United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-94-010
June 1994

Reregistration Eligibility Decision (RED)

Maleic Hydrazide

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 0381 which includes the active ingredients maleic hydrazide, and maleic hydrazide potassium salt. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date 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 Susanne Cerrelli at (703)-308-8077.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for 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 date of this letter (RED issuance date).**

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

MALEIC HYDRAZIDE

LIST A

CASE 0381

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

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MALEIC HYDRAZIDE REREGISTRATION ELIGIBILITY DECISION TEAM

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Phyllis Johnson	Biological Analysis Branch
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Environmental Fate and Effects Division	
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Susanne Cerrelli	Reregistration Branch
Linda Propst	Reregistration Branch
Carol Stangel	Planning and Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

GLOSSARY OF TERMS AND ABBREVIATIONS

Ldlo	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
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard

GLOSSARY OF TERMS AND ABBREVIATIONS

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.
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

Reregistration Decision

The Agency has determined that all uses of currently registered products containing maleic hydrazide and maleic hydrazide potassium salt are eligible for reregistration. The maleic hydrazide diethanolamine salt is not addressed in this document because all maleic hydrazide diethanolamine salt products are cancelled. Except where otherwise noted, the term "maleic hydrazide," in this document refers to the technical acid and the potassium salt of maleic hydrazide. The Agency has determined that the uses of maleic hydrazide and maleic hydrazide potassium salt as currently registered will not cause unreasonable risk to humans. The use of maleic hydrazide and maleic hydrazide potassium salt may adversely effect non-target plants. The scientific data base is adequate to support the reregistration eligibility of all registered uses of maleic hydrazide. The Agency is, however, requiring the following additional data to confirm the risk assessments: animal metabolism [Guideline 171-4(b)]; residue analytical method for animal commodities [Guideline 171-4(d)]; magnitude of the residue in animal commodities [Guideline 171-4(j)]; confined rotational crops [Guideline 165-1]; droplet size spectrum [Guideline 201-1]; and drift field evaluation [Guideline 202-1] data requirements. All of these data requirements except for Guidelines 171-4(b), 171-4(d) and 17-4(j) were included in a Data Call-In (DCI) issued November 16, 1992 and are currently being generated. The Data Call-In Notice in Appendix F addresses the remaining generic data requirements (Guidelines 171-4(b), 171-4(d) and 171-4(j)). The rationale for these requirements is presented below.

Background

Maleic hydrazide is a plant growth regulator (sprout inhibitor) and herbicide whose mode of activity is as a uracil antimetabolite. It is registered for use on tobacco, potatoes, onions, non-bearing citrus, turf, utility and highway rights-of-way, airports, industrial land, lawns, recreational areas, ornamental/shade trees and ornamental plants. Use on cranberries is neither registered nor supported. The existing tolerance for residues of maleic hydrazide on cranberries will be revoked.

In 1982 the Agency established an upper limit for hydrazine, a contaminant, at $\leq$ 15 ppm in technical grade products containing maleic hydrazide. Hydrazine has been associated with tumor induction in animals. This level alleviates any concern based on estimates of excess lifetime carcinogenic risks to humans considering both dietary and worker exposure. The Agency continues to require that the hydrazine content of the technical chemical be limited to $\leq$ 15 ppm.

In June 1988, the Registration Standard on Maleic Hydrazide (NTIS #PB88-236849) was issued. This document identified additional generic data required to support the continued registration of maleic hydrazide as an herbicide and plant growth regulator. A Data Call-In was issued November 15, 1992 for additional ecological effects and environmental fate data requirements. The Agency has now completed its evaluation of the data base for maleic hydrazide.

Supporting Rationales for Reregistration Decision

Maleic hydrazide and the potassium salt of maleic hydrazide are considered to be equivalent with respect to fulfillment of applicable toxicity study requirements.

Acute toxicity studies indicate that maleic hydrazide is practically non-toxic by the oral route (Toxicity Category IV in rat), practically non-toxic by the dermal route (Toxicity Category IV in rabbit), and practically non-toxic by the inhalation route (Toxicity Category IV in rat). Maleic hydrazide is a slight dermal irritant (Category IV in rabbit), causes only a slight irritation to the eyes (Toxicity Category III in rabbit), and is not a dermal sensitizer.

Maleic hydrazide does not appear to cause any adverse developmental or reproductive effects of concern. The potassium salt of maleic hydrazide was not found to be carcinogenic and the chemical was classified as a "Group E" carcinogen by OPP's Health Effects Division RfD Peer Review Committee.

Maleic hydrazide appears to be genotoxic at high doses in some of the mutagenicity tests. Since maleic hydrazide is an uracil antimetabolite and this is presumably its mechanism of action with respect to its plant growth regulator/herbicidal properties, it might be expected that equivocal or positive results would be observed in some genotoxicity tests. When the totality of genotoxicity studies is considered together with the results of all the other toxicological studies on maleic hydrazide and its potassium salt, including, negative carcinogenicity studies in rats and mice, it was concluded that the potential human genotoxic hazard is negligible.

The RfD was established at 0.25 mg/kg/day based on chronic feeding studies in rats and dogs and an uncertainty factor of 100. The estimated TMRC for the overall U.S. population from food uses of maleic hydrazide is 0.074 mg/kg bodyweight per day, which represents 29.5% of the reference dose. The vast majority of the estimate (27.5% of the RfD) was from potatoes. For the most highly exposed subgroup, children (one to six years old), the estimated TMRC is 0.151 mg/kg bodyweight per day, which represents 60.3% of the RfD.

There is a potential for mixer/loader/applicator (handlers) exposure via the inhalation and dermal routes. However, the risk posed by this chemical is considered minimal for all workers based on the lack of toxicological concerns. A mixer/loader/ applicator risk assessment based on potential developmental toxicity was discussed in the Registration

Standard Guidance document issued in June 1988. Since then, additional information and studies have been submitted which demonstrate developmental effects are no longer a concern.

