate (lbs a.i./A)	Peak	4 Days	21 Days	56 Days
21*	219	219	219	219

*Application rate of PI is based on 55% conversion efficiency from parent folpet. This conversion efficiency is based on the maximum concentration (expressed as percent of folpet) found in the aerobic soil metabolism study (MRID 42122021).

Because folpet exhibits a clear biphasic degradation pattern in an aerobic soil metabolism study (MRID 42122021), the Agency estimated a new half-life of 2.55 days utilizing an integrated first-order degradation model fit to non-transformed data. This half-life provides a better description of folpet degradation without censoring the data. The surface water assessment for PI is based on the same assumptions.

4. Ecological Exposure and Risk Characterization

a. Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC)

The Agency characterizes the ecological risks of a pesticide by assessing the acute and chronic toxicity to four nontarget faunal groups and acute toxicity for each of two nontarget floral groups. Acute toxicity is expressed as follows:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

Chronic toxicity is expressed as follows:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and *either*
-The NOEL for chronic aquatic studies, *or*
-The Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

A risk quotient is then calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. The risk quotient is then compared with an appropriate level of concern (LOC), which is a criterion used to indicate the level at which significant adverse effects may be expected to nontarget organisms. The LOC indicates whether a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. When the risk quotient exceeds the LOC for a particular category, the Agency presumes a risk of concern to that particular category. Risk presumptions are presented along with the corresponding LOC's.

Table 22. Levels of Concern (LOC) and associated Risk Presumption

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5,	High acute risk
The acute RQ >LOC of 0.2,	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1,	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	High acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ >LOC of 0.05	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered species
Plants	
The RQ > LOC of 1	High risk
The RQ > LOC of 1	Endangered plants may be affected

No separate criteria exist for restricted use or chronic effects for plants.

b. Exposure and Risk to Nontarget Terrestrial Animals

i. Birds

Residues found on dietary food items following folpet application may be compared to LC_{50} values to predict hazard. The maximum concentrations of residues of folpet which may be expected to occur on selected avian or mammalian dietary food items following both single and multiple foliar application rates are provided in the tables below. Residues per pound of active ingredient applied for the four food types are developed from Hoerger and Kenaga (1972) and Kenaga (1973), with modifications suggested by Fletcher, et. al. (1994); the "broadleaf plants" category includes forage and is considered applicable to small insects while the "fruits" category includes seeds and is considered applicable to large insects. The maximum recorded values for an application rate of 1 lb/a.i./acre reported in these studies are: short grass (240 ppm), long grass (110 ppm), broadleaf (135 ppm), and fruits (15 ppm).

There are no definitive risk quotients for acute risk because definitive LC_{50}s are not available for the core avian studies. However, folpet applied at the highest label rate is not expected to exceed the maximum doses at which avian species were tested. Maximum residues from a single application are below the no-mortality levels for all species tested and are thus unlikely to result in avian mortality from dietary exposure.

For multiple applications of a pesticide, the terrestrial exposure model FATE is used to estimate residues based on accumulation from repeat applications at a given interval and degradation rate due to estimated foliar dissipation. Because actual foliar half-life data are not available, the dissipation half-life of 2.55 days is estimated by the Agency based on data submitted by the registrant. Maximum initial residue values are used, as described in Fletcher (1994). Folpet concentrations are expressed as EEC maximum and average maximum. The model assumes that folpet is applied to avocados grown in an orchard with an understory and between row vegetation of short grass. The Agency assumes an initial foliar residue of 720 ppm following 7 applications with a 14 day interval between applications and a half life of 2.55 days. When the model simulation is run for a time duration of 100 days, the model predicts maximum residue of 736 ppm and average residue of 210 ppm.

Table 23. Terrestrial Estimated Environmental Concentrations (EECs) for Folpet

Use Site	App. rate (lbs a.i./A)	No. of applications	Application interval (days)	Food item	EEC (ppm) maximum	EEC (ppm) average mean
Single Application						
Avocados	3	1	N/A	short grass	720	N/A
				long grass	330	N/A
				broadleaf plants/ insects	405	N/A
				seeds	45	N/A
Multiple Applications						
Avocados	3	7	21	short grass	736	209
				long grass	338	96
				broadleaf plants/ insects	414	118
				seeds	46	13

Based on a review of the data, it appears that folpet applied to avocados in Florida, at maximum label rates, would provide minimal acute or chronic exposure risks to avian species.
Estimated maximum residues resulting from multiple applications at the maximum rates and minimum

intervals are below the no-mortality level in all avian LC_{50} test data. Therefore, it appears unlikely that these dietary residues would result in avian mortality. Avian reproduction testing was conducted up to 1000 ppm, with no effects reported. Use of folpet on avocado at the maximum label rate of 3 lbs/a.i./A, maximum number of applications and minimum application interval would result in maximum residues less than 1000 ppm on all avian food items.

ii. Mammals

Small mammal exposure is addressed using the acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food consumption per day (g)}}$$

Table 24. Small Mammal Food Consumption (Based on an LD_{50} = 19.5 gm/kg)

Small Mammal	Body Weight (g)	% of Weight Eaten Per Day	Food Consumed Per Day (g)	Estimated LC_{50} Per Day (ppm)
Meadow Vole	46	61	28.1	31,922
Adult Field Mouse	13	16	2.1	120,714
Least Shrew	5	110	5.5	19,500

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the residues listed above to calculate a risk quotient (EEC/LC_{50}). The estimated LC_{50} in these calculations can be considered as the concentration of toxicant in the diet for one day that is lethal to 50% of a test population. Table 25 below indicates the risk quotients for each of the indicated application rates. These risk quotients are based on maximum Fletcher values for folpet residues.

The current standardized models are as follows: meadow vole consuming short grass; adult field mouse consuming seeds; least shrew consuming forage and small insects. Single applications of folpet at 3 lbs a.i./A predict a residue below the level of concern for all acute risk categories of mammals, including endangered species. Risk quotients for multiple applications, using maximum Fletcher values, for acute risk and average FATE model values for chronic risk, are presented in the following table. A chronic NOEL of 200, obtained from mammalian reproduction and developmental studies, is used to calculate chronic LOCs.

No acute LOCs are exceeded for small mammal species. Chronic risk to the meadow vole is slightly above the level of concern (LOC=1.05) when using maximum residues (Fletcher 1994) on short grass. The Agency believes that this risk estimate is conservative and contains a great deal of uncertainty for the following reasons:

1. Maximum residue values are based on direct applications to the target plants. The between row vegetation in the avocado orchard would be subject to indirect spray.

2. A portion of the airblast spray would be lost to drift.

3. Understory and between-row vegetation in the avocado orchard is likely to consist of mixed vegetation and not uniform cover of short grass.

At this time, the Agency does not believe that risk to small mammals warrants regulatory action on folpet given the limited use pattern and the conservatism inherent in the risk assessment.

Table 25. Mammalian Risk Quotients for Folpet Use on Avocados

Application rate (lbs a.i./A)	No. of applications	Application interval (days)	Small mammal	Acute Risk Quotient	Chronic Risk Quotient
Single Application					
3	1	N/A	meadow vole	<0.1	N/A
	1	N/A	field mouse	<0.1	N/A
	1	N/A	least shrew	<0.1	N/A
Multiple Applications					
3	7	14	meadow vole	<0.1	1.05
			field mouse	<0.1	<1.0
			least shrew	<0.1	<1.0

iii. Insects

Ecological toxicity data on honey bees indicate that folpet does not appear to pose a risk to honey bees. No further risk assessment is required at this time.

c. Exposure and Risk to Nontarget Aquatic Animals

Folpet displays high acute toxicity to most aquatic animal species tested. The Agency uses GENEEC to calculate screening level EECs in water based on drift and runoff from a 10 hectare field to a 1 hectare wide and 2 meter deep water body. These EECs take into account degradation in the field prior to a rain event as well as degradation and partitioning in the pond.

Table 26. Estimated Environmental Concentrations (EECs) for Folpet applied to Avocados by Airblast.

Application Rate in lbs a.i./A (No. of applications.)	EEC (ppb)				
	Initial	4-day	21-day	56-day	90-day
3 (7)	159.49	39.87	7.59	2.85	----------
3(1)	90.54	22.64	4.31	1.62	----------

i. Freshwater Fish

Risk quotients for freshwater fish are given in Table 27 below. Risk quotients for freshwater fish were calculated according to the following equations:

$$\text{Acute RQ} = \frac{\text{initial EEC}}{\text{LC50}}$$

Where the LC50 for rainbow trout, the most sensitive species, is 15 ppb.

$$\text{Chronic RQ} = \frac{\text{56-day EEC}}{\text{Geom. mean of NOEC and LOEC}}$$

Where the geometric mean is of the NOEC from the fish early life-cycle and of the LOEC of 8.1 ppb for the fathead minnow.

