United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-94-016
September 1994

Reregistration Eligibility Decision (RED)

Oryzalin

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 and active ingredient oryzalin. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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 ingredient(s) 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 are due 90 days from the date of receipt of this letter. The second set of required responses are 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.

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 Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Judith Coombs at (703) 308-8046.

Sincerely yours,

Louis P. True, Jr., Acting 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"**--A Product Specific Data Call-In is enclosed with this RED and must be completed and submitted within 90 days of receipt of this package. The response consists of a "Data Call-In Response" form and a "Requirements Status and Registrant's Response" form. Additional generic may also be required to confirm or support the assessment of the active ingredient. If generic data are required, Generic Data Call-Ins are being sent only to certain manufacturing use registrants. Generic Data Call-Ins are not being sent to end use product registrants. However, please note that instructions for completing the Data Call-Ins, which are incorporated as an Appendix to the RED, may address both generic and product specific data. If you are an end use registrant, be sure to follow the instructions for product specific data.

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 data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. 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 RED issuance date (the cover letter 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 delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer 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; 703-487-4650).

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

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

e. **Certification With Respect to Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

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 ALL DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-0186)**
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-0186)**
Office of Pesticide Programs (H7504C)
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

ORYZALIN

LIST A

CASE 0186

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

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ORYZALIN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Neil Anderson	Biological Analysis Branch
Gabe Patrick	LUIS
Ghulam Ali	Economic Analysis Branch

Environmental Fate and Effects Division

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Health · Effects · Division

Linda Kutney	Chemical Coordination Branch
Pat McLaughlin	Toxicology Branch II
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Paula Deschamp	Reregistration Support Chemistry Branch
Jeff Evans	Occupational and Residential Exposure Branch

Registration Division

Wesley Allen	Fungicide-Herbicide Branch
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Special Review and Reregistration Division

Judith Coombs	Reregistration Branch
Walter Waldrop	Reregistration Branch
Carol Stangel	Planning and Reregistration Branch

Office of Compliance Monitoring

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested

GLOSSARY OF TERMS AND ABBREVIATIONS

LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
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.
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method

GLOSSARY OF TERMS AND ABBREVIATIONS

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
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide oryzalin, 3,5-dinitro-N4,N4-dipropylsulfanilamide.

Oryzalin is a 2,6-dinitroaniline herbicide produced by DowElanco. It is used to control annual grasses and broadleaf weeds on berries, vine and orchard crops, Christmas tree plantations, commercial/industrial and recreation area lawns, golf course turf, residential lawns and turf, ornamental and/or shade trees, nonagricultural rights-of-way/fencerows, nonagricultural uncultivated and industrial areas, power stations, paths/patios and paved areas. Oryzalin is also used to control herbaceous plants, woody shrubs and vines. The end-use formulations of oryzalin are granular (0.4 to 1% + 1 other active ingredient [a.i.]), wettable powder (75%), water dispersible granules (60 - 85% + 1 other a.i.), emulsifiable concentrate (2.84 to 40.4%), flowable concentrate (40.4%), and formulation intermediate/liquid (40.4%). The registered products are applied by foliar spray, broadcast, band treatment by sprayer, aircraft, or low pressure ground equipment and spot treatment by spreader.

Oryzalin was first registered for use in the United States in 1974. A Registration Standard was issued in June, 1987 (NTIS# PB89-102396). Additional data were required in a 1991 Data Call-In Notice. Subsequent to issuing the Registration Standard, several agricultural crops were deleted and the only food crops remaining on oryzalin labels are berries, vine and orchard crops.

Reregistration Eligibility

The Agency has now completed its review of all generic data submitted on oryzalin in response to the 1987 Registration Standard and the 1991 Data Call-In requirements. The Agency has determined that all of the currently registered oryzalin products are eligible for reregistration **except** for products labelled for use on residential lawns and turf. The Agency does not have sufficient information to make an eligibility determination for residential lawn and turf uses. In order to develop an adequate database to support this use, the Agency is requiring that additional data be submitted.

Health Effects

The Agency has classified oryzalin as a group C carcinogen with a Q_1* of 1.3×10^{-1} $(mg/kg/day)^{-1}$. The Agency has a substantially complete database to assess dietary risk and reassess existing tolerances for oryzalin. The dietary exposure data support the reregistration of oryzalin for uses limited to berries, vine and orchard crops. A dietary risk assessment has been conducted using tolerance data and anticipated residue data for oryzalin. The chronic dietary exposure based on anticipated residue contribution (ARC) estimates are less than 1/5,000th of the RfD for each of the population groups and subgroups analyzed. Based on the same data, the excess dietary carcinogenicity risk estimate for the U.S. population is 8.1×10^{-7}. When oryzalin tolerances are revoked for unregistered commodities,

the upper bound cancer risk estimate is expected to be 4.5×10^{-7}. Technical grade oryzalin has been shown to be in toxicity category IV for acute oral toxicity and category III for acute dermal and inhalation toxicity.

The qualitative nature of oryzalin residue in plants is adequately understood; the terminal residues of concern in vine and orchard crops consist of unchanged oryzalin. Storage stability studies (guideline 171-4e) are underway for apples and grapes and are considered confirmatory to the existing storage stability data on oryzalin. Oryzalin processed food/feed studies for citrus and olives are also in progress and are considered confirmatory to the existing evidence that residues of oryzalin do not significantly concentrate upon processing.

Occupational and Residential Exposure

Chronic post-application exposure from residential lawns treated with oryzalin by professional landscape/lawn care personnel is of concern because oryzalin is a possible human carcinogen and is persistent. The Agency does not have sufficient information available to estimate post-application/reentry exposure for residential lawn and turf uses, and therefore, could not conduct an exposure assessment for these uses for purposes of calculating risk. Based on its cancer classification, the Agency is requiring that the Restricted Entry Interval (REI) be increased to 24 hours instead of 12 hours. The REI applies to those uses within the scope of the Worker Protection Standard (WPS). For occupational uses outside the scope of WPS, the Agency is requiring that reentry be prohibited until sprays have dried and dusts have settled. This reentry prohibition also applies to homeowner use products.

Because of the cancer classification and the oryzalin exposure assessment, active ingredient based minimum Personal Protective Equipment (PPE) requirements are warranted for all uses within the scope of WPS. In addition, products with non-WPS occupational uses must also include the same PPE. Further, because of uncertainties regarding exposure to homeowners and children following treatment, the Agency is requiring certain PPE for homeowners who mix, load, and apply oryzalin to home lawns. These requirements are outlined in Section IV and in Section V.

In addition, the Agency is requiring the following data for the reregistration of the residential lawn use: foliar dislodgeable residues (guideline 132-1a), soil dislodgeable residues (guideline 132-1b), estimation of dermal exposure (guideline 133-3), and estimation of inhalation exposure (133-4). These data will also be used to assess risks for commercial turf use. These data are necessary to make an eligibility decision for these uses. Reentry protection data for guidelines 132-1a, 133-3, and 133-4 are also required for oryzalin use on Christmas trees and field grown roses. Reentry data for Christmas trees and field grown roses are considered confirmatory and these uses are eligible for reregistration.

The Agency is requiring mixer/loader/applicator studies (guideline 231: Estimation of Dermal Exposure at Outdoor Sites, and guideline 232: Estimation of Inhalation Exposure at Outdoor Sites). These data are required to refine the risk to private and commercial

applicators using low-pressure handwand equipment, and will be considered confirmatory. For the commercial applicator (M/L/A) using a low-pressure handwand, the estimated excess cancer risk is 2.6×10^{-4} and for the private applicator, the risk is estimated to be 2.6×10^{-5}. Exposure below the knees is of particular concern with the use of the low-pressure handwand, but the requirement for chemical resistant footwear will reduce exposure significantly.

Environmental Fate Assessment

The Agency has acceptable data on the mobility and dissipation route of parent oryzalin, which appears to biodegrade slowly with a first half-life of approximately two months. The submitted data on oryzalin suggest that parent oryzalin is not a groundwater or surface water concern, and the Agency is not requiring ground or surface water advisories. Parent oryzalin does not appear to be mobile under field conditions, however, it is expected that a maximum of 10-20% of oryzalin degradates may leach.

DowElanco is currently conducting a mobility/adsorption/desorption study to determine the mobility of nine oryzalin degradates, and to determine whether or not degradate leaching is a major route of dissipation. This study is considered confirmatory and does not affect the eligibility decision for oryzalin at this time. The Agency is reserving the requirement for additional terrestrial field dissipation testing (guideline 164-1) until the results of the degradate leaching study are submitted. If the degradates prove to be mobile, the Agency may either require re-analysis of the field samples from the terrestrial field dissipation study, or require a new field study.

Ecological Effects Assessment

The existing ecological effects data allow a preliminary risk characterization for acute and chronic freshwater fish effects, acute invertebrate effects, acute avian effects and chronic avian effects for single applications up to and including 4 lb a.i./acre. From an acute toxicity perspective, oryzalin is moderately toxic to freshwater fish and invertebrates and practically nontoxic to birds.

Oryzalin poses a potential risk to endangered aquatic species that occur in shallow regions of water. In shallow water (6 in.) adjacent to treated fields, the EECs exceed 0.05 LC_{50} values for all aquatic species tested and the Maximum Allowable Toxic Concentration (MATC) value for the fathead minnow.

As expected for an herbicide, non-target plants may be adversely affected from runoff and/or drift from the application of oryzalin at the labeled rates on all of the use sites. Aerial applications of oryzalin ranging from minimum rates of 1.0 lb a.i/A up to the maximum label rate of 6.035 lb a.i./A may pose a risk to nontarget plants. Because the EEC values are greater than the EC_{25} values, oryzalin is expected to adversely affect terrestrial plants including federally listed endangered and threatened plants.

The Agency is requiring several ecological effects studies that will be considered confirmatory for the reregistration of oryzalin. These data gaps do not affect the eligibility decision for oryzalin at this time. Acute toxicity to estuarine/marine organisms - fish, mollusk, and shrimp (guidelines 72-3a, 72-3b, and 72-3c) are required in order to assess the effects of oryzalin on marine and estuarine organisms for the following use sites: berries, citrus fruits, cherry trees, pecans, and golf course turf. Avian reproduction studies are required as confirmatory data to assess chronic avian risk for single applications greater than 4 lb a.i./A and multiple applications greater than 1.5 lb a.i./A. A Daphnia life-cycle study is required because oryzalin is expected to be transported to water from its intended use sites and the EEC for a 6-foot deep pond is greater than 0.01 of the daphnid LC_{50}. Droplet size spectrum (201-1) and field drift studies (202-1) are needed to support ground spray, aerial spray and air-blast application methods for oryzalin.

The technical producer of oryzalin has agreed to incorporate the following measures in order to reduce environmental risks from oryzalin use. The registrant will eliminate all airplane and helicopter applications of oryzalin except in California, where this use will be restricted to agricultural crop labels only. In addition, this Reregistration Eligibility Decision requires labelling changes to reflect the maximum amount of oryzalin that may be applied per year, the maximum number of applications, and the interval between applications (see Section V).

The Agency has determined that only the products containing oryzalin as the sole active ingredient for the uses declared eligible for reregistration will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product containing oryzalin, 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 for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" 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 database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of oryzalin. The document consists of six sections. Section I is the introduction. Section II describes oryzalin, 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 oryzalin. Section V discusses the reregistration requirements for oryzalin. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Oryzalin
- **Chemical Name:** 3,5-dinitro-N^4,N^4-dipropylsulfanilamide
- **Chemical Family:** Dinitroaniline
- **CAS Registry Number:** 19044-88-3
- **OPP Chemical Code:** 104201
- **Empirical Formula:** $C_{12}H_{18}N_4O_6S$
- **Trade and Other Names:** Ryzelan, SURFLAN, EL-119
- **Basic Manufacturer:** DowElanco

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of oryzalin is in Appendix A.

Type of Chemical: herbicide

Mode of Action:
2,6-Dinitroaniline herbicide, cell division inhibitor

Use Groups and Sites:

TERRESTRIAL FOOD CROP
Nuts, pears, small fruits, stone fruits, subtropical fruits

TERRESTRIAL FOOD + FEED CROP
Citrus fruits, almonds, apples, grapes

TERRESTRIAL NONFOOD CROP
Christmas tree plantings; commercial/industrial and recreation area lawns; golf course turf; nonagricultural rights-of-way/ fencerows/hedgerows; nonagricultural uncultivated and industrial (outdoor) areas; ornamental and/or shade trees, herbaceous plants, and woody shrubs and vines; power stations

TERRESTRIAL NONFOOD + OUTDOOR RESIDENTIAL
Ornamental and/or shade trees, herbaceous plants, lawns and turf, and woody shrubs and vines; paths/patios; paved areas (private roads/sidewalks)

Pests: black nightshade, carpetweed, chickweed, climbing milk-weed, coast fiddleneck, common mallow and purslane, several composite weeds, few cruciferous weeds, desert rockpurslane, filaree, Florida pusley, many gramineous grasses, henbit, ladys-thumb, lambsquarters, Mexican clover, Pennsylvania smartweed, prickly sida, prostrate knotweed and spurge, pigweed, puncture-vine, tall morningglory, velvetleaf, wiregrass, yardgrass

Formulation Types and Percent A.I. Ranges:
Granular--0.4 to 1% (may be formulated with other active ingredients)
Wettable powder--75%
Water dispersible granules--60 to 85% (may be formulated with other active ingredients)
Emulsifiable concentrate--2.84 to 40.4%
Flowable concentrate--40.4%
Formulation intermediate (manufacturing use)/liquid--40.4%

Methods and Rates of Application:

Granular

In any season, January through June, September through December, at nonbearing, postemergence, containerized, foliar, or postplant stages, broadcast or spot treat by spreader at 0.75 to 6 lb AI/ acre.

Wettable powder

At bearing or nonbearing stages, apply band treatment by low pressure ground equipment at 6 lb AI/acre. In any season, at bearing, nonbearing, foliar, postemergence, or containerized stages, or when needed, spray by aircraft or low pressure ground equipment at 0.75 to 6 lb AI/acre.

Water dispersible granules

In any season, at bearing, nonbearing, postemergence, nonbearing nurserystock, foliar, or containerized stages, or when needed, spray or apply band treatment by sprayer, aircraft, or low-pressure ground equipment at 0.75 to 6 lb AI/acre.

Emulsifiable concentrate

At bearing, nonbearing, or foliar stages, spray or apply band treatment by sprayer or low-pressure ground equipment at 5 to 6 lb AI/acre. At bearing or nonbearing stages, apply chemigation treatment by sprinkler irrigation at 6 lb AI/acre. In any season, at foliar stage, or when needed, spray by hose-end, pressurized tank, or tank-type sprayer at 6 to 8.5 gal product/acre.

Flowable concentrate

In any season, at nonbearing, postemergence, or containerized stages, or when needed, spray by aircraft or low-pressure ground equipment at 0.75 to 4 lb AI/acre.

Use Limitations:
Do not graze or feed forage from treated fields or orchards to livestock.

Estimated Usage of Pesticide

This section summarizes the best estimates available for the usage of oryzalin on an aggregate and site (crop) basis. These preliminary estimates are derived from a variety of published and proprietary sources available to the Agency. The range of data presented accounts for annual fluctuations in use patterns as well as the variability resulting from the use of data from various information sources. The table below summarizes the amounts of oryzalin used by site.

Typical Annual Usage (1991) and Percentage of various US Crops Treated with Oryzalin

Table 1. (November 1993)

Name of Site	Acres Planted/ Harvested[a] (000)	Acres Treated[b] (000) (Range)		Percentage of Acres Treated[c] (Range)		Active Ingredient[c] (1000 lbs A.I.) (Range)		Percentage of Total A.I. (Range)	
ALMOND	414	145	166	35	40	300	350	18.26	20.45
APPLES	483	24	48	5	10	40	90	2.73	4.69
APRICOT	19	6	8	30	40	5	10	0.34	0.52
AVOCADO	84	1	1	<	1	2	3	0.14	0.16
BLACKBERRIES	4	0	0	<	1	<	1	0.05	0.07
BLUEBERRIES	59	1	3	1	5	1	2	0.07	0.10
CHERRIES	98	15	20	15	20	20	25	1.30	1.36
FIGS	16	2	3	15	20	2	5	0.14	0.26
GRAPES	738	295	443	40	60	100	200	6.82	10.43
GRAPEFRUIT	144	1	1	<	1	<	1	0.05	0.07
HAZELNUTS	29	0	0	<	1	<	1	0.05	0.07
LEMONS	63	1	1	1	2	5	10	0.34	0.52
ORANGES	600	6	60	1	10	20	75	1.36	3.91
OLIVES	33	10	13	30	40	10	15	0.68	0.78
NECTARINES	27	14	16	50	60	15	20	1.02	1.04
KIWI	9	4	5	40	50	2	5	0.14	0.26
PEACHES	186	9	37	5	20	20	75	1.36	3.91
PEARS	71	4	14	5	20	20	25	1.30	1.36
PLUMS/PRUNES	131	13	26	10	20	40	75	2.73	3.91
POMEGRANATES	N.A.	0	0	50	60	1	2	0.07	0.10
PECANS	453	68	91	15	20	5	35	0.34	1.83
PISTACHIOS	52	26	31	50	60	30	40	2.05	2.09
RASPBERRIES	11	0	1	1	5	1	2	0.07	0.10
WALNUTS	180	9	27	5	15	25	50	1.70	2.61
								0.00	0.00
TURF	17,000	340	850	2	5	800	800[d]	41.73	54.53[e]
TOTAL[f]	20,904	994	1,865			1,467	1,917		

a/ Three years 1989-1991 or 1990-1992 average (with some 1987 data) when available is reported. For perennial crops harvested acres are indicated, and for other crops planted acres are reported.

b/ Acres treated are calculated from the percentages given in the immediately following two columns. The lowest limit of the range is zero.

c/ Sources: EPA Proprietary Sources; RFF. Herbicide Usage in the United States. December 1990; State of California. Pesticide Use Report, Annual 1990; USDA. Agricultural Chemical Usage, 1991 Fruits and Nuts Summary. June 1992.

d/ No credible upper limit is available. The Agency is relatively certain about the lower limit of turf a.i. which is about 0.8 million pounds. Hence, in view of the greater uncertainty of the upper limit estimate, the grand total is presented including the lower limit turf a.i.

e/ Based on 0.8 million pounds a.i.

f/ Usage information about dewberries, gooseberries, loganberries, and non-food crops such as ornamentals, and right of ways is not readily available. Oryzalin usage for ornamentals and right of ways is considered to be a significant amount. The Agency is relatively certain for the presented total usage, although individual crop usage could vary from the presented a.i. estimates.