There are currently no maleic hydrazide tolerances for animal commodities. The appropriate information concerning animal metabolism, analytical methodology and magnitude of the residue in meat, milk, poultry and eggs to establish tolerances at this time has not been submitted to the Agency, but are currently being generated and are due December 20, 1995. However, suitable data have been submitted to enable a reasonable worst case dietary risk assessment to be conducted. These data are derived from analysis of the total radioactivity in milk and tissues found in animals that were fed [^{14}C]maleic hydrazide. The additional data required on animal metabolism, analytical methodology and magnitude of the residue in meat, milk, poultry and eggs data will be used to confirm this assessment and to establish tolerances.

Preliminary studies have indicated that detectable residues could occur on winter wheat planted as a rotational crop in fields that have been treated with maleic hydrazide. Further data have been required to determine if there is a need for establishment of rotational tolerances or suitable plant-back intervals to avoid these residues. However, these data are considered to be confirmatory. The available data base is adequate to make a reasonable upper bound dietary risk assessment and conclude that the risk is not significant.

The major route of dissipation of maleic hydrazide in the environment is by biotic processes. Hydrolysis, photodegradation, and volatilization do not appear to play a significant role in the dissipation process. Based on available data, maleic hydrazide does not appear to be persistent in the soil under aerobic conditions but is somewhat more persistent under anaerobic conditions. However, because of its high solubility and mobility, there is potential for surface water runoff. The potential for maleic hydrazide to bioaccumulate in fish is very low.

Based on available information, maleic hydrazide is not likely to impact ground-water quality. However, maleic hydrazide has the potential to move off site and thus exceeds the level of concern for surface water contamination. In addition, maleic hydrazide is aerially or air-blast applied, so there is the potential for drift from approved use sites which could affect non-target crops or areas containing endangered plant species. Therefore, in order to assess the extent of this exposure, the spray drift data requirements (Guidelines 201-1 and 202-1) were imposed in the November 1992 DCI. The Agency is requiring that a surface water advisory statement and spray drift management information be added to the maleic hydrazide end-use product labels.

From the ecological effects data analyzed, the following conclusions were reached: there are minimal acute risks to avian, mammalian, and aquatic species from acute and dietary exposure to maleic hydrazide; no chronic data were required; and there is minimal risk to non-target insects and non-target aquatic plants from the use of maleic hydrazide.

The levels of concern (LOCs) for semi-aquatic plants were exceeded from runoff onto wet areas for all use sites and the LOCs for terrestrial plants were exceeded by direct application to rights-of-way. To mitigate the exposure of non-target plants at the sites where the highest application rates are used, the Agency is requiring that the number of applications to fallow land, rights-of way, turf, and lawns be limited to 1 per year. When the Agency completes its Endangered Species program, additional precautionary labeling may be required to mitigate the risk to endangered plant species.

Before reregistering the products containing maleic hydrazide, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registration. 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 reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of maleic hydrazide. The document consists of six sections. Section I is the introduction. Section II describes maleic hydrazide, 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 maleic hydrazide . Section V discusses the reregistration requirements for maleic hydrazide. 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 ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Maleic Hydrazide
- **Chemical Name:** 1,2-dihydro-3,6-pyridazinedione
- **CAS Registry Number:** 123-33-1
- **OPP Chemical Code:** 051501
- **Empirical Formula:** $C_4H_4N_2O_2$
- **Trade and Other Names:** MH
- **Basic Manufacturers:** Uniroyal Chemical Company, Inc., Drexel Chemical Company, and Fair Products Inc.

- **Common Name:** Maleic Hydrazide, potassium salt
- **Chemical Name:** 1,2-dihydro-3,6-pyridazinedione, potassium salt
- **CAS Registry Number:** 28382-15-2
- **OPP Chemical Code:** 051503
- **Empirical Formula:** $KC_4H_3N_2O_2$
- **Trade and Other Names:** KMH, Sucker-Stuff, Super Sprout Stop, Super Sucker-Stuff, Retard
- **Basic Manufacturers:** Uniroyal Chemical Company, Inc., Drexel Chemical Company, and Fair Products Inc.

B. Use Profile

Information on the currently registered uses of maleic hydrazide use sites and application methods is presented below. A detailed table of the uses of maleic hydrazide (051501) and the potassium salt of maleic hydrazide (051503) is presented in Appendix A.

For 1,2-dihydro-3,6-pyridinedione, potassium salt (maleic hydrazide, potassium salt):

Type of Pesticide: Plant growth regulator, Herbicide

Mechanism of Action: A growth retardant which inhibits miotic division in plants. This mode of action has been utilized to control suckers in tobacco, sprouting of potatoes, the growth of grasses (a substitute for mechanical mowing), and the growth of certain ornamental trees and shrubs (to reduce the frequency of manual pruning). Weeds are indirectly killed by the inhibition of growth, which prevents flowering and seed production or weakens perennial weeds to the point of not being able to survive a winter.

Use Groups and Sites:

TERRESTRIAL FOOD CROP
Onion

TERRESTRIAL FOOD + FEED CROP
Potato

TERRESTRIAL NONFOOD CROP
Agricultural fallow/idleland, airports/landing fields, non-bearing orchard crops (citrus fruits), commercial/industrial lawns, golf course turf, industrial areas, rights-of-way, nonagricultural uncultivated areas, ornamental and/or shade trees, ornamental lawns and turf, ornamental woody shrubs and vines, recreational areas, tobacco

OUTDOOR RESIDENTIAL
Residential lawns

Target Pests:
bigleaf maple, silver maple, quackgrass, bentgrass, bromegrass, bermudagrass, orchardgrass, fescue, perennial rye, red rice, bluegrass, wild onion, wild garlic, eucalyptus, sycamore, London planetree, cottonwood, silverleaf nightshade

Formulation Types Registered:

Single Active Ingredient Products
Emulsifiable concentrate--8%
Soluble concentrate/liquid--21.6 to 33.3%
Soluble concentrate/solid--80%

Multiple Active Ingredient (AI) Product
Emulsifiable concentrate--11.1% + 1 other AI

Method and Rates of Application:

Emulsifiable concentrate
In spring or fall, at dormant or foliar stage, spray by backpack or compressed-air sprayer at 2.1 to 6.6 lb acid equivalent (AE)/ acre or 0.08 to 0.12 lb AE/667 plants. In spring or fall, apply edging treatment by hose-end sprayer at 4.4 lb AE/acre.