Table 27. Risk Quotients (RQs) for Freshwater Fish

Application Rate, lb a.i./A	Number of applications.	Acute RQ	Chronic RQ
3	7	10.6	< 1.0
3	1	6.0	< 1.0

Air blast applications of folpet, at the maximum label rates for avocado, are expected to exceed high acute risk, restricted use, and endangered species LOCs for fish. Chronic risk to fish is not expected based on the MATC (geometric mean of the NOEL and LOEL) for growth effects derived from fathead minnow fish full life when compared to the EEC averaged over 56 days.

Tests with the PI degradate on freshwater fish reported LD_{50} values of 49 ppm for rainbow trout and 38 ppm for bluegill sunfish. No LOC for this degradate would be exceeded with the proposed use of folpet on avocado in Florida.

ii. Freshwater Invertebrates

Risk quotients for aquatic invertebrates are given in Table 28 below. Risk quotients for freshwater invertebrates were calculated according to the following equation:

$$\text{Acute RQ} = \frac{\text{initial EEC,}}{\text{LC50}}$$

Where the LC50 for *D. magna*, the most sensitive species, is 20 ppb.

The Chronic RQ was not calculated because the chronic NOEL was not reported.

Table 28. Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate (lb a.i./A) / no. of applications.	Acute RQ	Chronic RQ
Avocado (3)/7	8.0	Not calculated, no data available
Avocado (3)/1	4.5	Not calculated, no data available

Air blast applications of folpet, at the maximum label rates for avocado, are expected to exceed high acute risk, restricted use, and endangered species LOCs for freshwater invertebrates. Chronic risk to freshwater invertebrates cannot be calculated from the data submitted.

Tests with the PI degradate on *Daphnia magna* reported an LD_{50} value of 39 ppm. No LOC for this degradate would be exceeded with the current use of folpet on avocado in Florida.

iii. Estuarine and Marine Animals

As described previously in this document, the current location of the avocado growing region in Florida is unlikely to present a nontarget exposure scenario for estuarine and marine organisms. The risk assessment for estuarine and marine animals used a conservative model to predict the maximum amount of folpet that could occur in surface water following air blast applications to avocados at the maximum label rates. The risk quotients calculated by this method showed a potential concern for acute risks to estuarine and marine animals and risks to endangered species. However, as stated previously, actual exposure to estuarine and marine animals is extremely unlikely. If the folpet registration were expanded to include other use sites, risk to estuarine organisms could be a potential concern.

Tests with the PI degradate on Eastern oyster, Mysid shrimp, and Sheepshead minnow yielded LC_{50} values of 12.1, 13.8, and 47.7 ppm, respectively. No LOC for this degradate is likely to be exceeded with the proposed use of folpet on avocado in Florida.

d. Exposure and Risk to Nontarget Plants

There is no risk concern for terrestrial plants. There are neither phytotoxicity label statements or reports of nontarget phytotoxic effects, so there is no reason to test the toxicity of folpet on terrestrial plants. Further, exposure terrestrial plants is expected to be extremely limited.

The risk to aquatic plants cannot be determined at this time. Folpet shows high acute toxicity to the aquatic plant species tested; the EC50 for *S. subspicatus,* an alga is 0.1 ppm. Comparing this value to the maximum initial aquatic EECs shown earlier indicates a potential risk concern. However, as stated previously, actual exposure to aquatic plants is extremely unlikely given the limited use. If the folpet registration were expanded to include other use sites, risk to aquatic plants could be a potential concern. Additional data on aquatic plants would be required to support additional use sites. The Agency typically requires tests with five aquatic plant species.

e. Endangered Species

The Agency has concerns about the exposure of threatened and endangered species to folpet. Levels of concern (LOC) are expected to be exceeded for aquatic organisms exposed to single or multiple applications of this fungicide.

There are a number of endangered species in Dade County, Florida. These include the Everglades snail kite, whose primary diet consists of apple snails. Although folpet was considered practically nontoxic to avian species, the reported high toxicity of folpet to aquatic invertebrates requires measures to reduce the risk of folpet reaching bodies of water. These measures would include label advisories concerning drift potential when adjacent to apple snail habitat.

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.

f. Environmental Risk Characterization

Based on analysis of the data submitted, minimal non-target risks are expected by the use of folpet on avocados in Florida, with the possible exception of the endangered species mentioned above. None of the levels of concern (LOCs) for avian and mammalian species are expected to be exceeded at the maximum label application rates and frequencies. Although folpet is very highly toxic to freshwater fish and invertebrates, the avocado groves in Florida are spatially removed from water bodies (*e.g.*, Everglades, other wetlands, and the Atlantic Ocean). Additional uses would require new assessments of anticipated LOCs and adequacy of ecological toxicity data base. Although folpet residues appear to be mobile, folpet is not persistent in terrestrial or aquatic environments. Rapid degradation of folpet should limit the potential for off-site movement and accumulation in ground and surface waters.

Major degradates of folpet include PI and PAI. The environmental fate data suggest the phenyl-ring degradates of folpet are more persistent than parent folpet; the trichloromethyl moiety hydrolyzes rapidly to potentially form thiophosgene. Mobility of PI and PAI appears to be comparable to parent folpet. Thiophosgene dissipation is expected to be dependent on reactivity. Toxicity and exposure modeling indicate PI is orders of magnitude less toxic than parent to non-target animals and would not exceed LOCs, even for endangered species. No toxicity data are available for PAI.

The water resource assessment is based on the current labels, which restrict agricultural use of folpet to avocados in Florida. The limited potential use pattern for folpet on avocados in Florida is documented in the open literature. The 1992 Census of Agriculture lists only Brevard and Dade counties as having commercial acreage in avocado production. The total acreage for Brevard County is 5; the total acreage for Dade County is 5829. There were 585 avocado orchards in Dade County. This yields an average avocado orchard size of approximately 10 acres.

Dietary exposure through drinking water is likely to be greatly limited because of folpet's limited use area and its environmental fate properties (e.g., rapid hydrolysis). Therefore, Tier 1 modeling for folpet for the water resource assessment is considered conservative, because the extent of the use pattern and major routes of folpet dissipation (foliar dissipation processes) were not considered in this assessment. The SCI-GROW groundwater screening model predicts that the maximum acute and chronic concentrations of folpet are each 0.026 µg/L. Tier 1 surface water modeling predicts that the maximum acute concentrations of folpet is 159 µg/L and the maximum 56 average day annual chronic concentration of folpet is 2.6 µg/L. Tier 1 surface water modeling for the degradate phthalimide predicts that the maximum acute and chronic concentrations for phthalimide are both 219 µg/L.

Further characterization of the use area indicates that Dade County has extensive surface water areas (e.g., Everglades) and shallow ground water. There are no lakes in the avocado growing region. The avocado groves closest to estuarine marine environments are 5 to 6 miles from the coast. However, the folpet use area is approximately 3 miles from the Everglades. Because the folpet use area is not directly adjacent to large surface water bodies, direct deposition of folpet into surface water is expected to be

dependent on long-range spray drift. Because folpet is a foliar-applied fungicide, it is reasonable to assume that foliar interception will further reduce the environmental loading of folpet. Therefore, the Agency believes that long range spray drift of folpet is unlikely at this time.

The non-food uses for folpet include incorporation of the fungicide into paints and stains. The potential of leaching to aquatic systems could be a concern if folpet were used inadvertently in products designed to protect wood in contact with soil or water. However, folpet undergoes rapid hydrolysis, making it unsuitable for use in antifoulant paints. Further, there is a label restriction against release to water.

Limited acreage and spatial isolation are two of the mitigating factors limiting the potential risk to aquatic organism from the use of folpet on avocados in Florida. Agricultural practice may also be a factor.

In summary, acute and chronic ecological effects are not anticipated from folpet use at this time. Minimal acute and chronic effects are anticipated from avian and mammalian species exposed to folpet residues, at the maximum label rates, resulting from the use of this product on avocados in Florida. Estimated environmental concentrations (EECs) for this application are below either the no effect levels (NOELS) or the maximum dosing levels for tested avian and mammalian species. Folpet is also considered relatively nontoxic to honeybees.

Folpet is acutely toxic to both fish and aquatic invertebrates. Acute LOCs are above the level of concern for all aquatic animals tested, but chronic LOCs should not be exceeded for both fish and aquatic invertebrates. Since folpet degrades rapidly, a complete toxicity profile should include an analysis of the major, and relatively more stable, degradates. One degradate already tested, PI, was shown to be only slightly toxic to aquatic animals.