C. Data Requirements

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

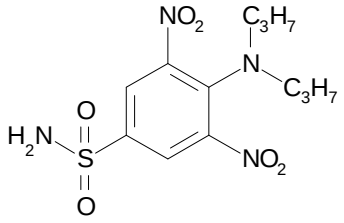
D. Regulatory History

Oryzalin was first registered in the United States in 1974 for use as a preemergence herbicide in fruits, nuts, vineyards, orchards, forestry, noncrop areas and agricultural crops. A Registration Standard for oryzalin was issued in 1987 which evaluated the studies submitted to that date. A Data Call-In was issued in 1991 for oryzalin requiring additional plant phytotoxicity data, plant and animal analytical methods, and non-dietary exposure data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and Data Call-In. There is currently one registered technical product, two registered formulation intermediates and thirty-five end-use products.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Technical oryzalin, 3,5-dinitro-N4,N4-dipropylsulfanilamide, is a yellow-orange crystalline solid with a melting point of 141-142°C. Oryzalin is soluble in water at 2.5 ppm at 25 C, and is readily soluble in organic solvents such as acetone, ethanol, methanol, and acetonitrile. The molecular weight is 346.35 and the empirical formula is $C_{12}H_{18}N_4O_6S$. The technical product is only slightly soluble in benzene and xylene, and is insoluble in hexane.



All product chemistry data submitted in support of the reregistration of oryzalin manufacturing-use products have been reviewed and found acceptable to fulfill 61-, 62-, and 63-series guideline requirements.

B. Human Health Assessment

1. Toxicology

The toxicological data base is adequate and will support reregistration. A dermal irritation study on Technical oryzalin is required as confirmatory data.

a. Acute Toxicity

Acute toxicity values and categories for oryzalin for technical products are summarized below.

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	> 10 g/kg	IV
Dermal LD_{50} - rabbit	> 2 g/kg	III
Inhalation LC_{50} - rat	> 3.17 mg/L	III

Acute toxicity values and categories derived from oryzalin Manufacturing-Use Products are summarized below.

TEST	RESULTS	CATEGORY
Eye Irritation - rabbit	slight damage	III
Dermal Sensitization - guinea pig	non-sensitizing	---

Oryzalin was generally of moderate toxicity in acute studies. In acute oral studies with rats, the LD_{50} was greater than 10 g/kg for oryzalin in 5% acacia and greater than 5 g/kg for oryzalin in DMSO (MRID# 00038668). The LD_{50} for oryzalin in acute dermal studies in rabbits was more than 2000 mg/kg (category III toxicity) (satisfies guideline 81-2; MRID#s 00041970, 00106681). The LC_{50} value for oryzalin (98%) in an acute inhalation study in rats was more than 3.17 mg/L (category III toxicity) (satisfies guideline 81-3; MRID# 41037201). Oryzalin, in a 5% acacia suspension, produced slight corneal damage in the rabbit eye which cleared by day 7 (category III toxicity) (satisfies guideline 81-4; MRID# 00106681). A dermal irritation study is required for the Technical. No dermal sensitization occurred with oryzalin in guinea pigs (MRID# 00026762).

b. Subchronic Toxicity

Three-month feeding studies with oryzalin were performed in rats, mice, and dogs. In a study with Fischer 344 rats the doses were 0, 500, 900, 1600, 2750, or 4500 ppm. The LOEL was 2750 ppm (137.5 mg/kg/day) based upon the accumulation of heme pigment in the kidneys. The NOEL was 1600 ppm (80 mg/kg/day) (satisfies guideline 82-2; MRID nos. 00026772, 00038677).

In a study with B6C3F1 mice, the doses were 0, 450, 900, 1800, 3650, or 8000 ppm. The LOEL was 8000 ppm (1200 mg/kg/day) due to increased weights of several organs. The NOEL was 3650 ppm (547.5 mg/kg/day) (satisfies guideline 82-1; MRID# 00026773).

In beagle dogs, the doses given by capsule were 0, 6.25, 18.75, or 56.25 mg/kg/day. The LOEL was 56.25 mg/kg/day as a result of reductions in red cell, hematocrit and hemoglobin levels, increases in blood urea nitrogen, alkaline phosphatase, sedimentation rate, glucose, and SGPT levels, and hyperplastic bone marrow and hepatocellular changes. The NOEL in dogs was 18.75 mg/kg/day. (MRID# 00106670).

c. Chronic Toxicity

In a combined chronic toxicity/carcinogenicity study, oryzalin was fed to Fischer 344 rats for two years at doses of 0, 300, 900, or 2700 ppm. The study resulted in a systemic toxicity NOEL of 300 ppm (13.82 mg/kg/day for females; 12.16 mg/kg/day for males). The systemic LOEL for females was 900 ppm (42.89 mg/kg/day) based upon hematologic changes (decreased red cells, hemoglobin and hematocrit) and organ weight changes (increased liver and kidney weights) seen in both sexes at 900 ppm (42.89 mg/kg/day for females; 36.86 mg/kg/day for males). There were also, at the high dose, reduced survival, reduced body weight and weight gain, reduced feed efficiency in the females, increased thyroid weight, and histopathological changes in the thyroid (satisfies guidelines 83-1 and 83-2; MRID# 00044332).

Beagle dogs were given, by capsule, doses of 0, 1.5, 5, 15 (later 250 and 500) or 50 mg/kg/day of 98.9% oryzalin for a period of one year. The systemic toxicity NOEL was determined to be 50 mg/kg/day. At the 250 and 500 mg/kg/day dosages (LOEL) there were decreased RBC count, hematocrit, and hemoglobin; increased serum cholesterol, decreased alanine transaminase, increased liver and kidney weights, and

decreased adrenal weights. There was an effect on thyroid function at 250 mg/kg/day but not at 50 mg/kg/day (satisfies guideline 83-1; MRID# 40024801).

d. Carcinogenicity

Long-term studies in rats and mice have been performed to evaluate the potential carcinogenic activity of oryzalin. Oryzalin was not carcinogenic in a two-year B6C3F1 mouse study in which feeding levels of the compound were 0, 500, 1350, or 3650 ppm. The NOEL for systemic toxicity was 1350 ppm (192.9 mg/kg/day). The LOEL was 3650 ppm (521.4 mg/kg/day) as a result of decreased body weight gain in females and males (satisfies guidelines 83-1 and 83-2; MRID nos. 00026780, 00068079).

Oryzalin was found to be carcinogenic in rats based on the increased incidence of mammary gland tumors in females and skin and thyroid tumors in both sexes. Carcinogenic effects were observed at 300 ppm (15 mg/kg/day) due to the occurrence of mammary gland tumors in females and skin and thyroid tumors in both sexes. Oryzalin is classified as a group C carcinogen with a Q_1* of 1.3×10^{-1} $(mg/kg/day)^{-1}$, based on the mammary gland tumors.
(MRID# 00044332)

e. Developmental Toxicity

In pregnant CD rats gavaged with 0, 50, 225, or 1000 mg/kg/day of oryzalin on gestation days 6 to 17, the maternal toxicity NOEL was 50 mg/kg/day. The maternal LOEL was 225 mg/kg/day based upon reduced body weight gain and food consumption. The developmental toxicity NOEL was 50 mg/kg/day. The developmental LOEL was 225 mg/kg/day based on decreased mean fetal body weights, an increased incidence of runts, and an increased incidence of incomplete ossification of the forepaw metacarpal bones (study satisfies guideline 83-3; MRID# 41163801).

When pregnant Dutch belted rabbits were gavaged with 0, 25, 55, or 125 mg/kg/day of oryzalin on gestation days 6 to 18, the maternal toxicity NOEL was 25 mg/kg/day. The LOEL was 55 mg/kg/day due to decreased food consumption and weight gain. The developmental toxicity NOEL was also 25 mg/kg/day. The developmental LOEL of 55

mg/kg/day was based on increased resorptions, increased post-implantation loss, and reduced mean litter size (MRID# 00026785).

Another study in pregnant Dutch belted rabbits used gavage doses of 0, 10, 25, 55, or 125 mg/kg/day on gestation days 6 through 18. The maternal toxicity NOEL was 25 mg/kg/day. The maternal LOEL was 55 mg/kg/day based on reduced food consumption. There was no evidence of developmental toxicity in this study and the developmental NOEL was equal to or greater than the highest dose, 125 mg/kg/day. Although these two studies do not satisfy the guidelines individually, these two rabbit studies combined satisfy guideline 83-3 (MRID# 00098461).

f. Reproduction

Dietary doses of 0, 250, 750, or 2250 ppm (12.5, 37.5, or 112.5 mg/kg/day) were given in a three-generation study with Fischer 344 rats. The reproductive NOEL was 2250 ppm (112.5 mg/kg/day, highest dose tested) or greater. The fetotoxic NOEL was 12.5 mg/kg/day, based upon depressed pup growth at 37.5 mg/kg/day. (MRID#s 00026786, 00038564).

An additional one-generation study was performed in Fischer 344 rats using dietary concentrations of oryzalin of 0, 0.025, 0.075, or 0.225% (equivalent to 0, 25, 75 or 225 ppm of the diet) in order to supplement the three-generation study. The reproductive NOEL was 0.225% or higher (178.8 mg/kg/day in males, 205.5 mg/kg/day in females). The systemic toxicity LOEL was 0.025% or lower (19.4 mg/kg/day in males, 22.3 mg/kg/day in females) based on increased liver and kidney weights plus the presence of bilateral cortical tubular hyaline droplets. In addition, clinical signs were noted in the mid and high dose groups. There were decreased body weight gain and food consumption in high dose males and females of both generations. Mid-dose females showed decreased weight gain, too. Although each reproduction study does not satisfy the guidelines separately, these two rat studies combined satisfy guideline 83-4 (MRID# 42401501).

g. Mutagenicity

Oryzalin was not mutagenic in tests for gene mutations, such as the Ames test using several strains of S. typhimurium and the WP2 μvrA$^-$ strain of E. coli (MRID nos. 00130427, 41050101 and

41289901). In tests for structural chromosome aberrations, oryzalin produced negative results in a rat dominant lethal study (MRID# 00115743). Oryzalin did not induce sister chromatid exchange in Chinese hamster bone marrow cells following oral administration whereas induction was observed following intraperitoneal injection (MRID# 00086801). In tests for other genotoxic effects, oryzalin was negative in an unscheduled DNA synthesis test in rat hepatocytes (MRID# 00086801). (These studies fulfill guidelines 84-2 and 84-4).

h. Metabolism

The Agency presently has adequate information on the metabolism of oryzalin and has waived the data requirement 85-1, General Metabolism. However, the Agency reserves the right to require this study in the future if oryzalin metabolites are detected in plant and/or animal residues or if the study is needed to clarify issues of toxicity and/or carcinogenicity of oryzalin.

i. Dermal Absorption

A dermal absorption study in monkeys indicated that 2.3% of the dermally applied oryzalin is absorbed through the skin. This absorption value is used for assessing human risk following dermal exposure (MRID#s 42784102, 43207001).

j. Reference Dose (RfD) (for Chronic Oral Exposure)

The reference dose for oryzalin was determined to be 0.12 mg/kg/day, based on the chronic feeding study with rats in which the NOEL was 12.16 mg/kg/day. An uncertainty factor of 100 was used to account for differences between species and variability between humans (00070569, 00026779, 00044332).

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has not issued an ADI for oryzalin to date.

2. Exposure Assessment

a. Dietary Exposure

The residue chemistry data necessary to assess dietary exposure and reassess existing tolerances are substantially complete. The dietary exposure data support the reregistration of oryzalin for uses limited to vine and orchard crops. Additional data on storage stability and processed citrus and olives are required as confirmatory data.

GLN 171-4 (a): Plant Metabolism: The qualitative nature of the residue in berries, vine and orchard crops is adequately understood. The residue of concern in plants is the parent, oryzalin. The submitted grape metabolism studies indicated that there was little uptake or translocation of oryzalin from the soil; no oryzalin or oryzalin-related compounds were identified. Grapes are representative of the crops (berries, vine and orchard) on which oryzalin is registered currently for use; therefore, only one plant metabolism study, with grapes, was required to satisfy plant metabolism data requirements. In the event an interested party wishes to obtain registration for use of oryzalin on crops other than berries, vine or orchard crops, additional plant metabolism data will be required. The residue of concern in plants is oryzalin, which is the residue presently included in the tolerance expression. (MRID#s 42558201, 43060001)

GLN 171-4 (b): Animal Metabolism: The qualitative nature of the residue in ruminants and poultry is adequately understood. Studies conducted at highly exaggerated feeding levels with laying hens and beef and dairy cattle indicated that oryzalin is either poorly absorbed or rapidly metabolized via hydroxylation and cleavage of the alkyl side chain to yield polar components that are excreted. The parent compound was identified only in eggs, in minor quantities (< 0.01 ppm). Since it is unlikely that detectable residues of oryzalin would occur in animal commodities at a 1x feeding level, this is considered to be a 40 CFR 180.6 category 3: "No reasonable expectation of finite residues in animal commodities", with respect to tolerances for residues in meat, milk, poultry and eggs. (MRID#s 42064901 and 42158502)

GLN 171-4 (c/d): Residue Analytical Methods - Plants/Animals: An adequate method is listed in the FDA Pesticide Analytical Manual (PAM Vol. II) for purposes of data collection and enforcement of tolerances for residues of oryzalin. Method I is a GLC/electron capture detection (ECD) method and involves conversion of oryzalin to its *N*,*N*-dimethyl derivative with methyl iodide. The detection limit for the method is 0.01 ppm for plant commodities. Modifications of Method I using GLC/ECD or HPLC are adequate for purposes

of data collection for residues of oryzalin in animal commodities; the detection limit is 0.05 ppm for these modified methods. Enforcement methodology for residues of oryzalin in animal commodities is not required at this time since finite residues of oryzalin are not likely to be present in animal commodities at detectable levels. (MRID#s 00023990, 00033976, 00106730, 41630302, 42064903, and 42064904)

The registrant has submitted data (1989; MRID# 41197001) pertaining to the analysis of oryzalin using PAM Vol. I FDA Multiresidue Protocols D and E for fatty and non-fatty foods; these data have been forwarded to the FDA for review.

GLN 171-4 (e): Storage Stability: Storage stability studies have been conducted using fortified samples of apples, apple processed commodities, pears, blueberries, grapes, grape processed commodities, and raspberries. Residues of oryzalin are stable under frozen storage conditions (-20$_o$ C) in/on apples, apple juice and pomace, grapes, grape juice, pomace, and raisins, pears, and raspberries for up to ca. 70 days, in/on blueberries for up to 95 days, and in/on soybeans for up to 9 months. Storage stability data for apples may be translated to pears, citrus fruits, stone fruits, figs, kiwifruit, and pomegranates. Storage stability data for soybeans may be translated to tree nuts, avocados, olives, and pistachios. Additional storage stability studies with apples and grapes have been required and are currently in progress. These data are considered confirmatory to the existing storage stability data which provide preliminary evidence that oryzalin residues are stable in frozen plant matrices for the storage intervals of residue samples used for tolerance reassessment. (MRID#s 00106730 and 41630301)

GLN 171-4 (k): Magnitude of the Residue in Plants: All magnitude of the residue data in food/feed crops which are presently supported have been evaluated and deemed adequate to reassess the 0.05 ppm tolerances for residues of oryzalin. The crop field residue data requirements for apples, pears, grapes, and rubus (caneberries) reflecting use of a WP or DF formulation were waived, because the AS (aqueous suspension) formulation used in previous studies was sufficiently representative of a WP or DF formulation. (MRID#s 00031663, 00106691, 41115501, 41733701, 41906001, 41906004, 41906005, 41906006, and 42050001)

GLN 171-4 (l): Processed Food/Feed: Except for citrus and olives, the magnitude of the residue data for processed commodities of presently supported food/feed crops have been evaluated and deemed adequate. Additional processing studies for citrus and olives have been required and are currently in progress. These data are considered confirmatory to the existing evidence that

residues of oryzalin do not significantly concentrate upon processing. (MRID#s 00031663, 00106691, 41906002, and 41906003)

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry and Eggs: The ruminant and poultry metabolism studies indicate that finite residues of oryzalin are not likely to be present in eggs, poultry tissues, milk, and ruminant tissues at detectable (> 0.05 ppm) levels. The use of oryzalin on livestock feed commodities is considered to be a 40 CFR 180.6 Category 3 with respect to tolerances for residues in meat, milk, poultry, and eggs, Thus, conventional livestock feeding studies and tolerances for oryzalin in meat, milk, poultry, and eggs will not be needed provided that: (i) tolerances for residues of oryzalin in/on soybeans, cottonseed, barley grain, wheat grain, potatoes, and peas (succulent), which no longer have registered uses, are revoked; and (ii) the required citrus processing study does not indicate concentration such that the theoretical dietary intake of -0.03 ppm for beef and dairy cattle exceeds feeding levels utilized in the ruminant metabolism studies.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops: These requirements have been waived since food uses of oryzalin are for berries, vine and orchard crops only, which are not rotated.

Currently, grazing and feeding restrictions appear on the 4 lb/gal EC and 75% WP, but not on the 85% DF labels. All end-use product labels must be amended to include a restriction against grazing or feeding crops grown in treated areas to livestock. In addition, all end-use product labels (e.g. multiple active ingredient, state and local needs, and products subject to generic data exemption) must be amended such that they are consistent with the basic producer labels.

Codex Harmonization

There are no proposed or established Codex MRLs (Maximum Residue Limits) for residues of oryzalin in/on food/feed items; therefore, there are no compatibility questions with respect to U.S. tolerances and Codex MRLs.

b. Occupational and Residential Exposure

Mixer/Loader/Applicator (Handler) Exposure

Mixer/loader/applicator (i.e., handler) exposure issues are addressed by Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator exposure monitoring data were not required in the Registration Standard for Oryzalin. However, chemical specific mixer/loader/applicator data (MRID# 42137901) have been submitted to

EPA. The initial evaluation of MRID# 42137901 indicates insufficient replicates were generated under Subdivision U Guidelines. Therefore, the chemical specific data from MRID# 42137901 were combined with the surrogate study MRID# 42974501 and the Pesticide Handlers Exposure Database (PHED) for a limited exposure/risk assessment. However, additional mixer/loader/applicator data are required in order to estimate dermal and inhalation exposure with the use of the low-pressure handwand.