Soluble concentrate/liquid
At pre-or postharvest, foliar, nonbearing, or dormant stage, or in spring, summer or fall, spray by aircraft, ground, airblast, boom, compressed-air, tractor-mounted, or hose-end sprayer at 1.2 to 9 lb AE/acre or 0.03 to 0.05 lb AE/gal or 0.3 to 0.6 lb AE/1,000 plants. When needed, treat trees by injection with suitable equipment at 0.9 lb AE/gal. In fall or spring, apply edging treatment by boom, compressed-air, or hose-end sprayer at 0.7 to 6 lb AE/acre or 0.035 lb AE/gal.

Soluble concentrate/solid
At pre- or postharvest or foliar stage, in spring, summer, or fall, spray by aircraft, ground, airblast, boom, tractor-mounted, or compressed-air sprayer at 2 to 9 lb AE/acre or 1.8 tbsp AE/gal or 0.03 to 0.2 lb AE/gal. In spring or fall, apply edging treatment by compressed-air or hose-end sprayer at 0.75 lb AE/acre or 1.8 Tbsp AE/gal or 0.2 lb AE/gal.

Use Practices Limitations:
Do not treat within 7 days of harvest. Do not graze or feed forage or hay from treated areas to livestock.

C. Estimated Usage of Pesticide

This section summarizes the best usage estimates available for maleic hydrazide. These estimates are derived from a variety of published and proprietary sources

available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Approximately 2.9 to 3.1 million pounds of maleic hydrazide active ingredient (a.i.) was applied on 722 to 1,045 thousand acres annually between 1990 and 1991 (see Table 1). Growers applied maleic hydrazide to tobacco, Irish potatoes, onions, and garlic. An overwhelming majority of the pounds (86%) was applied to tobacco. Only 3% of the total use on tobacco is applied to dark tobacco. Many of these acres appear to be treated more than once. If all of these applications were double treatments, an average of 78% of the total tobacco acres were treated annually. However, this estimate of a.i. and acres treated includes multiple treatments for a given year and; thus, would decrease depending on the number of multiple treatments.

Maleic hydrazide constitutes a small part of the non-agricultural plant growth regulator market. Information on the use of maleic hydrazide on rights-of-ways or roadways to slow the growth of weeds, hedges, and trees is limited. Maleic hydrazide comprises about 50% of the total pounds a.i. of plant growth regulators applied for electric utility uses in the United States. Electric utility companies may apply maleic hydrazide when utilizing mechanical tree trimming. Trees, mostly near residential areas and commercial developments, may be injected with maleic hydrazide to slow the growth. Maleic hydrazide is also applied on roadways to control the plant growth. State agencies may purchase large quantities of maleic hydrazide and apply it over more than one growing season. Documentation of the specific numerical statistics of these uses was not found.

The table below summarizes the usage by site.

ESTIMATED CURRENT U.S ANNUAL MALEIC HYDRAZIDE USAGE BY SITE, 1990-1991

	APPROXIMATE QUANTITY A.I.				ESTIMATED ACREAGE TREATED				
Site	Pounds (000)		Percentage of Total Usage[a]		Multiple Acre Treatments[b] (000)		U.S. Acres Harvested (000)	Percentage of Acreage Planted	
	low	high			low	high		low	high
Garlic	6 -	10	0.2 -	0.3	2 -	5	23	9 -	22
Irish Potatoes	300 -	350	10 -	11	100 -	115	1,343	10 -	20
Onions	40 -	55	1 -	2	20 -	25	138	15	18
Tobacco	2,500 -	2,700	88 -	86	600 -	900	724	65 -	91
dark	75 -	80	n/a		10 -	18	n/a	n/a	n/a
Trees, Shrubs, Ivy	3 -	4	.1 -	.1	n/a	n/a	n/a	n/a	n/a
Other	7 -	8	.2 -	.3	n/a	n/a	n/a	n/a	n/a
TOTAL	2,856 -	3127	100 -	100.0	722-	1,045		n/a	n/a

n/a not available
[a] Percentages are based on the average values.
[b] The number of acres treated per year including repeat treatments

D. Data Requirements

Data requested in the June 1988 Registration Standard for Maleic Hydrazide include studies on product chemistry, ecological effects, environmental fate, toxicology and residue chemistry. On November 16, 1992 a Data Call In was issued for MH and K-MH which required additional data to address ecological effects, environmental fate and residue chemistry data gaps. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Maleic hydrazide (MH) was first synthesized in 1895 but its ability to regulate plant growth was not discovered until 1949. The chemical was registered by USDA in 1952 for use as a plant growth regulator. In October 1976, it was referred to the Agency for a Rebuttable Presumption Against Registration (RPAR) (now known as Special Review) based on laboratory studies which indicated that MH induced carcinogenic, mutagenic, and reproductive effects. In October 1977, the Agency initiated the RPAR review by publishing a Position Document 1 (PD 1) for MH. The PD 1 described studies which met or exceeded the RPAR criteria for carcinogenic, mutagenic, and reproductive effects.