There are a number of endangered species in Dade County, FL. These include the Everglades Snail Kite, whose primary diet consists of apple snails, which may be endangered if exposed to folpet because folpet has been shown to be highly toxic to other aquatic invertebrates. However, the treated avocado groves are 3 miles from the Everglades. Therefore, the most likely route of exposure to snails would be long range spray drift, which can not be quantified at this time. The current spray drift label advisory should be continued. Additional drift mitigation practices may be identified following review of the Spray Drift Task Force database.

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 an active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e. active ingredient specific) data to support reregistration of products containing folpet as an active ingredient. 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 folpet for use on avocados in Florida and in sealants and coatings (such as caulking, paints, and stains). Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of folpet.

These data were also sufficient to allow the Agency to determine that folpet can be used on avocados in Florida and in sealants and coatings without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that the products registered for these specific uses containing folpet as the sole active ingredient are eligible for reregistration. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the review and evaluation of the data required for reregistration, the current guidelines for conducting acceptable studies to generate these data, and published scientific literature. Although the Agency has found that all uses of folpet 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 folpet, 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 folpet, the Agency has sufficient information on the health effects of folpet and on its potential for causing adverse effects in fish, wildlife, and the environment. The Agency has determined that folpet products, labeled and used as specified in this Reregistration Eligibility Decision Document, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency concludes that products containing folpet for use on Florida avocados and for use in sealants and coatings (such as caulking, paints, and stains) are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that use of folpet on Florida avocados and in coatings and sealants are eligible for reregistration under the conditions specified in this Reregistration Eligibility Decision. The

following uses of folpet are ineligible for reregistration because the data requirements for reregistration have not been fulfilled: apples, cranberries, cucumbers, grapes, lettuce, dry bulb onions, strawberries, tomatoes, and ornamental plants. Only two folpet products (EPA Reg. Nos. 66222-8 and 7401-231) are registered for these ineligible uses. Both of these products have been suspended for several years and the registrants have recently requested voluntary cancellation of both registrations. The Proposed Notice of Cancellation was published in the *Federal Register* on August 4, 1999 [FRL 6092-6; OPP 66269] for a 180 day comment period. The Agency's Reregistration Decision regarding folpet assumes that these uses will be canceled in the near future.

C. Regulatory Position

To lessen the risks posed by folpet, EPA is requiring the following mitigation measures for folpet-containing products:

- Gloves and dust/mist respirator to reduce exposure and risk to workers adding the wettable powder to sealants and coatings during the manufacturing process;
- Protective clothing requirements for ready to use products, including long sleeve shirt, long pants, shoes, and socks;
- Labeling changes to lessen risks to nontarget aquatic organisms, as provided in Section V of this document; and
- User safety requirements and recommendations as well as application restrictions for non-WPS products.

The following is a summary of the Agency's regulatory position and rationale for managing risks associated with the use of folpet. 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. Population

EPA has determined that the established tolerances for folpet, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water. Section 408(b)(2)(D)(v) of the Food Quality Protection Act 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. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

At this time, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments; however, there are pesticides for which the common mechanism issues can be resolved. For example, there are 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. There are also pesticides that produce a common toxic metabolite, in which case common mechanism of activity will be assumed.

Captan and folpet share a common metabolite, thiophosgene, which is believed to be responsible for the carcinogenic effects observed with both compounds. Thiophosgene is a highly reactive, short-lived species which is produced in the gut and believed to cause tumors through the irritation of the duodeum. Because it is so short lived, its residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult at this time to relate exposures of captan to those of folpet since the rate of formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worse case estimate. When this is done, the risks do not exceed the Agency’s level of concern.

The Agency considers residential postapplication exposure to folpet from its use in sealants and coatings to be negligible because dermal and inhalation exposures are likely to be minimal. Therefore, EPA has considered only residential handler exposure together with dietary and drinking water exposures in its aggregate risk assessment.

In assessing acute aggregate dietary risk, EPA used a NOAEL of 10 mg/kg/day from a developmental study in rabbits. Because the selected endpoint is from a developmental toxicity study, the

sub-population of females, 13-50 years old, is the subgroup of interest. The acute dietary risk assessment was a highly refined, and therefore reasonably realistic, probabilistic (Monte Carlo) assessment that used anticipated residues and percent crop treated data. EPA estimates that residues of folpet in diets of females 13-50 years old accounts for 25% of the acute PAD. This leaves 75% of the acute PAD for aggregate risk. The DWLOC corresponding to 75% of the acute PAD is 670 ppb. Because the modeled ground water concentration is only 0.06 ppb and the modeled peak surface water concentration is 156 ppb, aggregate acute exposure and risk are not of concern.

Short and intermediate term aggregate risk estimates do not exceed the Agency's level of concern. Short and intermediate term aggregate risk estimates considered only two potential homeowner exposure scenarios: application of Ready-to-Use paint or stain with either a paint brush or an airless sprayer. The highest exposure, from the airless sprayer, represents a short-term MOE of 407. The chronic dietary exposure from folpet represents less than 1% of the chronic PAD. This leaves 99% of the PAD available for aggregate risk, which corresponds to short-term DWLOC of 228 ppb available for water. The modeled 56-day GENEEC value is 1 ppb, and the modeled concentration of folpet in groundwater is 0.06 ppb. Because the short-term DWLOC is greater than the modeled concentrations of folpet in surface or groundwater, the short-term aggregate risk is not of concern.

The Agency used different exposure assumptions than those described above to estimate the chronic aggregate dietary risk from folpet residues in food and water. The chronic dietary risk assessment used percent of imported crop treated estimates and less refined, tolerance level residue values. The drinking water assessment used modeling, as above, to predict ground and surface water concentrations of folpet. Chronic dietary exposure to the US population accounts for less than 1% of the chronic PAD. This leaves 99% of the chronic PAD for aggregate risk. The DWLOC corresponding to 99% of the chronic PAD is 890 ppb, which is far greater than the modeled groundwater concentration of 0.06 ppb and the modeled surface water concentration of 3 ppb. Therefore, the Agency concludes that the aggregate chronic exposure and risk are not of concern.

As stated previously, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst case estimate. For captan, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 1.3×10^{-7}. For folpet, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 9.8×10^{-8} . If these two risks are added together the total risk is 2.3×10^{-7} The aggregate cancer Drinking Water Level of Comparison ($DWLOC_{cancer}$) based on this total cancer risk estimate is 11 ppb, using the captan Q_1^* of 2.4×10^{-3} . The estimated environmental concentration (EECs) for folpet are 1 ppb for surface water and less than 1 ppb for ground water. The EECs for captan are 4 ppb for surface water and less than 1 ppb for ground water. The largest EEC of 4 ppb is less than the DWLOC, the Agency's level of concern. This aggregate assessment is for dietary exposure only. The tumor of concern occurs in the GI tract (duodenum/jejunum-ileum) as a result of oral dosing. The relevance of dermal exposure to a GI tract tumor is unknown at this time. Thus, the Agency concludes that an aggregate cancer risk estimate considering dietary exposure (food and water) only for captan and folpet based on their common

metabolite thiophosgene is appropriate.

b. Determination of Safety for Infants and Children

The Agency has determined that the established tolerances for folpet, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm 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 the toxic effects of folpet residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from folpet residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on the current data requirements, folpet has a complete database for developmental and reproductive toxicity. Reliable studies cited earlier in this document indicate limited concern for special sensitivity of young organisms to folpet (see Section IIIb). However, the Agency has determined that the Safety Factor can be reduced to 3X based on the developmental and reproductive toxicity studies available for folpet, as described previously in Section III(B)1(d) of this document. The Agency has retained a 3X FQPA safety factor to ensure adequate protection of infants and children. This FQPA safety factor applies only to females 13-50 for acute and acute and short-term exposures. Therefore, the Agency has concluded that a total uncertainty factor of 300 is adequate to protect infants and children. This uncertainty factor of 300, which includes the FQPA 3X, was incorporated into the acute dietary and short-term residential risk assessments for females 13-50.

The Agency has not yet made a final decision concerning the possible common mechanism of toxicity and the potential for cumulative effects of folpet and other compounds. Also, the Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, captan and folpet will be revisited to assess the cumulative effects of both fungicides. Therefore, for the purposes of the tolerance reassessments in this RED document, EPA has considered the risks of folpet only.

During the early stages of the FQPA implementation process, the Agency recognizes that some decisions will be made as if FQPA were fully implemented. Decisions made on a case-by-case basis are not intended to set broad precedent regarding the application of FQPA to other Agency regulatory determinations nor are these meant to constrain the Agency as it proceeds with further policy development and future rulemaking. Therefore, the Agency reserves the right to reconsider actions or decisions described in this RED.

c. Endocrine Disruptor Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inerts or inactive ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of folpet and end-use products for endocrine effects may be required.