Based on the use patterns described above, seven major exposure scenarios were identified, including groundboom tractors, chemigation, backpack, low pressure handwands, tractor drawn solid broadcast spreaders, manually operated broadcast spreaders (i.e., hand-pushed), and whirly-bird spreaders. The exposure scenarios for private and commercial applicators and the daily dose appropriate for use in an "intermediate term" risk assessment are summarized in Tables 2, 3, and 4.

Table 2. Summary Exposure Values for Oryzalin

Exposure Scenario (Scen. #)	Dermal Exposure[a] (mg/lb ai)	Inhalation Exposure[b] (Fg/lb ai)	Maximum Label Application Rate[c] (lb ai/cycle)	Daily Max.[d] Treated	Daily Dermal Dose[e] (mg/kg/day)	Daily Inhalation Exposure[f] (mg/kg/day)
Mixer/Loader Exposure						
Open Mixing Granulars (I)	0.02	2.4	1 percent formulation	2000 pounds	0.0001	0.0007
Open Mixing Liquids (II)	0.15	0.4	6 lb ai/A	80 acres	0.024	0.003
Applicator Exposure						
Solid Broadcast-Tractor (III)	No Data	No Data	1.5 lb ai/A	No Data	No Data	No Data
Solid Broadcast-Push type (IV)	No Data	No Data	0.035 lb ai/1000 ft^2	No Data	No Data	No Data
Chemigation (V)	No Data	No Data	6 lb ai/A	No Data	No Data	No Data
Groundboom Application (VI)	0.01	1.1	6 lb ai/A	80 acres	0.002	0.008
Backpack (VII)	1.3	30	0.094 lb ai/1000 ft^2	2 acres	0.004	0.004
Mixer/Loader/Applicator						
Solid Broadcast-Whirly Bird (VIII)	27.0	790	0.07 lb ai/1000 ft^2	1 acre	0.028	0.036
Low Pressure Handwand (IX)	52	39	0.094 lb ai/1000 ft^2	2 acres	0.144	0.005

[a] Dermal unit exposures are reported as the best fit mean, unless noted. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. Protection factors were used to calculate dermal unit exposure values because insufficient data are available for PPE in these scenarios. Fifty percent of the total dermal exposure is assumed to be attributed to hand exposure. Fifty percent protection factor is applied to the hand exposure for chemical resistant gloves. Seventy-five percent protection factor is applied to total deposition for coveralls. Fifty percent protection factor is applied to long pants, long-sleeved shirts and the addition of coveralls.

[b] Inhalation exposure values are reported as geometric means (lognormal distributions), unless otherwise noted.

[c] Luis Report dated 3/7/94, Oryzalin.

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/cycle)} * \text{Max. Treated}}{70\ \text{kg}} * (0.023\ \text{absorption factor})$

[f] Daily Inhalation Exposure (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/cycle)} * \text{Max. Treated}}{70\ \text{kg}}$

Table 3. Exposure Scenario Descriptions for Oryzalin[a]

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Standard Assumptions[b] (8 hr work day)	Comments[c]
Mixer/Loader Exposure					
Open Mixing Granulars (I)	PHED	Total Deposition	Open Mixing	Forty 50 lb. bags	All grades; Dermal = 3 to 14 replicates; Inhalation = 14 replicates.
Open Mixing (II)	PHED	Long Pants, Long-Sleeved Shirt, No gloves	Open Mixing	80 acres @ 6 lb ai/A (Groundboom)	Acceptable grades; Dermal = 14 + replicates; Inhalation = 40 replicates.
Applicator Exposure					
Solid Broadcast-Tractor (III)	No Data	No Data	No Data	No Data	No Data
Solid Broadcast - Push Type (IV)	No Data	No Data	No Data	No Data	No Data
Chemigation (V)	No Data	No Data	No Data	No Data	No Data
Groundboom Application (VI)	PHED 421379-01 429745-01	Long Pants, Long-Sleeved Shirt, No gloves	Open Cab Tractor	80 acres/day	All grades; Dermal = 6 to 99 replicates; Inhalation = 102 replicates.
Backpack/ Knapsack (VII)	PHED	Long Pants, Long-Sleeved Shirt, Gloves	2 gallon Knapsack	2 acres/day	Inhalation grade B; Dermal grade B; Hand grade C Dermal = 9 replicates; Inhalation = 9 replicates.
Mixer/Loader/Applicator					
Solid Broadcast - Whirly Bird (VIII)	PHED	Long Pants, Long Sleeve Shirt, Gloves	Whirly Bird/Belly Grinder	1 Acre/Day	Inhalation grade E; Dermal grades C and E; Dermal = 16 to 20 replicates; Inhalation = 18 replicates.
Low Pressure Handwand (IX)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Portable handwand	2 acres/day	Inhalation grades B and C; Dermal all grades; Dermal = 25 to 95 replicates; Inhalation = 95 replicates.

[a] "No Data" indicates that no data were available to complete an exposure assessment.

[b] Standard Assumptions based on an 8 hour work day.

[c] If dermal and inhalation grades are not listed separately, then the listed grades pertain to both dermal and inhalation. "Acceptable grades," as defined for meeting Subdivision U Guidelines, are grades A and B for dermal and inhalation, and grade C for hand rinse method. All grades that do not meet the Agency's SOP are listed individually.

Table 4. Intermediate Oryzalin Exposure (greater than one week) for Commercial Applicators (Combined Dermal and Inhalation Exposure)

Exposure Scenario (Scen. #)	Total Daily Dose[a] (mg/kg/day)
Mixer/Loader	
Open Mixing Granulars (I)	0.0008
Open Mixing Liquids (II)	0.027
Applicators	
Solid Broadcast-Tractor (III)	No Data
Solid Broadcast-Push Type (IV)	No Data
Chemigation (V)	No Data
Groundboom Application (VI)	0.010
Backpack (VII)	0.008
Mixer/Loader/Applicator	
Solid Broadcast-Whirly Bird (VIII)	0.064
Low Pressure Handwand (IX)	0.149

[a] See Table 1 for calculations.

[b] The dermal dose was adjusted for a 60 kg individual.

The available PHED exposure estimates were based on the following clothing scenario: coveralls over long pants, long-sleeved shirt, and chemical resistant gloves. Protection factors were applied to the PHED data to simulate appropriate clothing (see Table 3 for the actual exposure clothing scenarios). Based on the results of the exposure assessment, and because this chemical is a possible human carcinogen the following handler PPE are required for oryzalin:

- coveralls over long-sleeved shirt and long pants
- chemical-resistant gloves
- chemical-resistant footwear
- chemical-resistant headgear for overhead exposures

Mixers and loaders must also wear a chemical-resistant apron.

Postapplication/Reentry Exposure (Workers):

Based on its cancer classification, oryzalin meets the Agency's toxicity criteria for requiring reentry data. For some scenarios, oryzalin also meets the Agency's exposure criteria (substantial contact with treated foliage/surfaces). There are no reentry data available for use in an exposure assessment for calculating a Restricted Entry Interval. Reentry data are required for applications to Christmas trees and field-grown roses. These data requirements are specified in Part IV. For agricultural and ornamental crops, an REI of 24 hours is required instead of the 12 hour REI that has been imposed by the Worker Protection Standard (WPS).

Orchard, Vineyard and Ornamental Crops:

Postapplication harvester exposure is not expected after directed soil applications because the foliage is not treated. However, limited postapplication exposure during pruning activities can be expected following overtop treatments to dormant orchards or vineyards using chemigation equipment. These exposures are expected to be low since there is no treated foliage at that time. Due to contact with treated branches and because this chemical is a possible human carcinogen, the Agency is requiring a 24 hour REI.

Established Turf (warm-season turfgrasses):

Residential lawns are treated with oryzalin by professional landscape/lawn care personnel and certain products are available for use by the homeowner. Chronic postapplication exposure from these applications is of concern because oryzalin is a possible human carcinogen and persistent. There is a potential for continued, substantial contact with treated surfaces, particularly among children. There are no data to evaluate potential exposure to turfgrass, and therefore the safety of this use cannot be evaluated. Data are required to support this use and are specified in Part IV of this document.

For golf courses and residential turf uses, the following entry restriction is required:

- for the liquid applications: a prohibition on entry until the sprays have dried;
- for dry applications: a prohibition on entry until dusts have settled;

Non-WPS Uses (includes both occupational and non-occupational):

The Agency requires that the entry restriction for all non-WPS uses of oryzalin be the following:

- for the liquid applications: a prohibition on entry until the sprays have dried;
- for dry applications: a prohibition on entry until dusts have settled.

Data for Other Uses:

Data are not required for the remaining uses for which no data are available. The Agency believes these uses represent lower exposure potential than those uses for which data were available.

3. Risk Assessment

Toxicological Endpoints

The reference dose for oryzalin was determined to be 0.12 mg/kg/day, based on the chronic feeding study with rats in which the NOEL was 12.16 mg/kg/day. An uncertainty factor of 100 was used to account for differences between species and variability between humans (MRID#s 00070569, 00026779, 00044332).

Oryzalin was found to be carcinogenic in rats, based on increased incidences of mammary gland tumors in females and of skin and thyroid tumors in both sexes. Oryzalin is classified as a group C carcinogen with a Q_1* of 1.3×10^{-1} $(mg/kg/day)^{-1}$, based on mammary gland tumors.

Subchronic toxicological endpoints from a 3-generation reproduction study in the rat (83-4), (MRID#s 00026786, 00042908), indicated that risk assessment is required for occupational and residential exposure of 1 week to several months. A fetotoxic NOEL of 12.5 mg/kg/day was observed. The LOEL (depressed pup growth) was 37.5 mg/kg/day.

Dietary Risk

Sufficient tolerance data and anticipated residue data are available to conduct a dietary risk assessment. The chronic dietary exposure based on anticipated residue contribution (ARC) estimates are very low--less than 1/5,000th of the RfD for each of the groups and subgroups analyzed in the DRES analyses. Based on the same data, the dietary excess carcinogenicity risk estimate for the U.S. population is 8.1×10^{-7}. The upper bound excess cancer risk estimate is expected to be even lower (4.5×10^{-7}) when tolerances are revoked for unregistered commodities.

Occupational and Residential Risk

Oryzalin is used by both private and commercial applicators. Private applicators are exposed typically once a year (considered a "short term" exposed individual); commercial applicators are exposed typically 10 times a year (considered an "intermediate term" exposed individual).

Lifetime Average Daily Dose (LADD) (mg/kg/day) = Total Daily Dose (from Table 4) (mg/kg/day) x (Work Days Per Yr/365 Days) x (35 Yrs/70 Yrs)

Excess cancer risk to workers may be estimated by the following equation:
Excess Cancer Risk = Total LADD (mg/kg/day) (Total Dermal + Inhalation) x Q_1
where,
$Q_1 = 0.13 \text{ (mg/kg/day)}^{-1}$

The summary risk values are given in Table 5. Low pressure handwand application has the highest exposure potential of all of the exposure scenarios. The private applicator (M/L/A) using a low pressure handwand has an estimated excess cancer risk of 2.6×10^{-5}. The commercial applicator (M/L/A) using the same handwand equipment has the greatest estimated excess cancer risk, at 2.6×10^{-4}. There are no data for applicator exposure using solid broadcast (tractor or push type) or chemigation. However, these uses are expected to present lower exposure potentials than the others listed in the preceding tables.

For the low pressure handwand spray, the additional use of chemical resistant footwear and coveralls will serve as risk mitigation measures since exposure below the knees is significant during this application scenario. Mixer/loader/applicator data are required to support the reregistration of this use. Because the Agency believes that the exposure estimate is conservative and the chemical resistant footwear should adequately mitigate risk, these data will be considered confirmatory. In addition, chemical resistant footwear is being required for all uses including those within the scope and those outside the scope of the Worker Protection Standard.

Table 5. Total Lifetime Average Daily Dose (LADD) and Excess Cancer Risk Values for Oryzalin

Exposure Scenario (Scen. #)	Total Daily Dose (mg/kg/day)	Dermal LADD (mg/kg/day)		ESTIMATED EXCESS RISK	
		Private Applicator *	Commercial Applicator **	Private Applicator *	Commercial Applicator **
Mixer/Loader					
Open Mixing Granulars (I)	0.0008	1.1×10^{-6}	1.1×10^{-5}	1.4×10^{-7}	1.4×10^{-6}
Open Mixing Liquids (II)	0.027	3.7×10^{-5}	3.7×10^{-4}	4.8×10^{-6}	4.8×10^{-5}
Applicator					
Solid Broadcast-Tractor (III)	No Data	No Data	No Data	No Data	No Data
Solid Broadcast-Push type (IV)	No Data	No Data	No Data	No Data	No Data
Chemigation (V)	No Data	None	No Data	None	No Data
Groundboom Application (VI)	0.010	1.4×10^{-5}	1.4×10^{-4}	1.8×10^{-6}	1.8×10^{-5}
Backpack (VII)	0.008	1.1×10^{-5}	1.1×10^{-4}	1.4×10^{-6}	1.4×10^{-5}
Mixer/Loader/Applicator					
Solid Broadcast-Whirly Bird (VIII)	0.064	8.8×10^{-5}	8.8×10^{-4}	1.1×10^{-6}	1.1×10^{-5}
Low Pressure Handwand (IX)	0.149	2.0×10^{-4}	2.0×10^{-3}	2.6×10^{-5}	2.6×10^{-4}

* Private applicators are assumed to have 1 day exposure/year

** Commercial applicators are assumed to have 10 days exposure/year

Because commercial applicators are exposed 1 week or more in a year, they may potentially be at risk for systemic toxicity. The margin of exposure (MOE) may be calculated from the following equation:

MOE = NOEL/Total Daily Dose (mg/kg/day)
NOEL = 12.5 mg/kg/day

Table 6. Risk from Intermediate Exposure for Commercial Applicators of Oryzalin

Exposure Scenario (Scen. #)	Total Daily Dose (mg/kg/day)	Dermal MOE Commercial
Mixer/Loader		
Open Mixing Granulars (I)	0.0008	15,600
Open Mixing Liquids (II)	0.027	460
Applicators		
Solid Broadcast-Tractor (III)	No Data	No Data
Solid Broadcast-Push Type (IV)	No Data	No Data
Chemigation (V)	No Data	No Data
Groundboom Application (VI)	0.010	1200
Backpack (VII)	0.008	1600
Mixer/Loader/Applicator		
Solid Broadcast-Whirly Bird (VIII)	0.064	200
Low Pressure Handwand (IX)	0.149	84

* The dermal dose was adjusted for a 60 kg individual.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

161-1. Hydrolysis:

Based upon data from acceptable studies, oryzalin is stable to hydrolysis at pH's 5, 7, and 9. However, oryzalin has a pKa of 8.6 (Helling, 1976, published literature) and is more than 50% deprotonated (removal of hydrogen from the sulfanilamide group) at pH 9. (MRID 41378401; acceptable)

161-2. Photodegradation in Water:

Oryzalin can photolyze with a half life of 5 hours in aqueous solution (pH 5, (2.47 ppm) at 25EC). The aqueous solution was exposed to a Xenon arc lamp for 12 hours. Identified aqueous photoproducts include:

3-nitro-5-aminosulfanilamide (2.9%),

3-nitro-5-amino-N-propylsulfanilamide (OR-5, 4.0%),

3,5-dinitro-sulfanilamide (OR-3, 5.7%), and

2-ethyl-7-nitro-1-propyl-5-sulfonylaminobenzimidazole 3-oxide (14%).

The calculated first-order photodegradation half-life of oryzalin was 2.3 artificial hours or 1.4 sunlight hours. Oryzalin remained relatively stable in the dark control. (MRID #41278701, supplemental information; acceptable)

161-3 Photodegradation on Soil:

Oryzalin applied to sandy loam soil and irradiated for 61 hours with a xenon lamp degraded with biphasic kinetics. The biphasic photolysis half-life observed on soil is somewhat longer than the first-order half-life in aqueous solution. A linear regression of the initial phase (hours 0 through 13.0) line resulted in a half-life of 22.4 hours. Identified photoproducts in soil include:

3,5-dinitro-4-amino-sulfanilamide (OR-3, 2.6%),

2-ethyl-7-nitro-5-sulfamoyl benzimidazole (OR-15, 3.2%) and

3,5-dinitro-N,N-dipropyl sulfanilic acid (OR-21, 4.6%).

After 61 hours of radiation, 14.5% of the applied was bound to the soil. Approximately 35% of the applied material appears to have been left unresolved by the two HPLC systems used in this study.

Degradation of oryzalin in the dark control was not substantial enough to calculate a half-life. (MRID 41050001; acceptable)

162-1 Aerobic Soil Metabolism:

In aerobic soil, oryzalin exhibited an average overall half-life of 2.1 months at 24E C. The major degradate was 4-Hydroxy-3,5-dinitro-benzenesulfonamide (OR-20), which accounted for a maximum of 4.7% of 0 time radioactivity at 1 month post-treatment. Eight other degradates were isolated, each accounting for $\leq$ 2.4% of the applied radioactivity. The benzenesulfonamide ring remained intact in all of the identified metabolites. By the end of the experiment at 6.1 months, 63.1% of the applied radioactivity was nonextractable and 5.7% had been mineralized to CO2. (MRID 41322801; acceptable)

162-2 Anaerobic Soil Metabolism:

Oryzalin degraded with a 10 day half-life when anaerobic conditions were established after 23 days of aerobic incubation at 28EC in sandy loam soil. By the end of the experiment at 6.1 months, 63.1% of the applied radioactivity was nonextractable.

An initial half-life of 1.2 months was calculated for the first 7 data points of the biphasic curve (first 2 months of the study) and a 3 month half-life was calculated for the last 4 data points of the curve (last 4 months of the study).