The Agency did not issue the PD 2/3 for maleic hydrazide because of the absence of adequate risk data for carcinogenic, mutagenic, and reproductive effects. The potential risk of maleic hydrazide could not be adequately assessed because of the paucity of valid toxicological information and conflicting results of studies. In an attempt to resolve these issues, the Agency issued a Data Call In Notice (DCI) August 14, 1980 requiring all MH registrants to submit data regarding the reproductive effects and mutagenic potential of the diethanolamine salt of maleic hydrazide (DEA-MH) and the potassium salt of maleic hydrazide (K-MH).

On February 26, 1981, the manufacturers agreed to submit the required data on K-MH. The manufacturers of the DEA-MH did not commit to submit the additional data. Consequently, the Agency suspended all DEA-MH registrations in November 1981. At the present time, all DEA-MH registrations are cancelled.

The Agency evaluated the information submitted in response to the August 1980 DCI and determined that two of the three RPAR triggers (carcinogenicity and reproductive effects) were not supported. It was also determined that only extremely weak suggestive evidence supported the contention that MH is mutagenic in mammalian systems, and that additional mutagenicity studies were needed.

During this evaluation the Agency considered the possibility that hydrazine contamination might help determine the carcinogenic potential of maleic hydrazide. The Agency reached this conclusion because two similar studies showed different results: Epstein and Mantel (1968) reported an increased incidence in hepatomas, at the same time Cabral et. al. (1981) reported no significant increase in tumor incidence. A primary difference between the two studies was the level of hydrazine contamination in the MH they used: 4000 ppm in the Epstein study and less than 1 ppm in the study by Cabral. Several animal studies have associated hydrazine with tumor induction.

In June 1982, the PD-4 was published. The final decision was to allow the continued use of potassium salt of MH and to establish an upper limit of 15 ppm hydrazine (a contaminant) in technical grade products containing maleic hydrazide. The Agency

determined that this level would not cause concern based on estimates of excess lifetime carcinogenic risks to humans for both worker and dietary exposure.

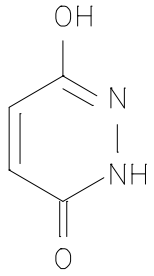
The Registration Standard on Maleic Hydrazide (NTIS #PB88-236849) was issued in June 1988. In the Standard the Agency continued to require that the hydrazine content of the technical chemical be limited to $\leq$15 ppm. On November 16, 1992 a Data Call In was issued for MH and K-MH which required additional data to address ecological effects, environmental fate and residue chemistry data gaps. This Reregistration Eligibility Decision reflects a reassessment of all data submitted to date in response to the Registration Standard and the November 1992 DCI.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

DESCRIPTION OF CHEMICAL

Maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) is a plant growth regulator and herbicide. The molecular structure of maleic hydrazide is illustrated below:



Maleic Hydrazide

Other identifying characteristics and codes are:

Empirical Formula: $C_4H_4N_2O_2$
Molecular Weight: 112.1
CAS Registry No.: 123-33-1
OPP Chemical Code: 051501

IDENTIFICATION OF ACTIVE INGREDIENT

Technical maleic hydrazide is a white crystalline powder with a melting point of 292°C and decomposes at above 300°C. It is stable to hydrolysis but is decomposed by strong oxidizing agents with release of nitrogen. Maleic hydrazide behaves as a mono-basic acid and forms salts; its alkali metal (potassium) salt is water soluble (50% at 25°C). The Agency published a Position Document (PD-4) for maleic hydrazide in June, 1982 and established an acceptable limit of hydrazine (a contaminant) at 15 ppm in technical grade products to avoid the potential for unreasonable adverse effects.

Other Product Chemistry Issues

All pertinent data requirements for Uniroyal's maleic hydrazide 97% T (EPA Reg. No. 400-97) have been satisfied. All pertinent data requirements for Drexel's maleic hydrazide 95% T and 97% T (EPA Reg. Nos. 19713-25 and 19713-26, respectively) have been satisfied. In addition, Fair Products Inc. has satisfied all pertinent data requirements for the maleic hydrazide 96% T (EPA Reg. No. 51873-10) with the exception of the required information regarding oxidizing/reducing action, and storage stability (Guideline Ref. Nos. 63-14 and 63-17). These data are considered confirmatory.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base in support of the food uses for maleic hydrazide is adequate and will support reregistration.

a. Acute Toxicity

Acute toxicity data for maleic hydrazide are listed in the table below.

Acute Toxicity

Test	Result	Category
Acute Oral LD_{50} (rat)[1, a]	> 5000 mg/kg	IV
Acute Dermal LD_{50} (rabbit)[2, a]	> 20,000 mg/kg	IV
Acute Inhalation LC_{50} (rat)[3, b]	> 4.0 mg/L	IV
Eye Irritation (rabbit)[4, a]	slight irritation	III
Dermal Irritation (rabbit)[5, a]	slight irritation	IV
Skin Sensitization (guinea pig)[6, b]	Negative	N/A

[1-6] MRIDs 00079657, 00079658, 41185401, 00079661, 00079660, and 41289101
[a] Test material was technical grade maleic hydrazide.
[b] Test material was 97.8% potassium salt of maleic hydrazide.
N/A = not applicable

b. Subchronic Toxicity

In a 21-day dermal toxicity study, male and female Sprague-Dawley rats were treated for 6 hours per day for 3 weeks with a solution of the potassium salt of maleic hydrazide in distilled water. Dosage levels were 0, 100, 500 or 1000 mg/kg/day. Parameters examined included clinical signs of toxicity, mortality, body weights, food and water consumption, hematology, clinical chemistry, necropsy, organ weights and histopathological examination of selected tissues/organs. The test material was essentially non-irritating to the skin and there were no treatment-related effects observed at any dosage level. The NOEL for dermal toxicity and the NOEL for systemic toxicity are both $\geq$ 1000 mg/kg/day. (MRID 41289102)