2. Tolerance Reassessment

As part of EPA's reregistration eligibility decision for folpet, all agricultural (except avocado), ornamental, and greenhouse registrations will be voluntarily canceled. The registrants have requested voluntary cancellation of EPA Registration 66222-8 and 7401-231, which were suspended due to lack of supporting data. The following uses will be canceled: apples, cranberries, cucumbers, grapes, raisins, lettuce, melons, dry bulb onions, strawberries, tomatoes, and ornamental and greenhouse uses. However, the registrant is supporting import tolerances for these commodities. For some commodities, the import tolerances will be lower than the old tolerance with a US registration because the import tolerances are based on different use information than was used previously. A new tolerance will be established for imported raisins because residue data show that folpet concentrates in raisins.

For import tolerances, or tolerances without a US registration, EPA requires the same technical chemistry and toxicology data as for a domestic tolerance. In addition, EPA requires residue chemistry crop field trials that are representative of growing conditions in exporting countries. The data required to support these import tolerances are substantially complete. To support the import uses listed above, the following additional data are needed: storage stability data on cucumbers, melons, and tomatoes; analytical method for apples.

Tolerances for residues of folpet in/on plant raw agricultural commodities (RACs) are currently expressed in terms of folpet *per se* [40 CFR §180.191]. No food/feed additive tolerances have been established for residues of folpet. A summary of the folpet tolerance reassessment and recommended modifications in commodity definitions are presented in the following table.

Table 29. Tolerance Reassessment Summary for Folpet

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.191:			
Apples	25.0	5.0	Residue data support lower tolerance. Import only. No U.S. registrations for this commodity. Analytical method data are required.
Avocados	25.0	25.0*	Regional registration for Florida only. Storage stability data are required.
Cranberries	25.0	15.0	Residue data support lower tolerance. Import only.
Cucumbers	15.0	15.0*	Import only. Storage stability data are required.
Grapes	25.0	50.0	Residue data support higher tolerance. Import only.
Lettuce	50.0	50.0	Import only.
Melons	15.0	15.0*	Import only. Storage stability data are required.
Onions, dry bulb	15.0	2.0	Residue data support lower tolerance. Import only.
Raisins	none	80.0	New tolerance required because residue data show folpet concentrates in raisins. Import only.
Strawberries	25.0	5.0	Residue data support lower tolerance. Import only.
Tomatoes	25.0	25.0	Import only.

* The available data indicate that re-assessment of the tolerance at its current level is appropriate. Tolerance will be re-evaluated upon submission of required storage stability data.

Tolerances Listed Under 40 CFR §180.191:

Avocados is the only commodity presently being supported in the U.S. Use of folpet on avocados is limited to the State of Florida. As part of the reregistration eligibility decision, the avocado tolerance will be amended to indicate that it is limited to a regional registration for the state of Florida . As such, folpet use on avocados will be limited to Florida. Additional data would be required to support folpet use on avocados outside the state of Florida or use on other agricultural commodities.

Codex Harmonization

The Codex Alimentarius Commission has established temporary maximum residue limits (TMRLs) for folpet residues in/on various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1997*). The Codex residue definition and the U.S. tolerance expression for folpet are currently compatible, as each includes only the parent, folpet. A comparison of the Codex TMRLs and the corresponding U.S. tolerances is presented in the table below.

Table 30. Codex Temporary Maximum Residue Levels (TMRLs) and Applicable U.S. Tolerances

Commodity (As Defined)	Codex TMRL (mg/kg)	Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Cucumber	2 0.5*	15	Storage stability data being generated for import tolerance
Grapes	2 10*	50	U.S. import tolerance cannot be made compatible with proposed MRL, based on residue data submitted to Agency
Potato	0.02	None	
Strawberry	20 5*	5	Proposed modification and import tolerance are compatible

* Proposed amendment to existing limit

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex TMRLs:

- The reassessed grape tolerance cannot be made compatible with the existing MRL or the proposed modification because different residue data were used to establish the MRL. the Agency recommends that the registrant submit the residue data used by the Agency to establish the grape tolerance to Joint Meeting on Pesticide Residues (JMPR) for further consideration.

- Additional information on storage stability is required to support an import tolerance for cucumbers. Compatibility with the Codex MRL will be addressed when a final recommendation for a U.S. tolerance is made.

3. Human Health Risk Mitigation

a. Acute Dietary Mitigation

Acute dietary exposure is below the Agency's level of concern for the population of concern (females 13-50 years of age). At the 99.9th percentile, acute exposure through food to females 13-50 years occupies 25% of the acute PAD. Therefore, no additional mitigation is required.

b. Chronic Dietary Mitigation (non-cancer)

The chronic dietary risk from folpet is below the Agency's level of concern. The most exposed group is non-nursing infants less than 1 year old. The exposure to this group occupies less than 1% of the chronic PAD using the reassessed tolerances and occupies 1% of the chronic PAD with the current tolerances. No additional mitigation is required.

c. Carcinogenic Mitigation

The dietary cancer risk for folpet is below the Agency's level of concern. The upper bound dietary cancer risk was calculated to be 7 X 10^{-7} for all registered uses of folpet, assuming residues at the tolerance level and including refinements such as processing factors and percent crop treated data. No additional mitigation is required.

d. Worker Mitigation

Adding wettable powder to sealants and coatings during manufacturing process: The margin of exposure (MOE) to workers involved in the manufacture of folpet-containing sealants and coatings is of concern. For short-, intermediate-term, and chronic exposure durations, the total MOEs range from 15 to 17 under baseline conditions (long sleeve shirt and long pants). Cancer risk to these workers ranges from 4.5 to 9.1 X 10^{-5}. These risks can be mitigated to an acceptable level with the addition of chemical resistant gloves and a dust/mist respirator. Cancer risk after mitigation is 4.5 X 10^{-5}; total MOE ranges from 120 to 130. If available, engineering controls such as closed loading systems are an adequate substitute for the PPE.

Airblast application: The total MOE to workers mixing/loading/applying wettable powder for airblast application of folpet to avocados range from 1400 to 3300 under baseline conditions (i.e., long-sleeved shirt, long pants, shoes, and socks). Estimated cancer risk for these mixer/loaders/applicators range from 1.9 x 10^{-7} to 2 x 10^{-6}. Therefore, no additional mitigation is required.

Post-application exposure to avocado harvesters: Since folpet is toxicity category II for inhalation exposure and eye irritation, a 24-hour restricted entry interval (REI) is required for avocado harvesters. Early entry PPE is required for any workers who enter treated avocado orchards before the 24-hour REI.

Applying folpet-containing sealants and coatings: The total MOE for workers applying folpet-containing sealants and coatings is not of concern to the Agency. Of the possible scenarios, the highest exposure is to workers applying a stain with an airless sprayer, which results in an MOE of 212. The estimated cancer risk to these workers is $6 \times 10^{-6.}$ No additional means of mitigating cancer risks are practical; therefore, no additional mitigation is required.

The following table summarizes the personal protective equipment (PPE) that are required for handlers for each use scenario of folpet. These PPE are required either to mitigate a risk that was identified during the reregistration process, or because the risk assessment supporting reregistration assumed that these PPE were being used by pesticide handlers or applicators.

Table 31. Summary of Required Handler Personal Protective Equipment

Exposure Scenario	Baseline* PPE Required	Additional PPE Required	Engineering Controls	Reentry Interval (REI)
Adding WP to Paint at the Manufacturing Process	Yes	Chemical-resistant gloves, dust/mist respirator	None	N/A
	Yes	None	Yes	N/A
Mixing/Loading WP for Airblast Application to Avocados	Yes	None	None	N/A
Applying Liquids with an Airblast Sprayer to Avocados	Yes	None	None	24 Hours
Applying Ready-to-Use with a Paint Brush	Yes	None	None	N/A
Applying Ready-to-Use with an Airless Sprayer	Yes	None	None	N/A
Applying Ready-to-Use with a Paint Roller**	Yes	None	None	N/A
Applying Ready-to-Use as a Wood Dip Treatment**	Yes	None	None	N/A

* Baseline PPE includes long sleeve shirt, long pants, shoes, and socks.