The major degradates formed during the anaerobic incubation were several benzeneimidazoles with a reduced nitro group and smaller amounts of benzenesulfonamides with 1 or 2 nitro groups reducing to amines. Gingerich and Zimdahl (1979, published literature) suggest that a highly oxidized parent compound like oryzalin will degrade more rapidly under reducing than under oxidizing conditions, and the submitted data is consistent with the oryzalin half-lives measured in the Gingerich and Zimdahl study.

Oryzalin accounted for 62.3% of the applied radioactivity after 23 days of the initial aerobic incubation in sandy loam soil. The major degradates formed during the aerobic incubation were:

4-hydroxy-3,5-dinitrobenzenesulfonamide;

2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide,3-oxide;

3,3'-azoxybis[4-(propylamino)-5-nitro]benzenesulfonamide; and

3,5-dinitro-4-(propylamino) benzenesulfonamide

which were present in 4.7, 2.4, 1.4, and 1.2% respectively of 0 time radioactivity. After conversion to anaerobic conditions these aerobic metabolites (at 30 and 60 day samples) each accounted for $\leq$ 0.2% 0 time radioactivity. At 60 days of anaerobic incubation 1.0% of 0 time radioactivity remained as oryzalin. (MRID 413228-02; acceptable)

163-1 Mobility/Adsorption/Desorption:

Unaged batch equilibrium

Uniformly ring-labeled ^{14}C oryzalin solutions at 1.0, 0.2, 0.04, 0.008 ug/ml in $CaCl_2$ were equilibrated for 22 hours at 25E C in a sandy loam (O.M. 1.4%, pH 5.7, CEC 4.9 meq/100g), a loam (O.M. 1.8%, pH 6.5, CEC 10.5 meq/100g) and a clay loam soil (O.M. 2.0%, pH 6.9, CEC 21.2 meq/100g). The results suggest that oryzalin may be moderately mobile:

Unaged Batch Equilibrium: (at 1 mcg/ml)

Soil Type	$\mathbf{K_{d(ads)}}^*$	$\mathbf{K_{d(des)}}^*$	**%OM**
sand	2.1	1.3	-
sandy loam	4.9	1.9	1.4
loam	8.4	2.3	1.8
clay loam	12.9	2.6	2.0

* Ad/des values were an average of three replicates.

Total recoveries from all extractions ranged from 89.2% to 105.5%. Oryzalin was stable throughout the experiment as confirmed by thin layer chromatography (TLC).

Jacques and Harvey (1979a, published literature) showed that oryzalin adsorption was more strongly correlated to the amount of organic matter in the soil than to any other soil feature, with an r value of .95. They also showed that unlike other dinitroaniline herbicides, which diffuse as vapors through dry soil, oryzalin diffused most rapidly when the soil was wet (48.8% weight/weight wetness). This suggests that oryzalin would be most mobile in coarse, wet, alkaline soils with little organic matter. Helling (1976, published literature) confirms that, although oryzalin is not especially mobile, "oryzalin leaching was greater when the soil was initially moist rather than dry."
(MRID# 41479802, additional supporting data; acceptable; MRID 41479801; supplemental)

Aged Soil Column Leaching:

Potential mobility of oryzalin degradates is not well understood. Mobile degradates that degrade further and then bind irreversibly in the closed laboratory system may leach before the additional biodegradation and soil binding can occur in the field.

Oryzalin aged in sandy loam soil at 25°C ± 1°C for 30 days was leached from a loam soil (sieved through 2mm mesh) with 0.01M $CaCl_2$. In the soil column leaching experiment, 2.9-3.9% of total applied radioactivity was found in the leachate. Greater than 50% of the radioactivity found in the leachate was 4-hydroxy-3,5-dinitro-benzenesulfonamide. It is not clear whether leaching of 4-hydroxy-3,5-dinitro-benzenesulfonamide and other oryzalin degradates could represent a significant route of oryzalin dissipation in the field. Oryzalin comprised 0.3-0.6% of radioactivity found in the leachate from the loam soil.

Aged Adsorption/Desorption (Batch Equilibrium) Data:

The registrant has offered to submit additional aged oryzalin desorption data on three soils to provide information on the mobility of the 9 metabolites identified in the aerobic soil metabolism (162-1) study. The Agency has already reviewed a protocol for this study. However, the Agency has also recommended that the registrant complete an adsorption/desorption study on the major aerobic soil biodegradate, 4-Hydroxy-3,5-dinitro-benzenesulfonamide.

164-1: Terrestrial Field Dissipation:

The terrestrial field dissipation data are inconclusive at this time because they provide no information about the dissipation route of oryzalin but merely indicate its rate of disappearance. While it is true that no single degradate in the aerobic soil metabolism study comprised more than 4.7% of the applied radioactivity, all of the reported degradates retained the benzenesulfonamide structure. It may be possible to monitor this structure, if not the individual degradates in the field. Data on the mobility of oryzalin degradates (proposed study discussed below) has not yet been received, and it is not possible at this time to judge whether oryzalin dissipation in the field is due solely to biodegradation or whether oryzalin degradates might leach before further biodegradation occurs.

Oryzalin demonstrated moderate persistence with a first order half life of 68 days in sand soil in Florida and biphasic degradation in Michigan and California. First phase half-lives were 77 days in silty clay loam in Michigan and 58 days in loam soil in California, while second phase half lives were 146 days in Michigan and 138 days in California. This approximates the aerobic soil half-life observed in the laboratory, and appears to rule out photodegradation and anaerobiosis as major field processes for typical uses of oryzalin. Biphasic field dissipation of

oryzalin at a similar rate was observed by Jacques and Harvey (1979, published literature). In their study, oryzalin dissipated rapidly to day 50, but was continually found near the limit of detection to day 350 with little change.

Parent oryzalin did not appear to be mobile. However, as no degradates were monitored in the field and the laboratory mobility data is incomplete, it is not possible to define the dissipation route of oryzalin. Oryzalin is not volatile, and volatile by-products other than $14CO_2$ were not significant in any submitted study.

Ring-labeled ^{14}C-oryzalin has also been tested in the field (1975, Golab et. al., published literature). After 36 months, 35% of the applied radioactivity was soil bound, 20% was extractable (approximately 1% was parent oryzalin), and 45% "dissipated" from the upper 15 cm of the soil. Only a "small" amount of radioactivity was taken up by the crop. Bound residue content appeared to remain stable between 2 months and 3 years. While this confirms that irreversible soil binding is a significant field dissipation route for oryzalin, it may not be the only significant route, as suggested by the submitted aerobic soil metabolism laboratory study.

For complete fulfillment of the terrestrial field dissipation data requirement, the registrant must first provide an acceptable study of the mobility of oryzalin degradates. The registrant may be required to re-analyze the field samples from this study, or to conduct a new study, if the degradates prove to be mobile. Also, acceptable data on the wettable powder formulation at two typical use field sites may be required. (MRID 41859701, 42138001; not acceptable at this time)

165-4: Bioaccumulation in Fish:

Oryzalin does not accumulate significantly in fish. The concentration of oryzalin in tissues reached a steady state at approximately 3 days after treatment. The study indicates that oryzalin was not highly concentrated in bluegill sunfish: having a BCF of 32.2 in edible tissue, 105.7 in nonedible tissue, 66.1 in whole fish. Within 24 hours depuration period there was 79.2%, 81.4% and 80.8% loss of radioactivity in edible, nonedible and whole fish respectively. By day 14 there was a loss of 88.7%, 95.1% and 93.6% in edible, nonedible and whole fish respectively. Residues consisted primarily of oryzalin, two metabolites resulting from the hydroxylation of the N-propyl group and a N-dealkylated metabolite.
(MRID 40787501, additional supporting information; acceptable)

201-1: Droplet Size Spectrum and 201-1: Field Drift Studies

Droplet size spectrum (201-1) and field drift studies (202-1) are needed to support ground spray, aerial spray, and air-blast application methods for oryzalin. Spray drift studies are required for aerially applied herbicides (*e.g.*, air blast, etc.) with Tox. 1 or Tox. 2 classifications, or if the herbicide poses a potential environmental risk such as non-target phytotoxicity. The registrant may elect to satisfy both data requirements through the Spray Drift Task Force,

provided that the Agency does not require these data in advance of the Task Force's final report (currently scheduled for December 1994).

b. Environmental Fate Assessment

There are acceptable data on the mobility and dissipation route of parent oryzalin (3,5-dinitro-N^4,N^4-dipropylsulfanilamide). However, there is no acceptable data on the mobility and dissipation of the oryzalin degradates. The degradates have not been monitored in the field. Submitted field studies monitored only the dissipation of parent oryzalin, which appears to biodegrade slowly with a first half-life of approximately two months. Parent oryzalin does not appear to be mobile under field conditions. While it appears that most of the applied oryzalin either binds to soil or is fully mineralized, a maximum of 10-20% of oryzalin degradates may leach. The identity and leaching rate of these compounds is not known. Without data on the mobility and dissipation route of the oryzalin degradates, it is not clear whether leaching of these degradates could represent a significant route of oryzalin dissipation in the field.

Published and submitted data indicate that parent oryzalin would be most mobile in coarse, wet, alkaline soils with little organic matter. However, parent oryzalin would not be stable if it were to leach to groundwater. Anaerobic conditions below the soil surface would cause the chemical reduction of the compound. Oryzalin is not volatile.

Oryzalin can be applied aerially and by ground spray, and therefore could contaminate surface waters by spray drift at application. Substantial quantities of oryzalin could also be available for runoff for several days to months post-application depending in part upon the degree of exposure to sunlight (photodegradation on soil half-life of 3.9 days; aerobic soil half-life = 2.1 months; terrestrial field dissipation half-lives of 77-146 and 58-138 days). The moderately low to intermediate soil/water partitioning of oryzalin (K_d = 2.1, 4.9, 8.4, and 12.9; K_{oc} from SCS database = 600) indicates that substantial fractions of oryzalin could be transported via both dissolution in runoff water and adsorption to eroding soil.

The susceptibility of oryzalin to direct photolysis in water (half-life = 1.4 hours) should limit its persistence in clear shallow waters with low light attenuation. However, its resistance to abiotic hydrolysis coupled with only a moderate susceptibility to aerobic and anaerobic biodegradation indicate that it will be somewhat more persistent in receiving surface waters that are deeper, have high light attenuation, low microbiological activities and long hydrological resident times. Based upon its relatively low to intermediate soil/water partitioning, significant fractions of the oryzalin in receiving surface waters should exist both dissolved in the water column and adsorbed to suspended and bottom sediment. The reported BCFs for oryzalin (32X to 106X) indicate that the bioaccumulation potential of oryzalin is relatively low.

The available data on the major degradates of oryzalin are insufficient to assess their runoff characteristics or persistence in surface waters.

No MCL or drinking water health advisories have been established for oryzalin. In addition, oryzalin exhibits susceptibility to rapid direct photolysis in water and somewhat intermediate soil/water partitioning which should contribute somewhat to its removal by the primary treatment methods employed by most surface water source supply systems. Consequently, the Agency is not currently recommending any monitoring of surface water source drinking water supplies for oryzalin.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

(a) Avian

The avian reproduction study conducted in 1982 did not have test doses for application rates greater than 4 lb a.i./A. Many non-crop and industrial uses at specialty sites were added since the 1982 study was conducted and have application rates of 6 lb a.i./A with a maximum application of 12 lb a.i./yr.

In order to determine whether these higher application rates pose a serious avian reproduction threat, further avian reproduction tests must be conducted at higher doses appropriate for single application rates greater than 4 lb a.i./A and for multiple applications greater than 1.5 lb ai./A. The avian chronic assessment has great uncertainty. Data from avian reproduction studies conducted at higher doses levels would reduce this uncertainty. Additional data would confirm whether there are actual chronic avian effects at single application rates greater than 4 lb ai./A and multiple applications greater than 1.5 lb ai./A.

Avian Acute and Dietary Tests, Avian Reproduction Test

The minimum data required to establish toxicity of oryzalin to birds are: 1) an avian acute oral LD_{50} for one waterfowl species or upland game bird species and 2) a dietary LC_{50} for one waterfowl species and 3) a dietary LC_{50} for one upland game bird. The preferred test species are the mallard duck (waterfowl) and the bobwhite quail (upland game bird). Due to the persistence of oryzalin, avian reproduction studies are required on both a waterfowl species and an upland game bird species.

Avian Acute

An acute oral study on the bobwhite quail revealed an LD_{50} of 506.7 mg/kg. (MRID# 00098462)

Avian Dietary

Dietary studies on the bobwhite quail and the mallard duck revealed LC_{50}s > 5000 ppm (the highest concentration tested) for both species. (MRID# 00072593, 00072694)

In the dietary study conducted with the bobwhite quail, there was one mortality at the 5000 ppm concentration but it was attributed to a mechanical injury and was not considered a toxicant related death. Even though there was no mortality observed, the bobwhite quail study did show reduced food consumption and body weight gain in all concentrations tested including the lowest concentration of 625 ppm. In the dietary study conducted with the mallard duck, there were no mortalities and no observable effects at any of the concentrations tested.

Based on test results, oryzalin may be characterized as "slightly toxic" in acute studies and "practically non-toxic" in dietary studies.

Avian Reproduction

Avian reproduction studies for the bobwhite quail and the mallard duck were previously submitted in 1982. An avian reproduction study on the bobwhite quail was submitted but did not fulfill guideline requirements due to control mortality. (MRID# 00129050)

An avian reproduction study on the mallard duck determined a NOEL of 1000 ppm, the highest level tested. This study was classified as core at the time the study was first reviewed in 1982; however, it is now classified as supplemental because the application rates for a single application have increased 4-fold from 1.5 lbs a.i./A to 6.035 lbs a.i./A. (MRID# 00126843; acceptable) Thus, the data requirements for avian reproduction (71-4 (a) and (b)) have not been satisfied. Avian reproduction studies on both species are needed to assess potential chronic effects due to the higher application rates now in use as compared to 1982 and to assess the persistence of the chemical.

However, for those doses tested in 1982, the NOEL determined is lower than the calculated terrestrial EECs.

(b) Small Mammals

The minimum data required to establish toxicity to mammals is an oral acute toxicity study. An oryzalin acute oral toxicity study had a LD_{50} > 10 g/kg. This indicates oryzalin is practically nontoxic to small mammals on an acute oral basis.

(2) Aquatic Data

(a) Effects on Freshwater Fish

The minimum data required to establish toxicity of oryzalin to fish is a 96-hour acute toxicity test with 1) a coldwater and 2) a warmwater species. The preferred species are the rainbow trout (coldwater) and the bluegill sunfish (warmwater). In addition, fish early lifestage studies were required due to the persistence of the chemical.

The 96-hour acute toxicity of oryzalin to the rainbow trout and the bluegill sunfish were 3.26 ppm and 2.88 ppm, respectively. (MRID# 00072595) The MATC for fish early life-stage studies for the fathead minnow and the rainbow trout were 0.22 ppm and 0.46 ppm, respectively. (MRID#s 00126841, 00126842) Oryzalin is characterized as "moderately toxic" to fish, based on the acute exposure.

(b) Effects on Freshwater Invertebrates

The minimum data requirement to establish acute toxicity to freshwater invertebrates is a 48-hour acute study. The 48-hour LC_{50} value for oryzalin to *Daphnia Magna* was 1.4 ppm (MRID# 00072596). Oryzalin is characterized as "moderately toxic" to aquatic invertebrates.

The Aquatic Invertebrate Life Cycle study (72-4(b)) is required due to the persistence of oryzalin in the aquatic environment; acute toxicity to Daphnids, and the solubility of oryzalin, which indicates that it may be transported to aquatic habitat.

Based on existing information, the Agency anticipates that these new data would refine concerns for chronic aquatic risks. However, we do not anticipate that it will present one of the worst chronic risks compared to other pesticides.

(c) Effects on Marine and Estuarine Organisms

No data on estuarine studies for oryzalin has been submitted to the Agency for review. These data are necessary due to oryzalin's persistence and likelihood of transport to estuarine environments. Tests on marine and estuarine organisms are required for the following use sites: berries, citrus fruits, cherry trees, pecans and golf course turf. Although, oryzalin is moderately toxic to freshwater organisms, it cannot be assumed that it will be moderately toxic to estuarine species.

Toxicity tests are required on marine and estuarine species because it is not known how the chemical will react in saline environments. In order to establish the toxicity of oryzalin to estuarine and marine organisms, the following tests are required using the technical grade material:

1) an Estuarine Fish 96-Hour Acute Toxicity Study, using the silverside or sheepshead minnow and;

2) a Mollusk 48-Hour Embryo Larvae Study, using Pacific oyster, Eastern oyster, mussel (preferably Mytilus edulis) or Quahog (Mercenaria) and;

3) a Shrimp 96-Hour Acute Toxicity Study, using white, pink, brown, grass or mysid shrimp.

Based on the moderate toxicity of oryzalin to freshwater fish and invertebrates, the Agency predicts that when compared to other pesticides, oryzalin is probably not one of the most toxic chemicals to aquatic organisms. This assessment is based only on freshwater toxicity data and does not take into account the exposure or the toxicity to estuarine and marine organisms. The Agency is requiring the testing of marine and estuarine species to confirm this assessment because results from the freshwater tests cannot be extrapolated to estuarine and marine species.

(3) Non-Target Insects Data

The minimum data requirement to establish toxicity to non-target insects is an acute contact honey bee study. The acute contact 48-hour LD_{50} for honey bees is > 11 ug/bee (MRID# 00066220). Oryzalin is classified as "practically nontoxic" to honey bees.

(4) Non-Target Plants Data

As expected for an herbicide, non-target terrestrial plants may be adversely affected from runoff and/or drift from the application of oryzalin at the labeled rates on all of the use sites. Drift from aerial application may adversely affect non-target plants.

Tier II testing is required for seed germination, seedling emergence, and vegetative vigor using 10 terrestrial plant species and for aquatic plant growth using 5 aquatic plant species. Tier II studies are laboratory/greenhouse studies using a minimum of five progressive dosages and the end results should include a NOEL and an EC_{25} or EC_{50}.

The 10 species selected should represent a cross-section of the non-target terrestrial plant population. Six dicots from at least four different families and four monocots of at least two families are to be tested.

Based on all plant studies conducted with oryzalin on cabbage, corn, cucumber, lettuce, oat, onion, radish, ryegrass, soybean and tomato, the most sensitive monocot tested was ryegrass and the most sensitive dicot tested was tomato. Germination studies measured two parameters - percent germination and root length. The emergence and vegetative vigor studies measured shoot length.