c. Chronic toxicity

A chronic feeding/carcinogenicity study was conducted using male and female Sprague-Dawley rats (50/sex/group) which were fed diets containing the potassium salt of maleic hydrazide at dosage levels equivalent to 0, 25, 500 or 1000 mg/kg/day of maleic hydrazide for 104 weeks. Additional animals (20/sex/group) were fed identical diets but were sacrificed and examined at 52 weeks. Treatment-related decreases in absolute body weights were consistently observed after 72 weeks for males at 500 and 1000 mg/kg/day and after 4 weeks for females at 1000 mg/kg/day. Body weight gains for weeks 0 - 104 were decreased 13% for males at both 500 and 1000 mg/kg/day and 20% for females at 1000 mg/kg/day. There were no other effects observed during the study that were clearly attributed to treatment with the test material. Parameters examined included clinical signs of toxicity, mortality, food consumption, ophthalmoscopy, hematology, clinical chemistry, urinalyses, organ weights, necropsy and histopathologic examination of tissues/organs. Therefore, the NOEL for systemic toxicity is 25 mg/kg/day and the LOEL is 500 mg/kg/day. (MRID 42570101, 42770401)

The potassium salt of maleic hydrazide was incorporated in the feed of male and female beagle dogs (6/sex/group) at dietary levels of 0, 750, 2500 or 25000 ppm of maleic hydrazide for 52 weeks. These levels were equivalent to 0, 29, 87 and 974 mg/kg/day of maleic hydrazide for males and 0, 29, 105 and 974 mg/kg/day for females. No effects attributed to the test material were observed at 750 ppm. At 2500 ppm, decreased body weight gains of 32% were observed in males and 22% in females for weeks 0 - 52. Reduced heart weight was also observed in males at 2500 ppm. At 25000 ppm, additional treatment-related effects included reduced heart weight in females, increased thyroid weight in females and thyroid focal follicular epithelial hypertrophy in males and females, and increased hepatic lobulation and inflammation in males and females. The NOEL is 750 ppm (29 mg/kg/day) of maleic hydrazide. The LOEL is 2500 ppm (87 mg/kg/day and 105 mg/kg/day for males and females respectively) of maleic hydrazide. (MRID 42214101, 42248101)

d. Carcinogenicity

A chronic feeding/carcinogenicity study was conducted using male and female Sprague-Dawley rats (50/sex/group) which were fed diets containing the potassium salt of maleic hydrazide at dosage levels equivalent to 0, 25, 500 or 1000 mg/kg/day of maleic hydrazide for 104 weeks. Additional animals (20/sex/group) were fed identical diets but were sacrificed and examined at 52 weeks. There were no neoplastic findings

observed in this study in either males or females that were considered related to the test material. The potassium salt of maleic hydrazide was not carcinogenic under the conditions of this study. (MRID 42570101, 42770401)

The potassium salt of maleic hydrazide was incorporated in the feed of male and female CD-1 mice (50/sex/group) at dietary levels of 0, 1000, 3200 or 10000 ppm of maleic hydrazide for 23 months. These levels were equivalent to 0, 157, 509 and 1545 mg/kg/day of maleic hydrazide for males and 0, 189, 598 and 1811 mg/kg/day for females. There were no treatment-related effects observed during the study. Parameters examined included clinical signs of toxicity, mortality, body weights, food consumption, hematology, necropsy and histopathologic examination of tissues/organs. At 10000 ppm, slightly increased incidence in female mice of uterine hemangiomas (0, 0, 0 and 2 in the control, low, mid and high dose groups, respectively) and of lung adenomas (3, 3, 0 and 7 in the control, low, mid and high dose groups, respectively) were not considered to be related to treatment with the test material. The potassium salt of maleic hydrazide was not carcinogenic under the conditions of this study. (MRID 00097886, 00098466)

e. Developmental Toxicity

A developmental toxicity study was conducted with pregnant Sprague-Dawley rats (23-25/group) which were given daily doses of the potassium salt of maleic hydrazide by oral gavage on days 6 through 16 of gestation. Doses were selected to be equivalent to 0, 30, 300 or 1000 mg/kg/day of maleic hydrazide. The dams were sacrificed on day 20 and the fetuses examined. No treatment-related maternal effects or effects on reproductive performance of dams were observed. Slightly increased incidence of numbers of fetuses with testicular displacements or with supernumerary 14th ribs were noted in the maleic hydrazide treated animals, but were determined to be within the range of recent historical control incidence and were not considered to be related to treatment with the test material. The NOELs for maternal toxicity and for developmental toxicity are both $1000 mg/kg/day of maleic hydrazide. (MRID 41458201, 41702901)

In a second developmental toxicity study on rats, pregnant Wistar rats (20/group) were given daily doses of 0, 400, 800, 1200 or 1600 mg/kg/day of maleic hydrazide dissolved in corn oil by oral gavage on days 6 through 15 of gestation. The dams were sacrificed on day 22 and the fetuses examined. No adverse maternal effects or effects on reproductive

performance were observed. At 1600 mg/kg/day, a slightly increased incidence of numbers of fetuses with minor skeletal variations was observed. The NOEL for maternal toxicity is 1600 mg/kg/day of maleic hydrazide. The NOEL and LOEL for developmental toxicity are 1200 mg/kg/day and 1600 mg/kg/day, respectively, of maleic hydrazide. (MRID 40874202, 41055903)