** Although no data were available to assess the exposure from these scenarios, the Agency does not expect the risk to be significantly higher than the that of the paint brush scenario. These data are being called in with this RED document, but are considered confirmatory.

e. Residential Mitigation

Residents (homeowners) may be exposed to folpet in while applying Ready-to-Use sealants and coatings containing folpet. The MOE for these homeowners ranges from 407 with application by airless

sprayer to 700 with application by paint brush. The cancer risk estimates for homeowners are 5.6 X 10^{-8} for application with an airless sprayer and 1.3 X 10^{-7} for application with a paintbrush. Risks from application of folpet-containing paint with rollers are expected to be comparable to risks from application with a paintbrush. Postapplication risks are expected to be negligible; therefore, nonoccupational residential risks are not of concern.

f. Drinking Water Mitigation

The Agency's upper bound estimates of acute, chronic, and lifetime (carcinogenic) drinking water exposure are below the corresponding Drinking Water Level of Comparison (DWLOC). Therefore, the risk from drinking water is below the Agency's level of concern. No additional mitigation is required.

g. Aggregate Mitigation

As discussed earlier, aggregate acute or chronic food and drinking water exposures are not expected to exceed 100% of the acute or chronic PAD, respectively. Likewise, aggregate food, water, and residential exposure over a lifetime are not expected to exceed a total estimated cancer risk of 1 x 10^{-6}. Therefore, the aggregate cancer risk, including drinking water, is below the Agency's level of concern. No additional mitigation is required.

4. Ecological Risk Mitigation

The ecological risk assessment and risk mitigation recommendations for folpet are based on the present limited use of folpet. At present, the only potential ecological risks are from the use of folpet on avocados in Florida. As stated previously, only a very small percentage of Florida avocados are treated with folpet.

a. Risk Mitigation for Nontarget Terrestrial Animals

Acute and chronic risks to birds and mammals from folpet are not of concern, even at maximum label application rates and frequencies. Folpet also does not appear to pose a risk to honeybees or other insects. Therefore, no additional risk mitigation for nontarget terrestrial animals is required.

b. Risk Mitigation for Nontarget Aquatic Animals

Folpet is highly toxic to most aquatic animal species tested. Based on toxicity test results and results of conservative modeling of folpet concentrations in water, airblast application of folpet to avocados in Florida are expected to exceed high acute risk LOCs for all aquatic animals. Because folpet is applied directly to leaves of avocado trees, only a small amount of folpet will be available for long range spray drift to water. Chronic LOCs are not expected to be exceeded for fish or aquatic invertebrates.

Folpet degrades rapidly in water to PI and PAI. The degradate PI has been shown to be only slightly toxic to aquatic animals. No toxicity data are available on PAI. However, since PAI is not exected to be toxicologically significant and usage is limited to two counties in Florida, no additional data will be required at this time. However, if the use pattern changes, the Agency may reconsider this position.

Because of the rapid degradation of folpet in water and the limited folpet use area, the Agency does not believe that these risks are of concern. No additional mitigation is required.

The current spray drift label advisory should be continued. Additional drift mitigation practices may be identified following review of the Spray Drift Task Force database.

c. Risk Mitigation for Nontarget Aquatic Plants

A full plant exposure and risk assessment cannot be done with the existing data. Because of the limited use area, no additional data or mitigation are required at this time. However, additional aquatic plant testing would be required with any expansion of folpet use.

d. Risk Mitigation for Endangered Species

The Agency has concerns about the exposure of threatened and endangered species to folpet. Levels of concern (LOC) are expected to be exceeded for aquatic organisms exposed to single or multiple applications of this fungicide. There are a number of endangered species in avocado growing regions in Florida. These include the Everglades snail kite, whose primary diet consists of apple snails. Although folpet is highly toxic to aquatic invertebrates, such as apple snails, the nearest avocado groves are approximately 3 miles from the Everglades. Therefore, the most likely route of exposure to snails would be long range spray drift, which is unlikely to occur and which can not be quantified at this time. The current spray drift label advisory should be continued. Additional drift mitigation practices may be identified following review of the Spray Drift Task Force database. After its review of the new studies, the Agency will determine whether a reassessment of the potential risks to nontarget organisms is warranted.

5. Occupational (both Worker Protection Standard and non-WPS) Labeling Rationale

During the reregistration process, EPA considers all relevant generic and product-specific information to decide what protections and risk mitigation are needed for all products. Products may be used in various occupational settings, which may or may not be covered by the Worker Protection Standard (WPS).

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses covered by the WPS. Uses covered by the WPS include all commercial and research uses on farms, forests, nurseries, and in greenhouses to produce

agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). The WPS covers not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. 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, some products containing folpet are intended primarily for occupational use and some are intended primarily for homeowner use. Of the occupational uses, only the avocado use is covered by the WPS.

a. Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

For each end-use product, PPE requirements for pesticide handlers will be determined by comparing the PPE requirements based on the toxicity of the active ingredient, as listed in the earlier table, with the PPE required based on the acute toxicity of the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) would apply to the end-use product.

b. Post-Application/Entry Restrictions

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REIs) for all uses covered by the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS. For folpet, a 24-hour REI is required because folpet is classified as Toxicology Category II for acute inhalation toxicity and for

eye irritation.

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. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

For folpet, EPA has determined that no regulatory action is needed as the result of acute or other adverse effects of the active ingredient. The early-entry PPE requirements will be established on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the end-use products.

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 folpet. For the specific labeling statements, refer to Section V of this document.

6. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED.

Currently, the Agency is developing a crop-based program ("The Endangered Species Protection Program") for the protection of these species. Limitations in the use of folpet may be required to protect endangered and threatened species, but these limitations have not been defined and may be specific to the formulation and use site. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. EPA is in the process of developing county-specific bulletins that specify measures to

protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has completed and distributed over 300 county bulletins.

7. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling as specified in section V . The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method:

"Do not allow this product to drift"

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements, responses and labeling changes 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 folpet for the eligible uses has been reviewed and determined to be substantially complete. However, the following confirmatory data must be provided to support the continuing registration:

OPPTS Guideline	OPP Guideline	Study Title
830.7050	None	UV/Visible Absorption for the PAI
860.1200	171-3	Direction for Use
860.1380	171-4(e)	Storage Stability for avocados, cucumber, and melon
860.1480	171-4(j)	Magnitude of the Residue in Meat and Milk (Ruminant Feeding Study)
850.1300	72-4(b)	Chronic *Daphnia* Toxicity
870.3700	83-3(b)	Prenatal Developmental Toxicity in the New Zealand White Rabbit
875.1100/1200 or 875.1300/1400	231 and 233 or 232 and 234	Exposure Monitoring for application with wood dip and paint roller

As previously mentioned, these data are confirmatory; i.e., they are not expected to change the conclusions of this RED.

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 MUP labeling must bear the labeling contained in the table at the end of this section.

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

Label changes are necessary to implement mitigation measures outlined in Section IV above. These changes include planting information for avocados to be consistent with the residue field trial data, updated PPE restrictions, and ecological restrictions.

3. Required Labeling Changes Summary Table

The summary of required labeling changes appears on next page.

Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Formulation Uses: 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	"Only for formulation into a fungicide for the following use(s) [fill blank only with those uses that are being supported by 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 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)."	
Environmental Hazards Statements required by the RED and Agency label policies	"This chemical is highly toxic fish and aquatic 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements following Hazards to Humans and Domestic Animals
End Use Products Intended for Occupational Use (WPS)		
RED PPE Requirements* for wettable powder products registered for use on avocados	"Personal Protective Equipment (PPE)" "Applicators and other handlers must wear: --Long-sleeved shirt and long pants, --shoes plus socks"	Precautionary Statements immediately below or after the Hazards to Humans and Domestic Animals.
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements immediately below or after PPE Requirements
User Safety Recommendations	"User Safety Recommendations"	Precautionary Statements

Environmental Hazards	"Environmental Hazards" "This chemical is highly toxic to fish and aquatic invertebrates. Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements immediately below or after User Safety Recommendations box
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. "Only protected handlers may be in the area during application." "Do not allow this product to drift." For any requirements specific to your state or tribe, contact the agency responsible for pesticide regulation.	Directions for Use directly above Agricultural Use Requirements box
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:" -- coveralls, -- chemical-resistant gloves -- shoes plus socks -- protective eyewear	
End Use Products Intended for Occupational Use (Non-WPS)		
RED PPE Requirements* for Industrial Use Powder Products add to Coatings and sealants.*	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." "Applicators and Other Handlers must wear: --Long-sleeved shirt and long pants, --Shoes plus socks" --Chemical-resistant gloves [such as (registrant insert correct gloves as per the WPS)] --Respirator with a dust/mist filter (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH-approved respirator with any N, R, P, or HE filter."	Precautionary Statements below or after the "Hazards to Humans and Domestic Animals" Section of the label
User Safety Recommendations	(same statements as for wettable powder products registered on avocados)	Precautionary Statements immediately following