TEST TYPE	MOST SENSITIVE MONOCOT	MOST SENSITIVE DICOT
Germination		
% Germination	EC_{25} = 0.011 ppm ai	EC_{25} = 0.179 ppm ai
Root Length	EC_{25} = 0.0024 ppm ai	EC_{25} = 0.0797 ppm ai
Emergence		
Shoot Length	EC_{25} = 0.0285 ppm ai	EC_{25} = 0.0505 ppm ai
Vegetative Vigor		
Shoot Length	EC_{25} = 0.174 ppm ai	EC_{25} = 0.028 ppm ai

The EC_{25}s for the germination test (MRID# 42602401), using root length as the parameter, were: 0.020 lb a.i./A for lettuce, the most sensitive dicot tested; 0.001 lb a.i./A for oat, the most sensitive monocot tested and 0.021 lb a.i./A for onion, the most sensitive root crop tested. Additional germination EC_{25}s include: 0.078 lb a.i./A for cabbage; 0.019 lb a.i./A for corn; 0.040 lb a.i./A for cucumber; 0.0252 lb a.i./A for radish; 0.011 lb a.i./A for ryegrass; 0.115 lb a.i./A for soybean and 0.027 lb a.i./A for tomato.

The EC_{25}s for the emergence test (MRID# 42602401), using shoot length as the parameter, were: 0.0285 ppm for ryegrass the most sensitive monocot tested and 0.0505 ppm for tomato the most sensitive dicot tested and 0.318 ppm for onion the most sensitive root crop tested. Additional EC_{25}s for the emergence test include: 0.656 ppm for cabbage, 1.7 ppm for cucumber, 0.152 ppm for lettuce and 0.278 ppm for oats.

The EC_{25}s for the vegetative vigor test (MRID# 42602401), using shoot length as the parameter, were: 0.0828 lb a.i./A for tomato the most sensitive dicot tested and 0.174 lb a.i./A for ryegrass the most sensitive monocot tested.

Additional EC_{25}s for the vegetative vigor test include: 0.244 lb a.i./A for corn; 0.144 lb a.i./A for lettuce and 0.445 lb a.i./A for oats.

Aquatic Plants Data

The minimum data required to establish phytotoxicity is growth and reproduction studies on five species from a cross-section of the non-target aquatic plant population. The following aquatic plant species with their corresponding EC_{50} values are presented below:

Anabaena flos-aquae	EC_{50} = 24 ppm
Lemna gibba	EC_{50} = 15.4 ppb
Navicula pelliculosa	EC_{50} = 72 ppb
Selenastrum capricornutum	EC_{50} = 42 ppb
Skeletonema costatum	EC_{50} = 41 ppb

3. Ecological Risk Assessment

a. Terrestrial Organisms

The maximum expected terrestrial residues based on a single application at different application rates and on different categories of plants is presented in Table 7. These expected environmental concentrations (EECs) are from the Kenaga and Hoerger (1972) monograph.

Table 7. Estimated Residue of Oryzalin After A Single Application At Different Application Rates on Different Categories of Plants

Application Rate (lbs a.i./A)	Short Grass (ppm)	Long Grass (ppm)	Leaves and Leafy Crops (ppm)	Forage (ppm)	Pods Containing Seeds (ppm)	Fruits (ppm)
0.75[1]	180	83	94	44	9	5
1.0[2]	240	110	125	58	12	7
1.6[3]	384	176	200	93	19	11
2.0[4]	480	220	250	116	24	14
2.2[5]	528	242	275	128	26	15
3.0[6]	720	330	375	174	36	21
4.0[7]	960	440	500	232	48	28
6.035[8]	1448	664	754	350	72	42

[1] Ornamental Herbaceous Plants

[2] Christmas Tree Plantings, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Woody Shrubs and Vines

[3] Commercial/Industrial Lawns, Golf Course Turf, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Recreation Area Lawns

[4] Commercial/Industrial Lawns, Golf Course Turf, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines, Recreation Area Lawns

[5] Commercial/Industrial Lawns, Golf Course Turf, Ornamental Lawns and Turf, Recreation Areas

[6] Almond, Apple, Cherry, Golf Course Turf, Grapefruit, Grapes, Nectarine, Nonagricultural-Rights-of-Way, Olive, Orange, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines, Peach, Pear, Pecan, Plum, Pomegranate, Power Stations, Recreation Area Lawns

[7] Christmas Tree Plantings, Industrial Area (Outdoors), Nonagricultural Uncultivated Areas, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines

[8] Almond, Apple, Apricot, Avocado, Blackberry, Blueberry Boysenberry, Cherry, Currant, Dewberry, Elderberry, Fig, Filbert (Hazelnut), Gooseberry, Grapefruit, Grapes, Kiwi, Lemon, Loganberry, Macadamia Nut (Bushnut), Nectarine, Olive, Orange, Peach, Pear, Pecan, Pistachio, Plum, Pomegranate, Prune, Raspberry (Black and Red), English Walnut

Acute Risk to Avian Species

The acute risk to avian species from exposure to oryzalin was analyzed by two methods - LD_{50} per square foot to characterize acute risk and LD_{50} per day to characterize risk from daily dietary intake. The level of concern (LOC) is exceeded when either index exceeds 0.5 LD_{50}/ft^2 or LD_{50} per day. As can be seen from the above calculations, the LOC is exceeded, 0.698 LD_{50}/ft^2 > 0.5 LD_{50}/ft^2, for LD_{50} per square foot index. However, the LD_{50} per day index is the more appropriate one to use to characterize acute risk to avian species when the innate toxicity of the chemical is less than highly toxic as is the case with oryzalin, As this index has a value of only 0.26 LD_{50} per day, birds would need to consume large amounts of the chemical in a single day to be at a high risk to oryzalin, which is unlikely.

Subacute dietary risks to birds were also analyzed by comparing the EEC's to the LC_{50} values. If the EEC is between 0.20 and 0.50 the dietary LC_{50} value, the chemical is a candidate for restricted use classification.

The EEC for short grass based on a single application rate of 6.0 lb a.i./A (1449 ppm) may be greater than 0.20 LC_{50} (> 1,000 ppm) for the bobwhite quail and mallard duck. The LC_{50}s from the avian dietary studies were shown to be in excess of 5,000 ppm, the maximum concentration tested. The mallard duck study had no mortalities and the bobwhite quail study had 1 mortality at the 5,000 ppm level, which was not attributed to toxicity.

Because there was no mortality observed at the highest concentration level tested, an LC_{50} was estimated to determine whether oryzalin was a candidate for restricted use. If the LC_{50} were estimated as 5 times the proven no mortality level, then the estimated LC_{50} would be 25,000 ppm. One-fifth of the estimated LC_{50} would be 5,000 ppm and 0.50 would be 12,500 ppm. Both values are greater than the EEC (1,449 ppm) for a single application at 6 lb a.i./A. Therefore, oryzalin does not pose an acute risk to avian species since the restricted use classification (0.20 LC_{50}) level of concern was not exceeded.

From the data analyzed, there are minimal risks to avian species from acute and dietary exposure to oryzalin.

To calculate mg a.i./ft^2:

$$\frac{6.035 \text{ lb a.i.}}{\text{A}} \times \frac{454{,}590 \text{ mg}}{\text{lb}} \times \frac{1 \text{ Acre}}{43{,}560 \text{ ft}^2} = 62.98 \text{ mg a.i./ft2}$$

The LD_{50} for the bobwhite quail is 506.7 mg/kg. According to Duning (1984), the average weight of a bobwhite quail is 0.178 kg.

To calculate LD_{50}s per square foot

$$\frac{62.98 \text{ mg/ft}^2}{506.71 \text{ mg/kg} \times (0.178 \text{ kg}^{[1]})} = 0.698 \text{ } LD_{50}/ft^2$$

To calculate LD_{50} per day:

$$\frac{\text{(highest expected residue)} \times \text{(Percentage eaten per day)}}{LD_{50}}$$

Using the highest expected residues for the highest application rate (see Table 7) and the LD_{50} for the bobwhite quail the following LD_{50} per day is calculated:

$$\frac{1448 \text{ ppm} \times 9.2\%}{506.7 \text{ mg/kg}} = 0.263 \text{ } LD_{50} \text{ per day}$$

Chronic Risk to Avian Species

The avian reproduction study conducted in 1982 did not have test doses for application rates greater than 4 lb a.i./A. These studies showed no observable adverse effects (NOEL) at 1000 ppm, the highest rate tested. However, the use of oryzalin at single applications greater than 4 lb a.i./A and multiple applications greater than 1.5 lb a.i./A may present a potential for chronic risk to birds because a lowest observable effect level (LOEL) has not been determined and the EEC's are higher than the actual doses tested.

Oryzalin has biphasic kinetics. In addition to the Kenaga approximation method used to calculate the terrestrial EECs, a second method, the "Fate Program" was also used to calculate EECs for multiple applications of oryzalin. The initial residue value for the "Fate Program" was based on the maximum residue amount on short grass from a single application. The "Fate Program" utilizes additional information about the chemical properties of oryzalin such as half-life. Oryzalin has a first phase half-life of 60 days and a second phase half-life of 120 days and it is reasonable to assume that the third phase is considerably longer. Residue values using the Fate Program were calculated using a one-phase half-life of 120 days. Oryzalin can be applied at 6.035 lb a.i./A twice a year with a 90-day interval period, at 4 lb a.i./A three times a year with a 60-day interval period, and 2 lb a.i./A four times a year with a 60-day interval period.

Using the "Fate Program" and the expected maximum application rate (6.035 lbs ai/A twice a year with a 90-day interval period) for one year, oryzalin could have an EEC of 2310 ppm. Based on the Kenaga approximation method (see

Table 6), the EEC for oryzalin used at the 6.035 lb a.i./A rate twice a year with a 90-day interval period for one year, would be 2896 ppm. These residues would be for the first year of use and do not take into account the residues that would build up over years of use.

Based on the Kenaga approximation method (see Table 7), the EEC for the 2 lb rate used four times a year would be 1920 ppm for short grass. Using the Fate Program, the EEC for the 2 lb rate used four times a year would be 1229 ppm for short grass. Both the Kenaga approximation method and the Fate Model indicate that the EEC will be greater than the NOEL of 1000 ppm.

Oryzalin does not appear to pose a chronic risk to birds at single application rates of 4 lb a.i./A or less because the risk quotients for the different categories of plants are less than 1, the Level of Concern (LOC). However, the risk quotient for single applications at the 6 lb a.i./A is 1.5 for birds feeding on short grass. Multiple applications of the 1.5 lb a.i./A rate on turf (3 applications) and the 2.0 lb ai./A rate on a variety of uses (4 applications) will provide risk quotients of 1.2 and 2.0 for birds feeding on short grass, respectively. Risk quotients greater than 1 are in exceedance of the avian chronic LOC. These values indicate the potential for chronic risk to birds. The potential is increased because oryzalin is a moderately persistent compound.

The avian chronic assessment has great uncertainty due to the fact that a lowest observable effect level (LOEL) has not been determined and that the EEC's are higher than the actual doses tested. Data from avian reproduction studies conducted at higher doses levels would reduce this uncertainty. Additional data would confirm whether there are actual chronic avian effects at single application rates greater than 4 lb ai./A and multiple applications greater than 1.5 lb ai./A.

Risk to Small Mammals

This small mammals risk assessment is based on a sole toxicity test using laboratory rats. The test resulted in a rat $LD_{50} > 10$ g/kg which indicates that oryzalin is practically nontoxic to small mammals. Due to this lack of toxicity, oryzalin is not expected to present a risk to small mammals exposed under field conditions.

b. Aquatic Organisms

Estimated aquatic environmental concentrations (EECs) were calculated using the methods of Kenaga and Hoerger (1972) and are presented in Table 8.

Acute and Chronic Risk

A single inadvertent direct application to water at the maximum rate of 6.035 lb a.i./A would yield estimated environmental concentrations (EECs) of 4.43 ppm in shallow (6-inch) water and 0.368 ppm in deep (6-foot) water. The shallow water EEC exceeds the acute LOC LC_{50} values for all aquatic species tested (*Daphnia magna*, LC_{50} = 1.5 ppm; rainbow trout, LC_{50} = 3.3 ppm; and bluegill sunfish, LC_{50} = 2.9 ppm) in addition to the chronic MATC values for the fathead minnow (0.2 ppm). Multiple applications[9] of oryzalin may also pose a chronic risk to aquatic organisms.

Using a 10-acre field draining into a 1-acre pond with 1% runoff and 5% drift for aerial applications (including mist blowers), the 6-inch EEC is 0.487 ppm and the 6-foot EEC is 0.04 ppm. The EECs for unincorporated ground application (a 10-acre field draining into a 1-acre pond with 1% runoff) is 0.0368 ppm at 6-feet and 0.443 ppm at 6-inches. All EECs are based on a single application rate of 6.035 lb a.i./A.

Oryzalin does not appear to pose a risk to nonendangered freshwater species as all EEC's from ground and aerial application for oryzalin are below the level of concern (LOC = 0.50 LC_{50} value). The 6-foot EECs are lower than the 0.50 LC_{50} values of Daphnia magna (0.75 ppm), rainbow trout (1.65 ppm), and bluegill sunfish (1.45 ppm).

Based on existing information, the Agency anticipates that these new data would refine concerns for chronic aquatic risks. However, we do not anticipate that it will present one of the worst chronic risks compared to other pesticides. Therefore, a chronic aquatic invertebrate study is required to confirm this assessment because a potential chronic risk to aquatic invertebrates is possible.

The Agency requires data for guidelines 72-3a,b, and c for effects on marine and estuarine organisms. No data on estuarine studies for oryzalin have been submitted to the Agency for review.

Based on the moderate toxicity of oryzalin to freshwater fish and invertebrates, the Agency predicts that when compared to other pesticides, oryzalin is probably not one of the most toxic chemicals to aquatic organisms. This assessment is based only on freshwater toxicity data and does not take into account the exposure or toxicity to estuarine and marine organisms. The Agency is requiring the testing of estuarine species to confirm this assessment

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[9] Oryzalin has biphasic kinetics. See footnote 11.

because results from the freshwater tests cannot be extrapolated to estuarine and marine species.

Table 8. Estimated Aquatic Environmental Concentrations (EECs) Immediately after Application

Application Rate (lb a.i./A)	**EEC - Ground Application (ppb)[10]**	**EEC - Aerial Application (ppb)[11]**	**EEC - Direct Application (ppb)[12]**
0.75[13]	4.6	5.03	45.8
1.0[14]	6.1	6.71	61
1.6[15]	9.8	10.74	97.6
2.0[16]	12.2	13.42	122
2.2[17]	13.4	14.76	134.2
3.0[18]	18.3	20.13	183
4.0[19]	24.4	26.84	244
6.035[20]	36.8	40.49	368.1

10 The total aquatic EEC from a 10-acre field treated by unincorporated ground application and draining into a 6-foot deep 1-acre pond.

11 The total loading from both runoff (1%) and drift (5%) of a 10-acre field treated by aerial application and draining into a 6-foot deep, 1-acre pond. Aerial application includes mist blowers.

12 A single inadvertent direct application to a 6-foot deep, 1-acre pond.

13 Ornamental Herbaceous Plants

14 Christmas Tree Plantings, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Woody Shrubs and Vines

15 Commercial/Industrial Lawns, Golf Course Turf, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Recreation Area Lawns

16 Commercial/Industrial Lawns, Golf Course Turf, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines, Recreation Area Lawns

17 Commercial/Industrial Lawns, Golf Course Turf, Ornamental Lawns and Turf, Recreation Areas

18 Almond, Apple, Cherry, Golf Course Turf, Grapefruit, Grapes, Nectarine, Nonagricultural-Rights-of-Way, Olive, Orange, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines, Peach, Pear, Pecan, Plum, Pomegranate, Power Stations, Recreation Area Lawns

19 Christmas Tree Plantings, Industrial Area (Outdoors), Nonagricultural Uncultivated Areas, Ornamental and/or Shade Trees, Ornamental Herbaceous Plants, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Ornamental Woody Shrubs and Vines

20 Almond, Apple, Apricot, Avocado, Blackberry, Blueberry Boysenberry, Cherry, Currant, Dewberry, Elderberry, Fig, Filbert (Hazelnut), Gooseberry, Grapefruit, Grapes, Kiwi, Lemon, Loganberry, Macadamia Nut (Bushnut), Nectarine, Olive, Orange, Peach, Pear, Pecan, Pistachio, Plum, Pomegranate, Prune, Raspberry (Black and Red), English Walnut

Aquatic - Endangered Species

The level of concern is exceeded when the EEC exceeds 0.05 of the LC_{50} value. The 6-foot EECs are lower than the 0.05 LC_{50} (= LOC) value of the *Daphnia magna* (0.05 LC_{50} = 0.075 ppm), the most sensitive species tested. Therefore, oryzalin does not appear to pose an aquatic risk to either endangered or threatened species in deep water (6 ft) adjacent to treated fields at the current application rates.

However, in shallow water (6 in) adjacent to treated fields, the EECs exceed 0.05 LC_{50} values for all aquatic species tested (Daphnia magna, 0.075 ppm; rainbow trout, 0.165 ppm; bluegill sunfish, 0.145 ppm) and the MATC value for the fathead minnow, 0.2 ppm. In shallow water regions, application rates greater than or equal to 1.0 lb a.i./A may adversely impact endangered invertebrate species that inhabit these regions. Likewise, single application rates greater than or equal to 2.0 lb a.i./A may adversely impact endangered fish species that inhabit these regions. Therefore, oryzalin poses a potential risk to endangered aquatic species that occur in shallow regions of water.

c. Non-Target Plants

(1) Terrestrial Plant Risk

Terrestrial EEC due to Runoff from Unincorporated Ground Application

The runoff scenario for terrestrial nontarget plants from a terrestrial application assumes 1% runoff from 1 acre onto an adjacent acre.