Pregnant Dutch Belted rabbits (16/group) were given daily doses of the potassium salt of maleic hydrazide by oral gavage on days 7 through 27 of gestation. The doses were equivalent to 0, 100, 300 or 1000 mg/kg/day of maleic hydrazide. The does were sacrificed on day 28 and the fetuses examined for external, visceral and skeletal abnormalities. No treatment-related adverse maternal effects or effects on reproductive indices were observed. At 300 mg/kg/day and 1000 mg/kg/day, increased incidence of fetuses with malformations of the scapula were noted (0, 0, 4 and 2 for the control, low, mid and high dose groups, respectively). To more fully assess this potential effect, additional information was requested in the 1988 Registration Standard. Following receipt and evaluation of the requested information, the malformed scapulae observed in this study were determined to not be treatment-related. Therefore, the NOELs for maternal toxicity and for developmental toxicity in this study are both $1000 mg/kg/day of maleic hydrazide, the highest dose tested. (MRID 00128721, 40985311)

When the negative developmental toxicity study in rabbits was considered together with the two developmental toxicity studies in rats that were also negative (except for some minor skeletal variations noted in one study at the very high dose of 1600 mg/kg/day), the RfD Committee (8/5/93) dismissed developmental toxicity as an issue of concern for maleic hydrazide.

f. Reproductive Toxicity

In a standard 2-generation reproduction study with 2 litters per generation, the potassium salt of maleic hydrazide was incorporated continuously in the feed of male and female Sprague-Dawley rats at dietary levels of 0, 1000, 10000 or 30000 ppm of maleic hydrazide for 2 successive generations. These levels were equivalent to 0, 81, 791 and 2405 mg/kg/day of maleic hydrazide for males and 0, 97, 932 and 2874 mg/kg/day for females. Parental animal groups (F_0 and F_{1b}) consisted of 15 males and 30 females per group. An additional dietary level of 50000 ppm was discontinued during the study because of reduced body weights of F_0 adults and F_{1b} pups. The reproductive indices of male and female

parents were not adversely affected by the test material at any treatment level or at any time during the study. At 30000 ppm, however, reduced body weight gains were observed for F_0 female parental animals during growth and reproduction phases and increased mortality was noted for F_{1b} parental animals. Therefore, the parental NOEL is 10000 ppm (791 mg/kg/day and 932 mg/kg/day for males and females respectively) of maleic hydrazide and the LOEL is 30000 ppm (2405 mg/kg/day and 2874 mg/kg/day for males and females, respectively). At 30000 ppm, decreased body weight gains were also observed for F_{1b}, F_{2a} and F_{2b} pups during lactation. Based on these decreased body weight gains for pups, the developmental NOEL is 10000 ppm (791 mg/kg/day and 932 mg/kg/day for males and females, respectively) of maleic hydrazide and the LOEL is 30000 ppm (2405 mg/kg/day and 2874 mg/kg/day for males and females, respectively). (MRID 00128720)

g. Mutagenicity

A Salmonella typhimurium reverse mutation assay (Ames assay) was conducted using the potassium salt of maleic hydrazide as the test material. Strains TA98, TA100, TA1535, TA1537 and TA1538 were tested without and with S9 metabolic activation. No increases in reverse mutations were observed at concentrations up to 10000 µg/plate. (MRID 41149001)

The potassium salt of maleic hydrazide was tested in a chromosomal aberration assay using Chinese Hamster Ovary (CHO) cells in vitro. Based on the results of cytotoxicity testing, the test material was assayed at 1000, 2150 or 4640 µg/ml in the absence of S9 metabolic activation and at 2150, 4640 or 10000 (maximal limit concentration) µg/ml in the presence of S9. There was a marked increase in osmotic pressure (osmolality) at 10000 µg/ml. Results were considered to be negative in the absence of S9. In the presence of S9, a statistically significant ($p < 0.01$) increase in aberration-bearing cells was found in 10000 µg/ml cultures at the 12-hour sampling, but not at the 24-hour sampling. The apparent positive results in this assay are considered to be equivocal because of the possible confounding effect of the increased osmotic pressure. (MRID 41147302)

Male and female B6C3F1 mice were given a single intraperitoneal injection of the potassium salt of maleic hydrazide at dose levels up to 1100 mg/kg, the level causing death. Bone marrow cells were subsequently examined for sister-chromatid exchanges. No significant increases in exchanges over control levels were found in any treated male or female dose group. (MRID 41660001)

Male and female CD-1 mice were dosed once by oral gavage with the potassium salt of maleic hydrazide at doses equivalent to 2500 or 5000 (limit dose) mg/kg of maleic hydrazide. Bone marrow cells were scored 72 hours later for polychromatic erythrocytes with micronuclei (m-PCE). No significant increases in the incidence of m-PCE over control levels were observed in the treated male or female mice at either dose level. (MRID 41719101)

Cultures of strain M45 (rec$^-$) and strain H17 (rec$^+$) of Bacillus subtilis were treated with the potassium salt of maleic hydrazide or with technical grade maleic hydrazide at doses up to 10000 µg/plate, both in the absence and presence of S9 metabolic activation. Surviving colonies of each strain were counted after 1 - 2 days and the survival index (SI), i.e., the ratio of the relative survival of M45 to H17 strains, was determined for each treatment. For the potassium salt of maleic hydrazide, no differences in SI were observed for the various treatments in trials without S9. In trials with S9, however, differential toxicities, indicated by a decreased SI, were observed at the highest dose of 10000 µg/plate. For the technical grade maleic hydrazide, decreased SIs were observed at doses of 5000 and 10000 µg/plate in trials without and with S9. It was concluded that both the potassium salt of maleic hydrazide and technical grade maleic hydrazide appear to be genotoxic, i.e. have the potential to affect DNA repair processes, at the extremely high dose levels of 5000 to 10000 µg/plate. (MRID 41176601 and 41176602)