Engineering Controls	“Engineering Controls If this product is applied in a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled and if the system is functioning properly and is used and maintained in accordance with the manufacturer’s written operating instructions, handlers need not wear chemical-resistant gloves or a dust-mist-removing respirator, but must wear at least long-sleeve shirt, long pants, socks, and shoes.”	Immediately following User Safety Requirements
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."	Precautionary statement immediately following the PPE requirements/above User Safety Recommendations box
Environmental Hazards	“This chemical is highly toxic fish and aquatic 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.”	Precautionary Statement Immediately Following User Safety Recommendations box
Application Restrictions	"Do not apply this product in a way that it will contact workers or other persons." "Do not allow this product to drift."	Directions for Use
End Use Products Intended Primarily for Residential/Consumer/ Homeowner Use		
RED PPE Requirements	“Wear long sleeved shirt, long pants, shoes, and socks when handling or applying this product.	Precautionary Statements below or after the "Hazards to Humans and Domestic Animals" Section of the label
User Safety Recommendations	“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Users should remove clothing immediately after handling this product. As soon as possible, wash thoroughly	Precautionary Statements below or after the Personal Protective Equipment (must be placed in a box)

Environmental Hazards	"This chemical is highly toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water when disposing of equipment, washwater, or rinsate."	Precautionary Statements below or after the User Safety Recommendations box
Application Restrictions	"Do not apply this product in a way that it will contact any person or pet." "Do not allow this product to drift."	Directions for Use

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy;" *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell folpet products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. 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.

IV. APPENDICES

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year /cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
AVOCADO			Use Group: TERRESTRIAL FOOD CROP								
High volume spray (dilute), Foliar, Sprayer	WP	NA	3 lb A	*	7	NS NS	21 lb	14	24 h	FL	C94, CAU, H01(210)
Spray, When needed, Sprayer	WP	NA	1.5 lb A	*	NS	NS NS	NS	14	NS		CAA, CAC, CAS, CWH, CWK
NON-FOOD/NON-FEED											
ADHESIVES, INDUSTRIAL			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	RTU	W 4400	W 13200	*	NS	NS NS	NS	NS	NS		C18, C24, CWH, CWK, CWL
COATINGS, INDUSTRIAL			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	RTU	W 4400	W 13200	*	NS	NS NS	NS	NS	NS		C18, C24, CWH, CWK, CWL
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	RTU	W 4400	W 13200	*	NS	NS NS	NS	NS	NS		C18, C24, CWH, CWK, CWL
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS OUTDOOR			Use Group: OUTDOOR RESIDENTIAL								
Dip treatment, When needed, By hand	RTU	NA	.1269 lb 1K sq.ft	*	NS	NS NS	NS	NS	NS		C93
	RTU	NA	.2675 lb 1K sq.ft	*	NS	NS NS	NS	NS	NS		CAC
Dip treatment, When needed, Not on label	RTU	NA	.08316 lb 1K sq.ft	*	NS	NS NS	NS	NS	NS		C92, CAV, CWE, CWH

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS OUTDOOR (con't) Use Group: OUTDOOR RESIDENTIAL (con't)												
	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Wood surface treatment, When needed, Brush	RTU	NA	.1706 lb 1K sq.ft	*	NS	2/1 yr	NS	NS	6	NS		C04, C93, CWE, CWH
	RTU	NA	.08316 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CAV, CWE, CWH
	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
	RTU	NA	.1269 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C93
	RTU	NA	.2675 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAC
	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
	RTU	NA	.528 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAU, CAV, CWE, CWH
Wood surface treatment, When needed, Pad	RTU	NA	.528 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAU, CAV, CWE, CWH
Wood surface treatment, When needed, Roller	RTU	NA	.1706 lb 1K sq.ft	*	NS	2/1 yr	NS	NS	6	NS		C04, C93, CWE, CWH
	RTU	NA	.08316 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CAV, CWE, CWH

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS OUTDOOR (con't)				Use Group: OUTDOOR RESIDENTIAL (con't)								
	RTU	NA	.1269 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C93
	RTU	NA	.2675 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAC
	RTU	NA	.528 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAU, CAV, CWE, CWH
Wood surface treatment, When needed, Sprayer	RTU	NA	.1706 lb 1K sq.ft	*	NS	2/1 yr	NS	NS	6	NS		C04, C93, CWE, CWH
	RTU	NA	.08316 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CAV, CWE, CWH
	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
	RTU	NA	.2675 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAC
	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
	RTU	NA	.528 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAU, CAV, CWE, CWH
				Use Group: OUTDOOR RESIDENTIAL + INDOOR RESIDENTIAL								
Brush-on, Not on label, Brush	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Brush-on, Not on label, Roller	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Dip treatment, Not on label, Vat	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS OUTDOOR (con't) — Use Group: OUTDOOR RESIDENTIAL + INDOOR RESIDENTIAL (con't)												
Dip treatment, When needed, By hand	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Spray, Not on label, Sprayer	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Spray, When needed, Sprayer	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Wood surface treatment, When needed, Brush	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Wood surface treatment, When needed, Roller	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
Wood surface treatment, When needed, Sprayer	RTU	NA	.2957 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		CAS, CAV, CWE, CWH
WOOD PROTECTION TREATMENT TO FOREST PRODUCTS (SEASONED) — Use Group: TERRESTRIAL NON-FOOD CROP												
Dip treatment, When needed, Not on label	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
Wood surface treatment, When needed, Brush	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
Wood surface treatment, When needed, Sprayer	RTU	NA	.2197 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS		C92, CWH, CWK
End of USES ELIGIBLE FOR REREGISTRATION												

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
APPLE					Use Group: TERRESTRIAL FEED CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Delayed dormant, Sprayer	WP	NA	1 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK
					Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Delayed dormant, Sprayer	WP	NA	1 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK
CRANBERRY					Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Bloom, Sprayer	WP	NA	4.5 lb A	*	NS NS NS NS	10	NS					CAA, CAC, CAS, CWH, CWK, H01(30)
CUCUMBER					Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Directed spray, Foliar, Sprayer	WP	NA	4 lb A	*	NS NS NS NS	NS	NS					CAA, CAC, CAS, CWH, CWK
GRAPES					Use Group: TERRESTRIAL FEED CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Foliar, Sprayer	WP	NA	3 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK
					Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Foliar, Sprayer	WP	NA	3 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK
LEEK					Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Foliar, Sprayer	WP	NA	4 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	2 lb A	*	NS NS NS NS	7	NS					CAA, CAC, CAS, CWH, CWK

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
LETTUCE				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	2 lb A	*	NS	NS	NS	NS	NS	NS		CAA, CAC, CAS, CWH, CWK
MELONS, CANTALOUPE				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	4 lb A	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
MELONS, HONEYDEW				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	2 lb/100 gal	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	4 lb A	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
MELONS, MUSK				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	2 lb/100 gal	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
MELONS, WATER				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	2 lb/100 gal	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
ONION				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	4 lb A	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	2 lb A	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
SHALLOT				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION								

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
SHALLOT (con't)				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION (con't)							
Spray, Foliar, Sprayer	WP	NA	4 lb A	*	NS	NS	NS	NS	7	NS	CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	2 lb A	*	NS	NS	NS	NS	7	NS	CAA, CAC, CAS, CWH, CWK
TOMATO				Use Group: TERRESTRIAL FEED CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Foliar, Sprayer	WP	NA	2 lb/100 gal	*	NS	NS	NS	NS	7	NS	CAA, CAC, CAS, CWH, CWK
				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Spray, Foliar, Sprayer	WP	NA	2 lb/100 gal	*	NS	NS	NS	NS	7	NS	CAA, CAC, CAS, CWH, CWK
NON-FOOD/NON-FEED											
ORNAMENTAL HERBACEOUS PLANTS				Use Group: GREENHOUSE NON-FOOD CROP USES INELIGIBLE FOR REREGISTRATION							
Soil drench treatment, Transplant, Not on label	WP	NA	1 lb/100 gal	*	NS	2/1 yr	NS	NS	10	NS	CAA, CAC, CAS, CWH, CWK
Spray, Foliar, Sprayer	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	14	NS	CAA, CAC, CAS, CWH, CWK
Spray, Postplant, Sprayer	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	NS	NS	CAA, CAC, CAS, CWH, CWK
				Use Group: OUTDOOR RESIDENTIAL USES INELIGIBLE FOR REREGISTRATION							
Foliar treatment, Postplant, Hose-end sprayer	SC/L	NA	UC	*	NS	NS	NS	NS	3	NS	C24, CAG
Foliar treatment, When needed, Hose-end sprayer	SC/L	NA	UC	*	NS	NS	NS	NS	3	NS	C24, CAG