UNINCORPORATED GROUND APPLICATION

Runoff
6.04 lb a.i./A x 1% runoff x 1 A = **0.0604 lb a.i./A**

Terrestrial EEC due to aerial application

Runoff
6.035 lb a.i./A x 60% app. effc. x 1% runoff x 1 A = 0.03621 lb a.i./A

Drift
6.035 lb a.i./A x 5% drift = 0.302 lb a.i./A

Total
0.03621 (runoff) + 0.302 (drift) = **0.33821 lb a.i./A**

Germination

The germination EC_{25}s for three sensitive crops are equal to or exceeded by the EECs produced by a range of application rates for ground spraying. The germination EC_{25}s, based on root length, are: lettuce, the most sensitive dicot tested (0.1791 lb a.i./A); oat, the most sensitive monocot tested (0.0072 lb a.i./A) and onion, the most

sensitive root crop tested (0.18 lb a.i./A). Ground applications of oryzalin as low as 0.75 lbs ai/A exceed the germination EC_{25} for oat, a representative of monocots. Since oryzalin applications may occur as high as 6.035 lb a.i./A, there is an apparent high risk to nontarget plants posed by runoff due to the unincorporated ground application of oryzalin.

The minimum aerial application rates (with their corresponding EECs in lb a.i./A) likely to affect various crops according to seed germination EC_{25}s are shown in Table 9.

Table 9.

Application Rates EECs Which Exceed Seed Germination (based on root length) EC_{25} Values			
Application Rate (lb a.i./A)	**EEC(lb)**	**Crop of Concern**	**EC_{25}(lb)**
1.0	0.05	oat (monocot)	0.0072
4.0	0.2	lettuce (dicot)	0.1791
4.0	0.2	onion (root)	0.18

This table indicates that aerial applications (soil route of exposure) of oryzalin ranging from these minimum rates up to the maximum current label rate of 6.035 lb a.i./A may pose a risk to nontarget plants. Aerial applications as low as 1.0 lb a.i./A can affect oat, a representative of monocots and aerial applications of 4 lb a.i./A and above can affect lettuce and onion, representatives of a dicot and root crop, respectively.

Emergence

The EEC for terrestrial plants is 0.34 ppm from both runoff and drift. The emergence EC_{25} based on ryegrass shoot length is 0.03 ppm. The risk quotient is 11.3 (0.34/0.03). The Risk Quotient (RQ) Level of Concern (LOC) for plants including threatened and endangered plants is 1. Since 11.3 is greater than 1, the level of concern is exceeded. Risk to terrestrial plants including federally listed threatened and endangered terrestrial plants is expected. Eliminating aerial application would decrease but not eliminate this risk.

Vegetative Vigor

The vegetative vigor EC_{25}s for several crops are equal to or exceeded by the EECs produced by a range of application rates for aerial spraying. The vegetative vigor EC_{25}s, based on shoot length, are: corn (0.244 lb a.i./A), lettuce (0.144 lb a.i./A), oat (0.445 lb a.i./A), ryegrass (0.174 lb a.i./A) and tomato (0.0828 lb a.i./A). The total terrestrial EEC from aerial application (including mist blowers and sprinkler

irrigations) of 6.035 lb a.i./A was 0.338 lb a.i./A (see calculations above). The total terrestrial EEC from aerial application (0.338 lb) exceeds the vegetative vigor EC_{25}s for corn, lettuce, ryegrass and tomato. Therefore, these studies suggest that aerial application of oryzalin may pose a risk to these crops via the foliar route of exposure.

The minimum aerial application rates (with their corresponding EECs in lb a.i./A) likely to affect various crops according to vegetative vigor EC_{25}s are shown below in Table 10.

Table 10.

Application Rates EECs Which Exceed Seed Germination (based on root length) EC_{25} Values			
Application Rate (lb a.i./A)	**EEC(lb)**	**Crop of Concern**	**EC_{25}(lb)**
1.6	0.08	tomato (dicot)	0.0828
3.0	0.15	lettuce (dicot)	0.144
4.0	0.2	ryegrass (monocot)	0.174
6.0	0.3	corn (monocot)	0.244

This table indicates that aerial applications of oryzalin ranging from these minimum rates up to the maximum current label rate of 6.035 lb a.i./A may pose a risk to nontarget plants. Aerial applications as low as 1.6 lb a.i./A can affect tomato plants, a representative of dicots and aerial applications at 4 lb a.i./A and above can affect ryegrass, a representative of monocots.

(2) Aquatic Plant Risk

The EEC for 6.035 lb ai applied to a 10-acre field draining into a 1-acre 6-foot deep water body is 37 ppb. The most sensitive aquatic EC_{50} = 15.4 *u*g/L (*Lemna gibba)*. The risk quotient is 2.4 (37 ppb/15.4 ppb). The LOC for plants, including threatened and endangered plants is 1. Since 2.4 is greater than 1, the LOC is exceeded. Risk to aquatic plants including federally listed threatened and endangered aquatic plants is expected.

d. Endangered and Threatened Species

Federally listed endangered and threatened aquatic organisms may be at risk in shallow water adjacent to treated areas. In addition, oryzalin may adversely affect federally listed endangered and threatened plants.

The Endangered Species Protection Program is expected to become final in early 1995. Limitations on the use of oryzalin will be required to protect endangered and threatened species, but these limitations have not yet been defined (and may be formulation specific). OPP anticipates that 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.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing oryzalin as an active ingredient. However, upon review of the existing database, the Agency has determined that it does not have sufficient data at this time to make a reregistration decision for use on residential lawns and turf. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of oryzalin, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of oryzalin and to determine that oryzalin can be used without resulting in unreasonable adverse effects to humans except for residential lawn and turf uses for which insufficient data were available to assess exposure/risk to persons reentering treated lawns and turf. Further, oryzalin poses a potential risk to nontarget plants from runoff due to unincorporated ground and aerial application. To address these concerns, the registrant has agreed to limit aerial application to crop uses in California. Also, in order to be effective, oryzalin products need to be watered-in, a practice that should help reduce runoff. The registrant has also agreed to specify the maximum seasonal application rates and the intervals between applications. The Agency is incorporating these changes in this Reregistration Eligibility Decision. Oryzalin may also pose a risk to endangered aquatic and terrestrial plants, however, the Agency will be addressing these concerns through the Endangered Species Protection Program which is currently being developed and is discussed in item B.4. in this section. The Agency, therefore, finds that all products containing oryzalin, except for those products registered for use on residential lawns and turf, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found

that most uses of oryzalin 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 oryzalin, 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

The Agency has determined that products containing oryzalin are eligible for reregistration **except** for products labelled for use on residential lawns and turf. Eligible oryzalin products, labelled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable adverse effects to humans or the environment. The Agency does not have enough information at this time to make an eligibility determination for products labelled for use on residential lawns and turf. In order to develop an adequate database to support this use, the Agency is requiring that additional data be submitted. Those oryzalin products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that products labelled for the following uses of oryzalin are eligible for reregistration: Orchard, berries, and vine crops, Christmas tree plantations, field-grown roses, nursery stock, ornamentals, golf courses, non-crop areas, and parks and greenhouse drainage areas. No uses were found ineligible for reregistration. Residential lawn and turf uses had insufficient data available to make a reregistration eligibility decision.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for oryzalin. Where labeling revisions are imposed, specific language is set forth in Section V of this document. Except for those uses where there is an insufficient database, the Agency has determined that all uses are eligible for reregistration.

1. Tolerance Reassessment

Tolerances listed under 40 CFR §180.304(a):

Tolerances for residues of oryzalin in/on plant commodities listed under 40 CFR §180.304(a) are expressed in terms of the combined residues of oryzalin *per se*. No tolerances have been established for animal commodities.

The tolerance expression for 40 CFR §180.304(a), which incorrectly states that "Tolerances are established for the combined residues of the herbicide oryzalin (3,5-dinitro-N^4,N^4-dipropylsulfanilamide) in or on the following raw agricultural commodities:", will be modified to remove the words "the combined."

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.304(a) for: almonds; almond hulls; avocados; citrus fruits; figs; kiwifruits; olives; pistachios; pome fruits; pomegranates; small fruits; stone fruits; and tree nuts; see Table 11 for modifications in commodity definitions.

Sufficient data are available to determine that residues of oryzalin do not concentrate in any apple, grape, or plum processed food/feed item; thus, food/feed additive tolerances are not required for these commodities. Additional processing studies for citrus and olives have been required and currently in progress. These data are considered confirmatory to the existing evidence that residues of oryzalin do not concentrate upon processing. However, if residues are found to concentrate in citrus or olive processed commodities, the Agency, under current policy, would not be able to establish food or feed additive regulations because such regulations would be inconsistent with the Delaney Clause of Section 409 of the Federal Food, Drug and Cosmetic Act. Future policy decisions may impact Section 408 tolerances (raw agricultural commodities) for any oryzalin treated crop where concentration occurs in the processed commodity.

The Agency has proposed (58 FR 44990, August 25, 1993) revisions to the crop group classifications currently listed in 40 CFR §180.34(f). There are no proposed changes to the citrus fruits group, pome fruits group, stone fruits group, and tree nuts group. However, the crop group "small fruits and berries" will be changed to the crop group "berries" with the removal of grapes and strawberries, which will be classified as miscellaneous commodities. At such time as this proposed rule is finalized, the current oryzalin tolerance for "small fruits" should be revised to "berries" and a separate tolerance of 0.05 ppm for grapes should be established.

Tolerances currently exist for residues of oryzalin in/on cottonseed, barley grain, wheat grain, peas (succulent), potatoes, and soybeans. As there are currently no registered uses of oryzalin on these crops, these tolerances will be proposed for revocation.

The tolerances for oryzalin residues in/on peppermint hay, spearmint hay, sweet potatoes, peppermint oil, and spearmint oil have been revoked (56 FR 26915, June 12, 1991).

Tolerances listed under 40 CFR §180.304(b):

Tolerances for residues of oryzalin with regional registration listed under 40 CFR §180.304(b) are expressed in terms of the combined residues of oryzalin *per se* (57 FR 59823, December 16, 1992).

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.304(b) for guavas and papayas.

A tolerance of 0.05 ppm has been proposed (PP#8E3686) for residues of oryzalin in/on green coffee beans.

Table 11. Tolerance reassessment summary for oryzalin.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.304(a):			
Almond, hulls	0.05	0.05	*Almonds, hulls*
Avocados	0.05	0.05	
Citrus fruits	0.05	0.05	
Cottonseed	0.05	Revoke	No registered uses exist.
Figs	0.05	0.05	
Grain, barley	0.05	Revoke	No registered uses exist.
Grain, wheat	0.05	Revoke	No registered uses exist.
Kiwifruits	0.05	0.05	
Nuts	0.05	0.05	*Tree nuts*
Olives	0.05	0.05	
Peas (succulent)	0.05	Revoke	No registered uses exist.
Pistachios	0.05	0.05	
Pome fruits	0.05	0.05	
Pomegranates	0.05	0.05	
Potatoes	0.05	Revoke	No registered uses exist.
Small fruits	0.05	0.05	*Berries;* and *Grapes*/ Proposed crop group revision.
Soybeans	0.10	Revoke	No registered uses exist.
Stone fruits	0.05	0.05	
Tolerances listed under 40 CFR §180.304(b):			
Beans, green coffee	N/A	N/A	0.05 ppm tolerance proposed.
Guavas	0.05	0.05	
Papayas	0.05	0.05	

2. Restricted Use Classification

Oryzalin is not currently classified for restricted use. The Agency has determined that oryzalin products should not be classified for restricted use at this time. After an analysis of additional data submitted, the Agency will reassess whether any oryzalin uses warrant a restricted use classification.

3. Reference Dose/Cancer Risk

The reference dose for oryzalin was determined to be 0.12 mg/kg/day, based on the chronic feeding study with rats in which the NOEL was 12.16 mg/kg/day and an uncertainty factor of 100. The cancer potency factor for oryzalin is 1.3×10^{-1} $(mg/kg/day)^{-1}$.

a) Dietary Risk

The chronic dietary exposure based on anticipated residue contribution (ARC) estimates are very low--less than 1/5,000th of the RfD for each of the groups and subgroups that the DRES analyses. Based on the same data, the dietary excess cancer risk estimate for the U.S. population is 8.1×10^{-7}. The upper bound risk is expected to be even lower (4.5 E-7) when tolerances are revoked for unregistered commodities.

b) Worker Risk

The cancer risks to mixers, loaders and applicators, assuming the following minimum personal protective equipment (PPE): coveralls over long-sleeved shirt and long pants, and chemical-resistant gloves, were all less than 10^{-4}, or have margins of exposures (MOEs) greater than 100, except for low-pressure handwand application. Exposures for low-pressure handwand application will be adequately reduced (MOE greater than 100) with the imposition of chemical-resistant footwear. Other PPE and reentry intervals are addressed in Section V.

4. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered aquatic species in shallow waters to oryzalin as discussed in the science assessment section. Currently, the Agency is developing a program (The Endangered Species Protection Program") to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program will require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins will provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Protection Program in the Federal Register and have enforceable county-specific bulletins available by 1995. Because the Agency is taking this approach for protection endangered and threatened species, it is not imposing label modifications at this time through the RED document. Rather, any requirement for product use modifications will occur in the future under the Endangered Species Protection Program.

5. Worker Protection Requirements

a. Compliance with Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

(1) Mixer/Loader/Applicator Personal Protective Equipment (PPE) Requirements for Oryzalin

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects:

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns about oryzalin (classified as a Group C carcinogen) that warrant the establishment of active-ingredient-based minimum PPE requirements. These requirements, which are discussed below, are also based on the Agency's exposure assessment.

Handler PPE for Occupational-Use Products

- **WPS Uses:** End-use products with uses of oryzalin that are within the scope of the Worker Protection Standard (WPS) must have the following minimum (baseline) PPE: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear for overhead exposures for all handlers. Mixers and loaders must also wear a chemical-resistant apron.

- **Non-WPS Uses:** End-use products with occupational uses of oryzalin outside the scope of the Worker Protection Standard must have the following minimum (baseline) PPE: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear for overhead exposures for all handlers. Mixers and loaders must also wear a chemical-resistant apron.

Handler PPE for Homeowner-Use Products

For oryzalin products with homeowner uses, the following PPE are required: Long-sleeved shirt, long pants, and chemical resistant gloves.

(2) Early Entry Personal Protective Equipment (PPE) for Oryzalin

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated

surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who enter areas that remain under a restricted-entry interval and who contact treated surfaces are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Early Entry PPE for Occupational Use Products

- **WPS Uses:** Since oryzalin is categorized as a Group C carcinogen and the Agency's exposure assessment for handlers warrants it, the PPE required for early entry is coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposures.

- **Non-WPS Uses:** Some of the registered uses of oryzalin are outside the scope of the Worker Protection Standard. The Agency is not requiring early entry PPE for these uses (e.g. rights-of-way, golf courses) because significant exposure is unlikely. Exposure is limited primarily to walking on treated surfaces rather than full contact with foliage.

(3) Post-application Entry Restrictions for Oryzalin

Entry Restrictions for Occupational-Use Products

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established 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: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

- **WPS Uses:** For those end-use products with registered uses of oryzalin within the scope of the Worker Protection Standard, the following Restricted Entry Interval (REI) is required. The Agency is establishing a 24-hour interim restricted-entry interval pertaining to each use of the product that is within the scope of the Worker Protection Standard. This requirement is based on oryzalin being classified as a Group C carcinogen. The REI remains interim, since data on post-application exposures are being required. The Agency will establish a permanent REI once the required post-application exposure data are generated by the registrant and reviewed by the Agency. These data are specified in Part V.

The Agency notes that the labeling directions for some uses of oryzalin require the application to be watered-in to a specified level, such as 1/2 to 1 inch of rainfall or irrigation. If oryzalin has been correctly incorporated through watering-in at the label-specified rate, workers may enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

The WPS REI in effect until now was 12 hours. The Agency found no extenuating circumstance for retaining the 12-hour interim REI placed on oryzalin products by PR Notice 93-7. The Agency notes that the 12-hour interim WPS REI was established based on acute toxicity concerns only and did not take into account oryzalin's classification as a Group C carcinogen.

- **Non-WPS Uses:** The Agency is requiring that the entry for non-WPS occupational uses of oryzalin be the following. See section V of this document for specific label language.

  - for liquid applications: a prohibition on entry until the sprays have dried;
  - for dry applications: a prohibition on entry until dusts have settled.
  - for all other non-WPS applications: a prohibition on entry until sprays have dried or dusts have settled.

- **Residential Uses:** The Agency is requiring that the entry restriction for residential uses of oryzalin be the following:

  - for all applications: a prohibition on entry for people or pets until sprays have dried or dusts have settled.

Reentry Data Requirements

Since oryzalin is a possible human carcinogen and is persistent, the Agency is concerned about chronic post-application exposures to homeowners, including children, resulting from applications made to residential lawns. At this time, the Agency does not have sufficient information to estimate post-application exposure for uses of oryzalin on residential lawns and turfgrass and is, therefore, unable to conduct an exposure assessment for this use. For the residential lawn and turfgrass use to be eligible for reregistration, the following data are required: foliar dislodgeable residues (guideline 132-1a), soil dislodgeable residues (guideline 132-1b), estimation of dermal exposure (guideline 133-3), and estimation of inhalation exposure (133-4).

6. Other WPS-Related Labeling

User safety statements are required for all oryzalin products and are listed in Section V. In some cases, handler PPE requirements may be reduced or modified when engineering controls are used. This is also described in Section V.

7. Grazing Restrictions

All end-use product labels must be amended to include a restriction against grazing or feeding crops grown in treated areas to livestock.

8. Changes in Directions for Use

In order to minimize oryzalin exposure, the Agency is requiring that all end-use products specify application rates, number of applications per year, total pounds of a.i. per year, and intervals between application. These requirements are detailed in part V under End-Use Labeling.

9. Precautionary Statement for Fish

In order to provide protection for fish that may be exposed to oryzalin, a fish toxicity statement is required. See Part V under end-use labeling.