The potassium salt of maleic hydrazide was tested in a sister-chromatid exchange assay using Chinese Hamster Ovary (CHO) cells in vitro at doses up to 10000 µg/ml. Preliminary dose-selection testing, based on delays in cell cycling, indicated delays at 10000 µg/ml in the absence of S9 metabolic activation and at 3200 and 10000 µg/ml in the presence of S9. Significant increases in sister-chromatid exchanges were observed in cultures without S9 at 10000 µg/ml and in cultures with S9 at 3200 and 10000 µg/ml. Hence, the potassium salt of maleic hydrazide appears to be genotoxic in this assay, but only at cytotoxic doses, as measured by delays in cell cycling. (MRID 41147303)

Since maleic hydrazide is a uracil antimetabolite and this is presumably its mechanism of action with respect to its plant growth regulator/herbicidal properties, it might be expected that equivocal or positive results would be observed in some genotoxicity tests. When all of the genotoxicity studies are considered together with the results of all the other toxicological studies on maleic hydrazide and its potassium salt, including, especially the negative carcinogenicity studies in rats and mice,

it was concluded that the potential genotoxic hazard is negligible and does not warrant continued concern.

h. Metabolism

Male and female Sprague-Dawley rats were given ^{14}C-maleic hydrazide as a single intravenous dose of 2 mg/kg or as single oral doses of 2 or 100 mg/kg. Additional rats were given repeated oral doses of 2 mg/kg of maleic hydrazide for 14 days followed by a single oral dose of 2 mg/kg of ^{14}C-maleic hydrazide. Total recovery of radioactivity at 7 days post-dosing ranged from 92 - 98% in the various groups. Most of the administered radioactivity, regardless of dosing regimen, was recovered in the urine (76 - 87% at 7 days) with lesser amounts appearing in the feces (5 - 15%). Less than 1% of the administered radioactivity appeared in expired air. Absorption and elimination were rapid. Within 4 hours after intravenous dosing, about 63% of the administered radioactivity was excreted in the urine and after oral dosing at 2 or 100 mg/kg (single or repeated dosing groups), 43 - 55% was excreted in the urine. Excretion was nearly complete within 24 hours. There were no differences between sexes in the excretory rates. There was no evidence of bioaccumulation of radioactivity in any tissue or organ. Four-hour urine contained mostly unchanged maleic hydrazide (> 60% of urinary radioactivity in males and > 80% in females) with a lesser amount of the sulfate conjugate of maleic hydrazide. No other significant metabolite was present in the urine. Fecal metabolites were not identified. (MRID 41571701, 41679701 and 42432301)

i. Neurotoxicity

No neurotoxicity potential has been observed in any of the animal laboratory studies. Neither acute delayed neurotoxicity study or a 28-day delayed neurotoxicity study in hens is required.

j. Other Toxicological Considerations

Technical Impurity: Hydrazine - Technical grade maleic hydrazide contains hydrazine as a contaminant. Hydrazine has been associated with tumor induction in animals. In 1982, the Agency established (in the PD-4) an upper limit for hydrazine at 15 ppm in technical grade products containing maleic hydrazide. In the 1988 Registration Standard on Maleic Hydrazide, the Agency continued to require that the hydrazine content of the technical chemical be limited to $\leq$15 ppm. This was a level determined to not cause concern based on estimates of excess lifetime

carcinogenic risks to humans for both worker and dietary exposure. This limit is still in effect.

Potassium Salt - Toxicological studies on maleic hydrazide and on the potassium salt of maleic hydrazide are considered to be equivalent with respect to fulfillment of applicable toxicity study requirements. This was also the case in the 1988 Registration Standard for Maleic Hydrazide. This decision was confirmed by the HED RfD/Peer Review Committee in August, 1993. It should also be noted that in nearly all studies described in which the potassium salt of maleic hydrazide was the test material, dosage levels were expressed in units of maleic hydrazide, rather than in units of the potassium salt.

Pyrolysis and Inhalation Studies: Tobacco - Regarding the use of maleic hydrazide and its potassium salt on tobacco, the 1988 Registration Standard stated that a 90-day inhalation study "may be required for maleic hydrazide and pyrolysis products depending upon their presence in and nature on tobacco" (paragraph 158.340, Table A, footnote 4). The Standard also required submission of residue and degradation information/data on tobacco. The degradation data on tobacco were submitted and reviewed. The major pyrolysis products from maleic hydrazide were determined to be essentially similar to those of untreated tobacco. They included carbon dioxide, carbon monoxide, hydrogen cyanide, ammonia, and a complex mixture of over 1200 organic compounds. Furthermore, the level of hydrazine was also essentially the same in treated and untreated tobacco. The Agency concluded that residues of maleic hydrazide in/on tobacco would not be expected to result in increased hydrazine levels in tobacco smoke. Based on the residue and pyrolysis information described above and on the lack of significant toxicological concerns, additional inhalation studies on maleic hydrazide or on its pyrolysis products are not required to support the uses of maleic hydrazide on tobacco.

k. Reference Dose

On August 5, 1993, the Health Effects Division Reference Dose (RfD) Peer Review Committee recommended that the RfD for maleic hydrazide be established at 0.25 mg/kg/day. This value was based on a NOEL of 25 mg/kg/day observed in the 104-week chronic feeding study in rats. At the LOEL of 500 mg/kg/day, decreased body weight gains were observed in male rats. In addition, a NOEL of 29 mg/kg/day was observed in the co-critical 52-week chronic feeding study in dogs. At the

LOEL of 87 mg/kg/day (males) and 105 mg/kg/day (females), decreased body weight gains were observed in both males and females along with reduced heart weight in males. An uncertainty factor (UF) of 100 was used to account for inter-species extrapolation and intra-species variance.

2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues of maleic hydrazide in or on food items have been established in terms of the parent only *(Source: 40 CFR §180.175 and §185.3900)*. An adequate enforcement method is available for determination of maleic hydrazide per se in plant commodities.

The qualitative nature of the residue in plants is adequately understood. Studies conducted on potatoes and onions indicate that maleic hydrazide is translocated but not metabolized extensively in plants. The residue of concern is maleic hydrazide per se.