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL HERBACEOUS PLANTS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Spray, Foliar, Sprayer	WP	NA	1 lb/100 gal	*	NS	4/1 yr	NS	NS	14	NS		CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	3	NS		CAA, CAC, CAS, CWH, CWK
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: OUTDOOR RESIDENTIAL USES INELIGIBLE FOR REREGISTRATION								
Foliar treatment, At emergence, Hose-end sprayer	SC/L	NA	UC	*	NS	NS	NS	NS	3	NS		C24, CAG
Foliar treatment, Postplant, Hose-end sprayer	SC/L	NA	UC	*	NS	NS	NS	NS	3	NS		C24, CAG
Foliar treatment, When needed, Hose-end sprayer	SC/L	NA	UC	*	NS	NS	NS	NS	3	NS		C24, CAG
Soak, Cutting, Not on label	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS		C24, CAG
				Use Group: TERRESTRIAL NON-FOOD CROP USES INELIGIBLE FOR REREGISTRATION								
Soak, Cutting, Not on label	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	NS	NS		CAA, CAC, CAS, CWH, CWK
Spray, Foliar, Sprayer	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	7	NS		CAA, CAC, CAS, CWH, CWK
Spray, When needed, Sprayer	WP	NA	1 lb/100 gal	*	NS	NS	NS	NS	3	NS		CAA, CAC, CAS, CWH, CWK

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

RTU	: LIQUID-READY TO USE
SC/L	: SOLUBLE CONCENTRATE/LIQUID
WP	: WETTABLE POWDER

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 0630 [Folpet] Chemical 081601 [Folpet]

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APPLICATION RATE (CONT.)

cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C04 : Proper ventilation required.
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
C93 : Do not apply directly to water.
C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.
CAA : Do not apply to any body of water.
CAC : Keep out of lakes, streams, and ponds.
CAG : Do not apply where runoff is likely to occur.
CAS : Do not contaminate food or feed.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAV : Do not store or use in or around the home or home garden.
CWE : This product is highly toxic to birds, fish, and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed.
CWH : Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.
CWK : This product is toxic to fish.
CWL : Do not contaminate water, food, or feed by storage or disposal.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

FL : Florida

REENTRY INTERVAL ABBREVIATIONS

h : hour(s)

UNIT DESCRIPTIONS

A : acre
gal : gallon
lb : pound
sq.ft : square foot

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case folpet covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to folpet 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) 605-6000.

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 Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ABKMO	**00029463, 00057598, 00069464, 00074000, 00096475, 00144903, 00160424, 40119201, 40911201**
61-2A	**Start. Mat. & Mnfg. Process**	ABKMO	**40493602, 40493603, 40494202 40493604, 42332401, 00104841, 00109054, 00109055, 00133150, 00144903, 40119201**
61-2B	**Formation of Impurities**	ABKMO	**40493602, 40493604**
62-1	**Preliminary Analysis**	ABKMO	**42332400, 40750801**
62-3	**Analytical Method**	ABKMO	**40750801**
63-2	**Color**	ABKMO	**40493601, 42452601**
63-3	**Physical State**	ABKMO	**40493601, 42452602**
63-4	**Odor**	ABKMO	**40493601**
63-5	**Melting Point**	ABKMO	**40493601**
63-6	**Boiling Point**	ABKMO	**Not applicable**
63-7	**Density**	ABKMO	**40493601, 42470701**
63-8	**Solubility**	ABKMO	**40493601**
63-9	**Vapor Pressure**	ABKMO	**Not applicable**
63-10	**Dissociation Constant**	ABKMO	**Not applicable**
63-11	**Octanol/Water Partition**	ABKMO	**40493601**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	**pH**	ABKMO	**40493601**
63-13	**Stability**	ABKMO	**40493601, 42452607, 42832501**
63-14	**Oxidizing/Reducing Action**	ABKMO	Waived
63-17	**Storage stability**	ABKMO	42514101, 42868003, 42514201, 42868002
63-20	**Corrosion characteristics**	ABKMO	40493601, 42452606
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	AKMO	**00112793,00160000, 00137698***
71-1B	**Acute Avian Oral - Quail/Duck TEP**	AKMO	**00112793,00160000,**
71-2A	**Avian Dietary - Quail**	AKMO	**0012794**
71-2B	**Avian Dietary - Duck**	AKMO	**0012795**
71-4A	**Avian Reproduction - Quail**	AKMO	**00098004**
71-4B	**Avian Reproduction - Duck**	AKMO	**00098004, 00098005**
72-1A	**Fish Toxicity Bluegill**	AKMO	**40818804, 40094602*, 00074010***
72-1A	**Fish Toxicity Bluegill - PI degradate**	AKMO	**42122004**
72-1B	**Fish Toxicity Bluegill - TEP****	AKMO	**When Combined, MRIDs 4081884, 40818803, and 40098001 Satisfy Guideline**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
72-1C	**Fish Toxicity Rainbow Trout**	AKMO	**40818804, 40098001*, 40094602***
72-1C	**Fish Toxicity Rainbow Trout - PI**	AKMO	**42122002**
72-1D	**Fish Toxicity Rainbow Trout - TEP****	AKMO	**When Combined, MRIDs 4081884, 40818803, and 40098001 Satisfy Guideline**
72-2A	**Invertebrate Toxicity**	AKMO	**40844491, 00070507*, 00137697*, 40094602***
72-2A	**Invertebrate Toxicity - PI**	AKMO	**42122005**
72-2A	**Invertebrate Toxicity - PAI**	AKMO	**Guideline unfulfilled, new use may require additional studies**
72-2B	**Invertebrate Toxicity - TEP**	AKMO	**MRID 0007408**
72-3A	**Estuarine/Marine Toxicity - Fish**	AKMO	**40094602*, 42122007***
72-3B	**Estuarine/Marine Toxicity - Mollusk**	AKMO	**42122011*, Guideline unfulfilled, new use may require additional studies**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	AKMO	**42122006*, Guideline unfulfilled, new use may require additional studies**
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	AKMO	**42122007**
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	AKMO	**42122008*, Guideline unfulfilled, new use may require additional studies**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	AKMO	**42122006*, Guideline unfulfilled, new use may require additional studies**
72-4A	**Early Life Stage Fish**	AKMO	**43786301**
72-4B	**Life Cycle Invertebrate**	AKMO	**data gap, 42122013***
122-1A	**Seed Germination/Seedling Emergence**	AKMO	**00004423, 00006132, 00006473, 00007358**
122-1B	**Vegetative Vigor**	AKMO	**00011248, 00014515, 00021691, 00021693, 00104640, 00107563, 00113241, 00113242, 00107563, 00113241, 00113242, 00140166, 00140607, 00140905, 00140906,**
122-2	**Tier I Aquatic Plant Growth**	AKMO	**00137693**
122-3	**Tier II Aquatic Plant Growth (5 Species)**	AKMO	**Guideline unfulfilled, new use may require additional studies**
141-1	**Honey Bee Acute Contact**	AKMO	**00113613, 05001991**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ABKMO	**00144057**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ABKMO	**00141728**
81-3	**Acute Inhalation Toxicity - Rat**	ABKMO	**40592301**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
81-4	**Primary Eye Irritation - Rabbit**	ABKMO	**00160444**
81-5	**Primary Dermal Irritation - Rabbit**	ABKMO	**00160430**
81-6	**Dermal Sensitization - Guinea Pig**	ABKMO	**00160431**
82-1A	**90-Day Feeding - Rodent**	ABKMO	**00115269, 00125719**
82-1B	**90-Day Feeding - Non-rodent**	ABKMO	**00161315**
82-2	**21-Day Dermal - Rabbit/Rat**	ABKMO	**40750802**
82-4	**90-Day Inhalation - Rat**	ABKMO	**waived**
83-1A	**Chronic Feeding Toxicity - Rodent**	ABKMO	**00151560, 43640201, 00125718**
83-2A	**Oncogenicity - Rat**	ABKMO	**00157493, 40682501**
83-2B	**Oncogenicity - Mouse**	ABKMO	**00161315**
83-3A	**Developmental Toxicity - Rat**	ABKMO	**00132456, 00132452**
83-3B	**Developmental Toxicity - Rabbit**	ABKMO	**00160432, 00151490, 00156636**
83-4	**2-Generation Reproduction - Rat**	ABKMO	**00151489, 40051401, 40135901**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
84-2A	**Gene Mutation (Ames Test)**	ABKMO	**00160435, 00132582, 00149489, 00153085, 00162394,**
84-2B	**Structural Chromosomal Aberration**	ABKMO	**42122014**
84-4	**Other Genotoxic Effects**	ABKMO	**00148625, 00149567 & others**
85-1	**General Metabolism**	ABKMO	**42122017, 42122016**
85-2	**Dermal Penetration**	ABKMO	**42122018**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Dislodgeable Foliar Residue Dissipation**	ABKMO	**42122019**
133-3	**Dermal Passive Dosimetry Exposure**	ABKMO	**42122020, 44354802**
133-4	**Inhalation Passive Dosimetry Exposure**	ABKMO	**42122020, 44354802**
231	**Estimation of Dermal Exposure at Outdoor Sites**	ABKMO	**42122020**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	ABKMO	**42122020**
233	**Estimation of Dermal Exposure at Indoor Sites**	ABKMO	**41411801, 41411802**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
234	**Estimation of Inhalation Exposure at Indoor Sites**	ABKMO	**41411801, 41411802**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	AKMO	**40818801, 42451401**
161-2	**Photodegradation - Water**	AKMO	**42122021**
161-3	**Photodegradation - Soil**	AKMO	**42122026*, Guideline unfulfilled, new use may require additional studies**
161-4	**Photodegradation - Air**	AKMO	**waived**
162-1	**Aerobic Soil Metabolism**	AKMO	**42122022, 160422**
162-2	**Anaerobic Soil Metabolism**	AKMO	**42122023, 0160422-00160428***
162-3	**Anaerobic Aquatic Metabolism**	AKMO	**Waived**
162-4	**Aerobic Aquatic Metabolism**	AKMO	**Waived**
163-1	**Leaching/Adsorption/ Desorption**	AKMO	**42122025*, Guideline unfulfilled, new use may require additional studies**
163-2	**Volatility - Lab**	AKMO	**Waived**
164-1	**Terrestrial Field Dissipation**	AKMO	**42122027*, 42122028*, Guideline unfulfilled, new use may require additional studies**
165-4	**Bioaccumulation in Fish**	AKMO	**42122029, 42122030**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	AB	**42122032, 43024901, 43209901, 43550901, 43644501**
171-4B	**Nature of Residue - Livestock**	AB	**44807701, 4480702**
171-4C	**Residue Analytical Method - Plants**	AB	**43630001, 44029901, 44029902**
171-4D	**Residue Analytical Method - Animal**	AB	**Data gap**
171-4E	**Storage Stability**	AB	**43024902, 43190101, Data gap for avocados and**
171-4G	**Magnitude of Residues in Fish**	ABC	**Not applicable**
171-4J	**Magnitude of Residues - Meat/Milk**	AB	**Data gap**
171-4K	**Magnitude of Residue in Crop Plants (Crop Field Trials)**		
	Onions, dry bulb	A	**44235202**
	Tomatoes	A	**43796603, 43796604, 43796605, 43796606**
	Lettuce	A	**44235204**
	Cucumber	A	**43642301, 43598201, 4359802, 43774503, 44235207**
	Melons	A	**43796605, 43796606, 43774501, 44235203**
	Apples	AB	**44235209**