10. Spray Drift Advisory

The registrant has agreed to restrict aerial application of oryzalin products to agricultural uses in California only. In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labeling statements. This future labeling may be required for all oryzalin products that may be applied aerially to agricultural crops.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of oryzalin for the above eligible uses has been reviewed and determined to be substantially complete for all uses except residential lawns and turf. However, additional confirmatory data are needed to fulfill requirements for the studies listed below:

Avian Reproduction - mallard and quail (for single applications greater than 4 lb a.i./A and multiple applications greater than 1.5 lb a.i./A)
Acute Toxicity to Estuarine and Marine Organisms - fish, mollusk, shrimp
Aquatic Invertebrate Lifecycle
Dermal Irritation
Leaching/Adsorption/Desorption (current testing is underway to determine oryzalin degradate mobility)
Spray Drift
Storage Stability (apples and grapes - studies underway)
Processing Studies (citrus and olives - studies underway)

Mixer/Loader/Applicator Exposure Monitoring
Estimation of Dermal Exposure at Outdoor Sites (for low pressure handwand application)
Estimation of Inhalation Exposure at Outdoor Sites (for low pressure handwand application)

Reentry Protection
Foliar Dislodgeable Residues (Christmas trees, field-grown roses)
Estimation of Dermal Exposure (Christmas trees, field-grown roses)
Estimation of Inhalation Exposure (Christmas trees, field-grown roses)

The following data are required to support the use of oryzalin on residential lawns and turfgrass:

Foliar Dislodgeable Residues
Soil Dislodgeable Residues
Estimation of Dermal Exposure
Estimation of Inhalation Exposure

2. Labeling Requirements for Manufacturing-Use Products

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA (see 1987 Oryzalin Registration Standard).

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. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) 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

a. Worker Protection Standard

(1) Post-Application Reentry Restrictions; Labeling

- **WPS Uses:** In order to remain in compliance with FIFRA, a 24 hour REI is required for all oryzalin end-use products registered for uses that are within the scope of WPS.

  The 24 hour REI should be inserted into the standardized REI statement required by PR Notice 93-7.

- **Non-WPS Uses:** The following entry prohibition for non-WPS occupational use products of oryzalin is required:

For Liquids: "Keep all persons, children and pets out of the treated area until sprays have dried."

For Dry Formulations: "Keep all persons, children and pets out of the treated area until dusts have settled."

For all other Non-WPS Formulations, including Residential Use Formulations: "Keep all persons, children and pets out of the treated area until sprays have dried or dusts have settled."

(2) Personal Protective Equipment; Labeling

- **WPS Occupational Uses:** For all uses of oryzalin within the scope of WPS, the minimum PPE requirements for pesticide handlers on all oryzalin end-use products are:

  - coveralls over long-sleeved shirt and long pants
  - chemical resistant gloves
  - chemical resistant footwear
  - chemical resistant headgear for overhead exposures
  - chemical resistant apron (mixers and loaders)

- **Non-WPS Uses:** For all uses of oryzalin outside the scope of WPS, the minimum PPE requirements for pesticide handlers on all oryzalin end-use products are:

  - coveralls over long-sleeved shirt and long pants
  - chemical resistant gloves
  - chemical resistant footwear
  - chemical resistant headgear for overhead exposures
  - chemical resistant apron (mixers and loaders)

- **Homeowner Uses:** For all homeowner uses, the minimum PPE requirements are:

  - Long-sleeve shirt and long pants
  - Chemical resistant gloves

Other Worker Protection Labeling Requirements

- **Reduced PPE when Engineering Controls Used**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

- **User Safety Statements**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside.

Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

For WPS uses and non-WPS uses do not apply this product in a way that will contact workers or other persons, either directly or though drift. Only protected handlers may be in the area during application.

b. Precautionary Label Statement for Fish

In order to provide protection for fish that may be exposed to oryzalin, the following fish toxicity statement is required:

"This pesticide is toxic to fish. Do not apply this product directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

c. Grazing Restrictions; Labeling

All oryzalin end-use product labels must be amended to include the following restriction against grazing or feeding crops grown in treated areas to livestock:

"Do not graze or feed forage from treated fields or orchards to livestock."

d. Changes in Directions for Use; Labeling

All end-use product labels must bear the specific application rates, number of applications per year, total pounds a.i. per year, and intervals between applications, as specified in Table 12.

e. Restriction on Aerial Application; Labeling

All end-use product labels must prohibit aerial application except for agricultural uses in California.

Table 12. Oryzalin Labels - Number of Applications Allowed and Interval Between Applications

Use	Application Rate (lb a.i./A)	Minimum Time Between Applications (months)	Total Amount Allowed (lb a.i./A/year)
Landscape ornamentals	1.5 - 2 3 - 4	2 4	8 12
Field-grown and container-grown ornamentals	2 3 4	3 3 3	8 9 12
Ornamental bulbs	0.75 - 1.5	3	3
Christmas tree plantations	2 - 4	2	8
Non-croplands	2 4 6	2 4 8	6 12 12
Warm-Season Turf	1.5 - 2	3	6
Florida Turf	1.5	3	4.5
All crops for all soil types	2 - 6	2.5	12

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 products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, 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.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Appendix A is approximately 75 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix D.

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case oryzalin covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to oryzalin in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	A,B,C,K	40455001, 40744901
61-2A	Start. Mat. & Mnfg. Process	A,B,C,K	40455001
61-2B	Formation of Impurities	A,B,C,K	40455001
62-1	Preliminary Analysis	A,B,C,K	40744902, 40744903, 41125501
62-2	Certification of limits	A,B,C,K	40744901, 40744902, 41125501, 42158501
62-3	Analytical Method	A,B,C,K	40744903, 40744904, 41125501
63-2	Color	A,B,C,K	40454801
63-3	Physical State	A,B,C,K	40454801
63-4	Odor	A,B,C,K	40454801
63-5	Melting Point	A,B,C,K	40454801
63-6	Boiling Point	A,B,C,K	40454801
63-7	Density	A,B,C,K	40454801
63-8	Solubility	A,B,C,K	40454801
63-9	Vapor Pressure	A,B,C,K	40454801
63-10	Dissociation Constant	A,B,C,K	40454801

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	Octanol/Water Partition	A,B,C,K	40454801
63-12	pH	A,B,C,K	40454801
63-13	Stability	A,B,C,K	40454801
63-14	Oxidizing/Reducing Action	A,B,C,K	40455002
63-16	Explodability	A,B,C,K	40455002
63-17	Storage stability	A,B,C,K	40455002
63-20	Corrosion characteristics	A,B,C,K	40455002
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C,K	00098462
71-2A	Avian Dietary - Quail	A,B,C,K	00072593
71-2B	Avian Dietary - Duck	A,B,C,K	00072594
71-4A	Avian Reproduction - Quail	A,B,C,K	00129050, (DATA GAP)
71-4B	Avian Reproduction - Duck	A,B,C,K	00126843, (DATA GAP)
72-1A	Fish Toxicity Bluegill	A,B,C,K	00072595
72-1C	Fish Toxicity Rainbow Trout	A,B,C,K	00072595
72-2A	Invertebrate Toxicity	A,B,C,K	00072596
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C,K	DATA GAP
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C,K	DATA GAP
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C,K	DATA GAP
72-4A	Early Life Stage Fish	A,B,C,K	00126841, 00126842

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT		USE PATTERN	CITATION(S)
72-4B	Life Cycle Invertebrate	A,B,C,K	DATA GAP
123-1A	Seed Germination/Seedling Emergence	A,B,C,K	42602401
123-1B	Vegetative Vigor	A,B,C,K	42602401
141-1	Honey Bee Acute Contact	A,B,C,K	00066220
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A,B,C,K	00038668
81-2	Acute Dermal Toxicity - Rabbit/Rat	A,B,C,K	00041970, 00106681
81-3	Acute Inhalation Toxicity - Rat	A,B,C,K	41034201
81-4	Primary Eye Irritation - Rabbit	A,B,C,K	00106681
81-5	Primary Dermal Irritation - Rabbit	A,B,C,K	DATA GAP
81-6	Dermal Sensitization - Guinea Pig	A,B,C,K	00026762
82-1A	90-Day Feeding - Rodent	A,B,C,K	00026773
82-1B	90-Day Feeding - Non-rodent	A,B,C,K	00106670
82-2	21-Day Dermal - Rabbit/Rat	A,B,C,K	00026772, 00038667
83-1A	Chronic Feeding Toxicity - Rodent	A,B,C,K	00026780, 00068079 00044332
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B,C,K	40024801
83-2A	Oncogenicity - Rat	A,B,C,K	00044332
83-2B	Oncogenicity - Mouse	A,B,C,K	0026780, 00068079

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT		USE PATTERN	CITATION(S)
83-3A	**Developmental Toxicity - Rat**	**A,B,C,K**	**41163801**
83-3B	**Developmental Toxicity - Rabbit**	**A,B,C,K**	**00026785, 00098461**
83-4	**2-Generation Reproduction - Rat**	**A,B,C,K**	**00026786, 00042908 42401501**
84-2A	**Gene Mutation (Ames Test)**	**A,B,C,K**	**00130427, 41050101, 41289901**
84-2B	**Structural Chromosomal Aberration**	**A,B,C,K**	**00115743, 00086801**
84-4	**Other Genotoxic Effects**	**A,B,C,K**	**00086801**
85-2	**Dermal Penetration**	**A,B,C,K**	**42784102**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	**A,B,C,K**	**DATA GAP**
132-1B	**Soil Residue Dissipation**	**A,B,C,K**	**DATA GAP**
133-3	**Dermal Passive Dosimetry Exposure**	**A,B,C,K**	**DATA GAP**
133-4	**Inhalation Passive Dosimetry Exposure**	**A,B,C,K**	**DATA GAP**
231	**Estimation of Dermal Exposure at Outdoor Sites**	**A,B,C,K**	**42137901**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	**A,B,C,K**	**42137901**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	**A,B,C,K**	**41378401**
161-2	**Photodegradation - Water**	**A,B,C**	**41278701**

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT		USE PATTERN	CITATION(S)
161-3	Photodegradation - Soil	A,B,C	41050001
162-1	Aerobic Soil Metabolism	A,B,C,K	41322801
162-2	Anaerobic Soil Metabolism	A,B,C	41322802
163-1	Leaching/Adsorption/ Desorption	A,B,C,K	41479801, 41479802, (DATA GAP)
164-1	Terrestrial Field Dissipation	A,B,C,K	41859701
165-4	Bioaccumulation in Fish	A,B,C	40787501
201-1	Droplet Size Spectrum	A,B,C	(DATA GAP)
202-1	Drift Field Evaluation	A,B,C	(DATA GAP)
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A,B	42558201
171-4B	Nature of Residue - Livestock	A,B	42064901, 42158502
171-4C	Residue Analytical Method - Plants	A,B	00023990, 00132710 00106730, 41630302
171-4D	Residue Analytical Method - Animal	A,B	42064903, 42064904
171-4E	Storage Stability	A,B	00106730, 41630301, (DATA GAP)
171-4K	Crop Field Trials	A,B	
	Citrus Fruits Group	A,B	
	Grapefruit		00031663, 00106691
	Lemons		00106691
	Oranges		00031663, 00106691

Data Supporting Guideline Requirements for the Reregistration of Oryzalin

REQUIREMENT	USE PATTERN	CITATION(S)
Pome Fruits Group	**A,B**	
Apples		**00031663, 00106691, 41906001**
Pears		**00031663, 00106691, 41906005**
Stone Fruits Group	**A,B**	
Apricots		**00031663, 00106691**
Cherries		**00106691**
Nectarines		**00031663, 00106691**
Peaches		**00031663, 00106691**
Plums (fresh prunes)		**00031663, 00106691**
Small Fruits and Berries Group	**A,B**	
Blackberries		**00106691**
Blueberries		**00106691**
Boysenberries		**00106691**
Currants		**00106691**
Elderberries		**00106691**
Gooseberries		**00106691**
Grapes		**00031663, 00106691, 41906004**
Loganberries		**00106691**
Pomegranates		**00106691**
Raspberries		**00106691, 42050001**
Tree Nuts Group		

REQUIREMENT		USE PATTERN	CITATION(S)
	Almonds		00031663, 00106691
	Pecans		00031663, 00106691
	Walnuts		00031663, 00106691
	Miscellaneous Commodities		
	Avocados		00106685
	Figs		41733701
	Guavas		00106691
	Kiwi		00106691
	Olives		41115501
	Papayas		00031663, 00106691
	Pistachio		00106691
171-4L	Processed Food	A,B	
	Apples		41906002
	Citrus		00031663, 00106691
	Figs		(DATA GAP)
	Grapes		00031663, 00106691, 41906003
	Olives		(DATA GAP)
	Plums		00031663, 00106691

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Oryzalin

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 Decision. 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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42064901 Graper, L. (1991) Nature of ¢carbon 14* Oryzalin Residues in Bovine Tissue and Milk: Lab Project Number: ABC 0457/0458. Unpublished study prepared by DowElanco. 49 p.

42064903 West, S. (1991) Gas Chromatographic Determination of Oryzalin in Meat, Milk or Eggs: Lab Project Number: AM-AA-CA-RO77-AA-755. Unpublished study prepared by DowElanco. 22 p.

42064904 West, S. (1991) Determination of Oryzalin in Meat, Milk or Eggs by High-Performance Liquid Chromatography: Lab Project Number: AMAA-CA-R078-AA-755. Unpublished study prepared by DowElanco. 22 p.

42137901 Saunders, D.; Elliott, S.; Emery, K. (1991) Exposure of Mixer/Loaders and Applicators to Oryzalin from Application of Surflan 85DF with a Groundboom Sprayer: Lab Project Number: AAC8508. Unpublished study prepared by Lilly Research Labs. 349 p.

42158501 Handy, P.; Coghlan, M. (1991) Response to EPA Product Chemistry Review for Oryzalin: Lab Project Number: PRH9108. Unpublished study prepared by DowElanco. 11 p.

42158502 Graper, L. (1991) Nature of Carbon 14 Oryzalin Residues in Chickens: Lab Project Number: MET91026. Unpublished study prepared by DowElanco. 103 p.

42401501 Hoyt, J.; Beckhelm, G.; Jordon, W. (1992) A One-Generation Study in Fischer 344 Rats Maintained on Diets Containing Oryzalin (EL-119, Compound 067019): Lab Project Number: R21990: R10991. Unpublished study prepared by Lilly Research Labs, Inc. 1139 p.

42558201 Rainey, D. (1992) Nature of Residue in Grapes Treated with carbon 14 Oryzalin: Lab Project Number: ABC0453. Unpublished study prepared by DowElanco. 19 p.

42602401 Feutz, E. (1992) Evaluating the Effects of Oryzalin on the Germination, Emergence, and Vegetative Vigor of Non-target Terrestrial Plants: Lab Project Number: 40292. Unpublished study prepared by ABC Labs, Inc. 155 p.

BIBLIOGRAPHY

MRID	CITATION

42784102 Bridge, T.; Lobb, K. (1982) Percutaneous Absorption of (carbon 14)-Oryzalin in Monkeys: Lab Project Number: DMR052193A. Unpublished study prepared by Toxicology Division, Lilly Research Labs. 30 p.

43207001 Jordan, W.; Bridge, T.; van Lier, R. (1983) Percutaneous Absorption of (carbon 14)-Oryzalin (EL-119, Compound 67019) in Monkeys: Lab Project Number: AWH041894: P03382: P04082. Unpublished study prepared by Lilly Research Labs, Toxicology Division. 48 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to oryzalin. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for oryzalin and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Oryzalin RED Fact Sheet (included in this RED)

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the com-plete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, …250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON**

THE TITLE PAGE. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with pet-itions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study

on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now

being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a tran-smittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ Name
Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

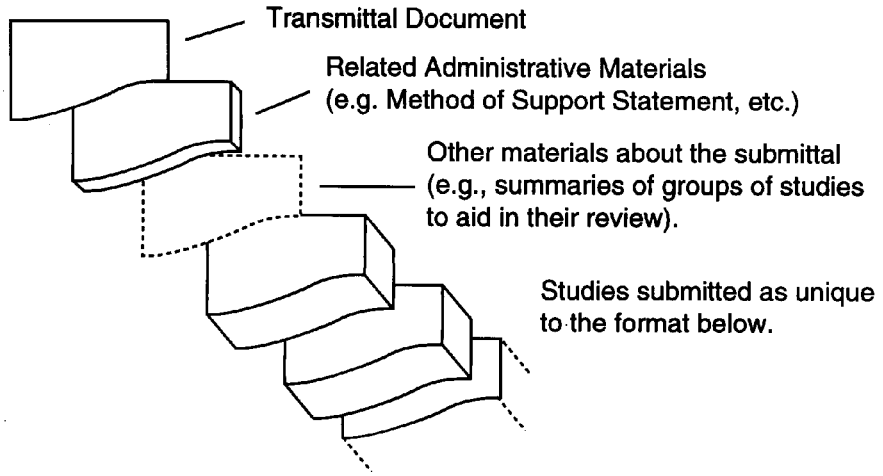
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

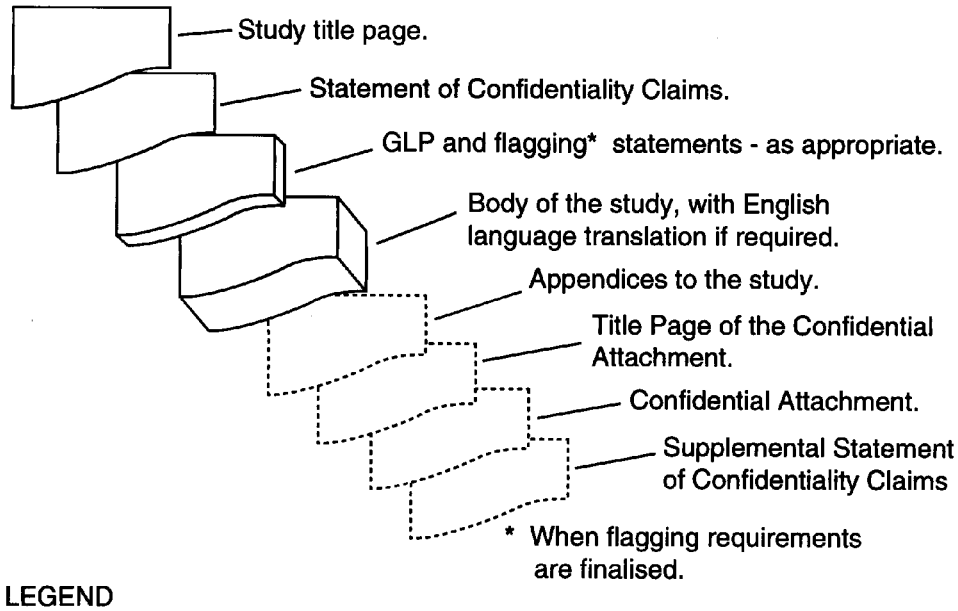
Submitter_____

ATTACHMENT 7.