Data Supporting Guideline Requirements for the Reregistration of Folpet

REQUIREMENT		USE PATTERN	CITATION(S)
	Avocado	A	**42122031, 43024902, 43190101, 44296704**
	Cranberry	A	**44235201**
	Grape	A	**43814701, 43774507, 43775501, 43787001, 44235208**
	Strawberry	A	**44235205**
171-4L	**Magnitude of Residues in Processed Food**		
	Apples	AB	**44235212**
	Grapes	A	**44235210**
	Tomatoes	A	**44235211**

* MRID does not satisfy guideline requirement but provides some useful information.
** Three wettable powder studies combined satisfy guideline requirement for TEP in freshwater fish.
***Data gap for 2-week storage stability study under refrigerated conditions.

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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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: 703-605-6000).

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

FOLPET DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing folpet.

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 folpet). 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 Folpet 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 folpet are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on folpet are needed. These data are needed to fully complete the reregistration of all eligible folpet 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 Ms. Christina Scheltema at (703) 308-2201.

All responsades to this Notice for the generic data requirements should be submitted to:

Ms. Christina Scheltema, Chemical Review Manager
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Folpet

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.

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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.

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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: 703-605-6000).

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.

SECTION 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 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(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

FOLPET DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing folpet.

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 folpet. 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 Folpet 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 folpet are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on folpet 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 folpet 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 Ms. Moana Appleyard at (703) 308-8175.

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 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Folpet**

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.

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.

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EPA'S BATCHING OF **FOLPET** 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 **FOLPET** 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 (DCI) 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.

EPA Batching of End-Use Products for Folpet

Batch	EPA Reg. No.	Active Ingredients
1	1100-70	Folpet 88%
	10182-294	Folpet 88%
	11678-18	Folpet 88%
2	11678-29	Folpet 50%
	66222-7	Folpet 50%
No Batch	577-538*	Folpet 0.66%, TBTO 0.34%
	577-539*	Folpet 0.66%, TBTO 0.34%
	577-542	Folpet 0.44%, TBTO 0.3%
	1100-78	Folpet 44%
	6557-17	Folpet 0.75%, TBTO 0.81%
	7313-6	Folpet 0.5%, TBTO 0.5%
	8177-32	Folpet 0.3%, TBTO 0.5%
	8177-36	Folpet 0.3%, TBTO 0.5%
	39702-3	Folpet 0.7%, TBTO 0.3%

* Reg. Nos. 577-538 and -539 appear substantially similar with the possible exception of the resin. Therefore, upon review of further information, it may be possible for the Agency to place these two products together in a separate 'batch'. The registrant may wish to submit chemical composition information and/or other evidence that the resins are similar as to their acute hazards.

TBTO, Tributyltin oxide

Comments

The three products in Batch No. 1 contain technical grade folpet. The Reg. No. 1100-70 and 10182-294 products are each a 100% repackaging of the 11678-18 product. The Reg. No. 66222-7 product is a 100% repackaging of the Reg. No. 11678-29 product; i.e., the two formulation are equivalent.

Reg. No. 1100-78 cannot be placed in Batch 2, even though it contains folpet at 44% of the formulation by weight (compare 50% for the other products in Batch 2). Whereas the inert ingredients (other than the impurities associated with the production of folpet) in the Batch 2 products do not appear to be of major acute hazard concern, there is a moderate degree of concern regarding the inert ingredients in the 1100-78 product. Of some concern is the presence of the product's dispersing agent – the exact

composition of which is not known to the reviewer – and the product's mineral spirits, which are problematic for acute oral toxicity because of a possible aspiration hazard. In addition, the possibility of synergistic effects between the large quantity of mineral spirits in the 1100-78 product and one or more other chemicals in the product cannot be ruled out. The inert ingredients composition of 1100-78 differs significantly from that of the Batch 2 products.

With the exception of EPA Reg. Nos. 1100-78 and 7401-231, the products in the 'No Batch' group in the table above contain both folpet and bis(tributyltin) oxide (TBTO) as pesticidal active ingredients. Although this commonality might suggest that some of the No Batch products could be batched, this is not the case. First, the percentage folpet or TBTO in one product versus the percentage in another may be significant in several cases. Additionally, most of these products differ in several ways because of their many other ingredients. These 'inert' ingredients have several functions in the products. They are resins or binders, solvents or thinners, suspension or anti-settling or rheologic agents, fillers, extenders, pigments, tinting aids, wetting agents, de-foaming agents, drying agents, anti-skin agents, water repelling agents, and ultraviolet absorbing agents. Given the number and variety of inert ingredients in the No Batch products, it is not surprising that the product formulations differ significantly as to both the ingredients' chemical identities and their concentrations. Also, a given ingredient (such as a resin) may have its own formulation which differs from the formulation of a similar kind of ingredient in another product. In some cases, one ingredient (such as mineral spirits) in a product or product component may represent a significant acute hazard by one or more routes of exposure. In other cases, several differences among several ingredients in a product, each of which is present in a small quantity, may possibly add up to a significant difference in the acute hazard. Also note that, with so many chemicals present in each product, the possibility of synergistic effects among chemicals should not be ignored.

Because of the above considerations, the Agency has no way of knowing whether or not the studies conducted on one product in the No Batch group would adequately characterize the acute hazards of another product in the group. A possible exception to this, however, is found in Reg. Nos. 577-538 and 577-539. These two product formulations would appear substantially similar to each other if not for the differences in their resin components, which constitute a major percentage of the product formulations. These differences may or may not be significant. Therefore, the registrant may wish to submit chemical composition information and/or other evidence that the resins are similar as to their acute hazards.

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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 Registrants 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) 605-6000. 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: ace.orst.edu/info/nptn.

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.