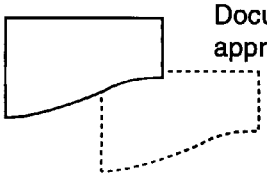
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Combined Generic and Product Specific Data Call-In

GENERIC AND PRODUCT SPECIFIC
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 A 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. 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 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant'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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

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 3-31-96).

This Notice is divided into six sections and seven 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

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 ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose 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 generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) 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(s) identified in Attachment 1.

a. 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 completed Generic and Product Specific

Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. 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 Reqistrant's Response Form (Attachment 3), 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 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (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, is allowed only if the product bears an amended label.

c. 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 if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. 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:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). 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, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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 requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not 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.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Reqistrant's Response Form (if this form is required) 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(s) identified in Attachment 1.

a. 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, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms 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.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form 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. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (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 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. 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 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 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

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 the 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 to 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 and a Requirements Status and Registrant's Response Form 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are 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 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 also should 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 EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form 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. 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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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 and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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 not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. 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 low volume pesticides to be only those active ingredients 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 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 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 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:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, 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.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient 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.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) 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.

(vi) 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.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, 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 in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient 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.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must 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 are not appropriate 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 indicating the option chosen.

2. Product Specific Data

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 product specific 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:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Reqistrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. 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 CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled 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 generally would 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 also must 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 cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a 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 must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms 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,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

ORYZALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 oryzalin. 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 oryzalin 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 oryzalin are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional toxicology, occupational and residential exposure, ecological effects, environmental fate and residue chemistry data on oryzalin are needed. These data are needed to fully complete the reregistration of all eligible oryzalin 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 Judith Coombs at (703) 308-8046.

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

Judith Coombs, Chemical Review Manager
RB/Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: oryzalin

ORYZALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 oryzalin. 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 oryzalin 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 oryzalin are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on oryzalin 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 oryzalin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of oryzalin, please contact Judith Coombs at (703) 308-8046.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) .

All responses to this Notice for the Product Specific data requirements should be submitted to:

Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **oryzalin**

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** 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.**ON BOTH FORMS:** Check 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. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and 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

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

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.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data 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 that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** 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 initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

Instructions For Completing
The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

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. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** 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 Reqistrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. 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. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	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 Indredient or Pute 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	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the

date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** 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.

Option 1. **ON BOTH FORMS:** (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 protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (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-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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.

Option 3. **ON BOTH FORMS:** (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 also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date 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.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite 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.

Option 6. **ON BOTH FORMS:** (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. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 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.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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" form specifying 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.

Item 10. **ON BOTH FORMS:** 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. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF PRODUCTS CONTAINING ORYZALIN AS THE ACTIVE INGREDIENT 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 the active ingredient oryzalin (3,5-dinitro-N4,N4-dipropylsulfanilamide) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient oryzalin.

Table 1.

Batch	EPA Reg. No.	Active Ingredient(s)	Formulation Type
1	34704-442	oryzalin 1.0%	granular
	62719-158	oryzalin 1.0%	granular
2	62719-112	oryzalin 40.4%	liquid
	62719-113	oryzalin 40.4%	liquid
	62719-141	oryzalin 40.4%	liquid
3	802-564	oryzalin 2.84%	liquid
	802-565	oryzalin 2.84%	liquid
	62719-140	oryzalin 3.00%	liquid
4	9198-89	oryzalin ..... 0.86% N-butyl-N-ethyl-",","-trifluoro-2,6-dinitro-p-toluidine 0.86%	granular
	9198-90	oryzalin ..... 0.57% N-butyl-N-ethyl-",","-trifluoro-2,6-dinitro-p-toluidine 0.57%	granular
5	55615-2	oryzalin 0.60%	granular
	55615-3	oryzalin 0.75%	granular
6	62719-106	oryzalin 75.0%	granular
	62719-110	oryzalin 75.0%	granular
	62719-138	oryzalin 85.0%	granular
	62719-153	oryzalin 85.0%	granular
	62719-183	oryzalin 75.0%	granular

Table 2 lists those products the Agency was unable to batch. These products were either considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table 2.

EPA Reg. No.	Active Ingredient(s)	Formulation Type
524-449	oryzalin ..... 11.8% glyphosphate 12.4%	liquid
961-349	oryzalin ..... 0.96% N-butyl-N-ethyl-",","-trifluoro -2,6-dinitro-p-toluidine 0.96%	granular

EPA Reg. No.	Active Ingredient(s)	Formulation Type
961-350	oryzalin ..... 0.865% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 0.865%	solid
961-352	oryzalin 1.00%	granular
1450-11	oryzalin 0.75%	granular
7401-413	oryzalin ..... 1.00% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 1.00%	solid
7401-415	oryzalin ..... 1.00% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 1.00%	granular
8660-16	oryzalin ..... 0.86% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 0.86%	granular
8660-139	oryzalin ..... 0.86% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 0.86%	granular
8660-146	oryzalin ..... 0.86% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 0.86%	granular
8660-150	oryzalin 1.00%	granular
32802-30	oryzalin ..... 0.85% N-butyl-N-ethyl-","-trifluoro-2,6-dinitro-p-toluidine 0.85%	granular
35512-28	oryzalin 0.67%	granular
35512-29	oryzalin 0.50%	granular
58185-127	oryzalin .... 1.00% oxyfluoren 2.00%	granular
62719-108	oryzalin 95.00%	granular
62719-136	oryzalin ..... 1.00% benefin ... N-butyl-N-ethyl-"-trifluoro-2,6-dinitro-p-toluidine 1.00%	granular

Table 2 continued

EPA Reg. No.	Active Ingredient(s)	Formulation Type
62719-149	oryzalin ..... 0.575% N-butyl-N-ethyl-",","-trifluoro-2,6-dinitro-p-toluidine 0.575%	granular
62719-159	oryzalin 0.75%	granular
62719-174	oryzalin ..... 60.0% isoxaben 20.0%	granular
62719-193	oryzalin ..... 0.86% isoxaben 0.29%	granular

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25E C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in EC
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in EC
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25E C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20E C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25E C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25E C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25E C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25EC)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25E C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25E C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22E C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\underline{<}2$ or $\underline{>}11.5$.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

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 suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

EPA

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-9(

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 suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Offic of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-012 September 1994

R.E.D. FACTS

Oryzalin

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED for reregistration case 0186, oryzalin.

Use Profile

Oryzalin is a herbicide that acts by inhibiting cell division in plants. It is used to control annual grasses, broadleaf weeds, woody shrubs and vines in grapes, berries and orchard crops, including both fruits and nuts. It also is used on residential and commercial/industrial lawns and turf, golf course turf, ornamentals and shade trees, Christmas tree plantations, fencerows/hedgerows, nonagricultural rights-of-way, and uncultivated areas including patios, paths, paved areas and power stations. Oryzalin is used most on turf, almond orchards and grapes. Formulation types include granular, wettable powder, water dispersible granules, emulsifiable concentrate, flowable concentrate and liquid.

Regulatory History

Oryzalin was first registered in the U.S. as a pre-emergence herbicide in 1974. EPA issued a Registration Standard for oryzalin in 1987 (NTIS #PB90-174137), and a Data Call-In notice in 1991. Currently, one technical product, two formulation intermediates and 35 end-use products containing oryzalin are registered.

Human Health Assessment

Toxicity

In acute toxicity studies using laboratory animals, oryzalin is practically non-toxic by the oral route and has been placed in Toxicity Category IV (the lowest of four categories) for this effect. It is of moderate dermal and inhalation toxicity and causes slight eye irritation, and has been placed in Toxicity Category III for these effects. No skin sensitization occurred in tests on guinea pigs.

In subchronic toxicity studies, oryzalin caused the accumulation of an iron-containing pigment in the kidneys of rats, an increase in the weights of several organs in mice, and blood, bone marrow and liver effects in beagle dogs.

Oryzalin is carcinogenic in rats, based on an increase in mammary gland tumors in females and skin and thyroid tumors in both sexes. It has been classified as a Group C carcinogen--that is, a possible human carcinogen for which there is limited animal evidence.

Another chronic toxicity study using beagle dogs showed effects to the blood, liver, kidneys and thyroid gland. In developmental toxicity studies using rats, oryzalin caused reduced maternal body weight gain as well as decreased fetal body weights, an increase in runts and bone development effects. In rabbits, it caused reduced maternal food consumption and weight gain, fetal effects and reduced litter size. Reproduction studies using rats showed increased liver and kidney weights, and decreased food consumption and body weight gain. Oryzalin was not mutagenic in several studies. A dermal irritation study using the oryzalin technical product is required as confirmatory data.

Dietary Exposure

People may be exposed to residues of oryzalin in the diet when consuming treated food commodities including almonds, avocados, citrus fruits, figs, kiwi fruits, olives, pistachios, pome fruits (apples and pears), pomegranates, small fruits (berries and grapes), stone fruits, tree nuts, guavas and papayas. Tolerances or maximum residue limits are established for these commodities (please see 40 CFR 180.304(a) and (b)), have been reassessed and are acceptable. Tolerances established for several other food crops will be revoked since no registrations for these uses currently exist. A new tolerance has been proposed for green coffee beans.

Available data indicate that residues of oryzalin do not concentrate in processed food or feed; therefore, no food/feed additive tolerances are established or required. If studies currently underway indicate that residues do, in fact, concentrate in processed foods, EPA will not be able to set such tolerances for oryzalin due to the Delaney Clause in Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which prohibits the establishment of food/feed additive tolerances for substances that cause cancer in test animals or humans.

No international Codex Maximum Residue Levels (MRLs) have been established or proposed for oryzalin.

EPA has assessed the dietary risk posed by oryzalin. For each of the population groups and subgroups analyzed, chronic dietary exposure is less than 1/5,000th of the Reference Dose (RfD), an amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The dietary excess cancer risk for the entire U.S. population is estimated to be 8.1×10^{-7}, or 8.1 extra incidences of cancer in 10,000,000. When tolerances for unregistered commodities are revoked, the upper bound excess cancer risk estimate will be even lower--4.5×10^{-7}, or 4.5 extra cancer cases in 10 million.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to oryzalin during application. EPA conducted a limited exposure/risk assessment based on available data, examining seven major exposure scenarios for private and commercial applicators. Low pressure handwand application was found to have the highest exposure and risk potential. The private applicator using handwand equipment has an excess risk of 2.6×10^{-5}, or 2.6 extra cancer incidences in 100,000. The commercial applicator using handwand equipment, who is exposed more frequently, has the greatest estimated excess cancer risk; that is, 2.6×10^{-4}, or 2.6 extra cancer cases in 10,000. To mitigate these risks, workers will be required to wear chemical-resistant boots during low pressure handwand application. This will reduce exposure below the knees, which is significant.

The Worker Protection Standard (WPS) requires workers handling oryzalin to wear long pants, long sleeved shirts and chemical-resistant gloves. Because the pesticide is a possible human carcinogen, EPA also is requiring the use of coveralls and chemical resistant footwear for all uses of oryzalin (except homeowner uses).

Post-application/reentry exposure also is of concern, and reentry data are not available to calculate a Restricted Entry Interval (REI). For agricultural and ornamental crops where reentry exposure is likely, EPA is requiring an REI of 24 hours instead of 12 hours as imposed by the WPS.

When residential lawns are treated with oryzalin, there is a potential for continued, substantial contact with treated surfaces, especially among children. EPA is concerned about these postapplication exposures because oryzalin is a possible human carcinogen and is persistent. Because of the lack of turfgrass exposure data, however, the safety of this use cannot be evaluated. Such exposure data are required by the RED document. Until they are submitted and evaluated, the residential lawn and turf use of oryzalin is not eligible for reregistration.

Human Risk Assessment

Oryzalin generally is of moderate acute toxicity, but is carcinogenic in animal studies and has been classified as a Group C, possible human carcinogen. Several food crop uses, including grapes and a variety of fruits and nuts, are registered. However, dietary exposure to oryzalin residues in foods is extremely low, as is the cancer risk posed by this pesticide to the general population.

Of greater concern is the risk posed to oryzalin handlers (mixers, loaders and applicators), and to field workers and others who come into contact with treated foliage, crops, lawns or turf following application of this herbicide. Exposure and risk to all applicators will be mitigated by the use of personal protective equipment (PPE) required by the Worker Protection Standard (WPS), supplemented by coveralls and chemical-resistant footwear, as required by this RED.

Post-application reentry workers will be required to observe a 24-hour Restricted Entry Interval (REI), which is twice as stringent as that set forth by the WPS. The residential lawn and turfgrass use of oryzalin is not eligible for reregistration until post-application exposure studies are submitted to EPA and evaluated.

Environmental Assessment

Environmental Fate

Parent oryzalin biodegrades slowly with a half-life of approximately two months. It is not mobile under field conditions and is not volatile. However, up to 20% of the oryzalin degradates may leach. The registrant is conducting a study to determine whether degradate leaching is a major route of dissipation.

Ecological Effects

A preliminary risk screening based on available data indicates that, from an acute toxicity perspective, oryzalin is moderately toxic to freshwater fish and invertebrates, and practically nontoxic to birds, small mammals and honeybees. As would be expected of a herbicide, oryzalin poses an acute risk to non-target plants, including threatened and endangered plants.

Ecological Effects Risk Assessment

Minimal risks to birds are posed from acute and dietary exposure to oryzalin. Chronic risks are not posed at single application rates of 4 pounds active ingredient per acre (4 lb ai/A) or less. However, EPA is unable to determine whether higher application rates pose a serious avian reproduction threat, and is requiring further studies to complete an assessment of chronic avian risks.

Oryzalin does not appear to pose a risk to nonendangered freshwater fish. However, a Daphnia life-cycle study is needed to determine the chronic risk to freshwater invertebrates. Acute toxicity studies also are needed to determine the risks to estuarine and marine organisms.

Oryzalin poses a risk to endangered aquatic species in shallow water adjacent to treated areas. It also poses a high risk to nontarget plants, including endangered and threatened plants, from runoff and spray drift. These risks will be addressed through implementation of the Endangered Species Protection Program.

Meanwhile, the technical producer of oryzalin has agreed to take several measures to reduce the pesticide's environmental risks. To mitigate exposure problems associated with spray drift, airplane and helicopter applications will no longer be allowed except to agricultural crops in California. In addition, labeling changes are being required to reflect the maximum amount of oryzalin that may be applied per year, the maximum number of applications and the interval between applications.

Additional Data Required

EPA is requiring the following additional generic studies for oryzalin to confirm its regulatory assessments and conclusions: Avian Reproduction (mallard and quail); Acute Toxicity to Estuarine and Marine Organisms (fish, mollusk and shrimp); Aquatic Invertebrate Lifecycle; Dermal Irritation; Leaching/Adsorption/Desorption (underway); Spray Drift; Storage Stability (apples and grapes, underway); and Processing Studies (citrus and olives, underway). In addition, Mixer/Loader/Applicator Exposure Monitoring studies are required for low pressure handwand application including Estimation of Dermal Exposure at Outdoor Sites and Estimation of Inhalation Exposure at Outdoor Sites. Reentry Protection studies are required for use of oryzalin on residential lawns and turf including: Foliar Dislodgeable Residues; Soil Dislodgeable Residues; Estimation of Dermal Exposure; and Estimation of Inhalation Exposure. The same studies (except Soil Dislodgeable Residues) also are required for Christmas tree and field-grown rose uses of oryzalin.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

All oryzalin end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection Standard (WPS)

POST-APPLICATION REENTRY RESTRICTIONS

- WPS Uses - A 24 hour Restricted Entry Interval (REI) is required for all oryzalin end-use products registered for uses that are within the scope of the WPS.

- Non-WPS Uses - The following entry prohibitions are required:
  - For Liquids: "Keep all persons, children and pets out of the treated area until sprays have dried."
  - For Dry Formulations: "Keep all persons, childrena nd pets out of the treated area until dusts have settled."
  - For All Other Non-WPS Formulations including Those for Residential Use: "Keep all persons, children and pets out of the treated area until sprays have dried or dusts have settled."

PERSONAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS

- WPS Occupational Uses and Non-WPS Uses - The minimum PPE requirements for pesticide handlers are:
  - Coveralls over long-sleeved shirt and long pants;
  - Chemical resistant gloves;
  - Chemical resistant footwear;
  - Chemical resistant headgear for overhead exposures; and
  - Chemical resistant apron (mixers and loaders).
- Homeowner Uses - The minimum PPE requirements are:
  - Long-sleeved shirt and long pants; and
  - Chemical resistant gloves.

WITH ENGINEERING CONTROLS

- When handlers use closed systems, enclosed cabs or aircraft in a manner consistent with the WPS, the requirements above may be modified or reduced. See the WPS for specifics.

USER SAFETY STATEMENTS

- Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.
- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.
- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.
- For WPS and non-WPS uses, 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.

Precautionary Statement for Fish - To protect fish, all oryzalin end-use product labels must include the following statement:

> "This product is toxic to fish. Do not apply this product directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark."

Grazing Restrictions - All oryzalin end-use products must include the following statement:

> "Do not graze or feed forage from treated fields or orchards to livestock."

Changes in Directions for Use - All end-use labels must bear specific application rates, number of applications per year, total pounds active ingredient per year, and intervals between applications, as specified in Table 12 of the oryzalin RED document.

Restriction on Aerial Application - All end-use product labels must prohibit aerial application except for agricultural uses in California.

Regulatory Conclusion

EPA has determined that products containing oryzalin are eligible for reregistration **except** products labeled for use on residential lawns and turf.

The use of eligible oryzalin products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to oryzalin will be reregistered when all of their other active ingredients also are eligible for reregistration.

EPA does not have enough information at this time to make an eligibility decision for oryzalin products labeled for use on residential lawns and turf. The Agency is requiring additional data in order to develop a more complete database regarding these uses of oryzalin.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for oryzalin during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the oryzalin RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the oryzalin RED, or reregistration of individual products containing oryzalin, please contact the Special Review and Reregistration Division

(7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 8:00 am to 6:00 pm Central Time, Monday through Friday.