The qualitative nature of the residue in animals is not adequately understood. Supplementary data are required to upgrade the existing poultry (MRID 42641501) and ruminant (MRID 42567801) studies. Three major components were identified in extracts from milk, eggs, and tissues: maleic hydrazide, a sulfate conjugate of maleic hydrazide, and metabolite 1, proposed to be an acid stable conjugate of either the N- or O-methyl derivative of maleic hydrazide. Further attempts to identify metabolite 1 in eggs, milk, and tissues are required.

An adequate method for purposes of data collection and enforcement of tolerances for maleic hydrazide per se in or on potatoes and potato processed commodities, onions, peaches, and cranberries is listed in PAM, Vol. II as Method I. There are no existing enforcement methods available for animal commodities in PAM, Vol. II.

The available storage stability data indicate that maleic hydrazide is stable under frozen storage conditions in animal commodities up to 20 months, potato and onion raw agricultural commodities stored up to 6 months and processed potato commodities stored up to 10 months.

Tobacco field data indicated that residues of maleic hydrazide ranged from 27 to 327 ppm in or on flue-cured tobacco treated with maleic hydrazide at 0.7X the maximum registered rate. The major pyrolysis products of maleic hydrazide are similar to those of untreated tobacco.

Residues of maleic hydrazide in or on tobacco will not result in an increase in the levels of hydrazine in tobacco smoke.

All data requirements for magnitude of the residue in plants have been satisfied.

Data are still required for magnitude of the residue in animals. Simulated feeding studies using [^{14}C] maleic hydrazide indicate that detectable residues may occur in livestock. When the nature of the residue in animals is adequately understood, feeding studies for ruminants and poultry must be conducted using analytical methodology specific for residues of concern.

A confined rotational crop study using winter wheat is required. The requirement for field studies will be determined when the data on confined rotational crop studies are evaluated. Preliminary studies have indicated that detectable residues could occur on winter wheat planted as a rotational crop in fields that have been treated with maleic hydrazide. Further data have been required to determine if there is a need for establishment of rotational tolerances or suitable plantback intervals to avoid these residues. However, these data are considered to be either confirmatory or supplemental to our recommendation that maleic hydrazide is eligible for reregistration because the available data base is adequate to make a reasonable upper bound dietary risk assessment and conclude that the risk is not significant. The outstanding rotational crop data are not expected to change our conclusions concerning dietary risk.

b. Occupational and Residential

Mixer/Loader/Applicator Exposure

There is a potential for mixer/loader/applicator (handlers) exposure via the inhalation and dermal routes. Maleic hydrazide is applied to foliar growth by ground boom equipment, backpack sprayers, and aircraft. A mixer/loader/applicator risk assessment was discussed in the Registration Standard based on potential developmental toxicity. In the assessment, it was determined that Margins of Exposure (MOE) were less than 100 for many of the scenarios (MOE's equal to or greater than 100 are considered acceptable to the Agency). As a result, the Agency required that handlers wear a long-sleeve shirt, long pants, and chemical resistant gloves at all times when mixing/loading and applying maleic hydrazide. Although there are several scenarios in which there is a potential for mixer/loader/applicator exposure, there are no longer any developmental

toxicological concerns; therefore, mixer/loader/applicator data are not required to support the reregistration of maleic hydrazide.

Post-Application Worker Exposure

Worker and residential post-application and reentry exposure data were not required in the 1988 Registration Standard based on the likelihood of low exposure due to 7 to 70 day preharvest intervals or because applications are made at the early stages of plant development. Since there are no longer any toxicological concerns, post-application/reentry data are not required to support the reregistration of maleic hydrazide.

Worker Protection

The Agency's Worker Protection Standard (WPS) for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- establishes a minimum restricted interval (REI) of 12 hours for maleic hydrazide based on its acute dermal toxicity, skin irritation potential, eye irritation potential Toxicity Category III or IV. The Agency considers the 12-hour REI for this chemical a prudent risk mitigation measure to protect workers. Therefore, the Agency retains the 12-hour REI for uses within the scope of the WPS and will allow workers to enter areas treated with maleic hydrazide during the REI only in the few narrow exceptions allowed in the WPS.

The WPS also requires personal protective equipment (PPE) for all handling activities in the form of a long-sleeved shirt, long pants, socks, and shoes.

3. Risk Assessment

a. Dietary

The appropriate data set(s) to assess dietary risk is the rat chronic feeding study (MRID 42570101, 42770401) and/or the dog chronic feeding study (MRID 42214101, 42248101). If any effects were observed in short term studies, they were minimal and occurred only at extremely high doses. For the purposes of evaluating acute worker exposure, there are no toxicological concerns associated with maleic hydrazide.

The chronic dietary risk analysis used *reassessed tolerance levels* for residues on cranberries, onions (dry bulb), potatoes, potato chips, potato granules and potato waste (from processing); upper bound residue levels for meat, milk, poultry and eggs; and assumed all of the crops were treated with maleic hydrazide to estimate the Theoretical Maximum

Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. These exposures (TMRCs) were then compared to the Reference Dose (RfD) of 0.25 mg/kg/day for maleic hydrazide to estimate chronic dietary risk. The analysis does not include a food form designated as *potato chips* and the entire RAC/food form *potatoes (white), peeled/cooked, not further specified* was substituted. The upper bound residue levels for meat, milk, poultry, and eggs were determined from data submitted to Agency for this dietary analysis since residues are possible, but tolerances have not yet been established. (See the Tolerance Reassessment Section of this document)

The estimated TMRC for the overall U.S. population from food uses of maleic hydrazide is 0.074 mg/kg bodyweight per day, which represents 29.5% of the reference dose. The vast majority of the estimate (27.5% of the RfD) was contributed by potato consumption. For the most highly exposed subgroup, Children (One to Six Years Old), the estimated TMRC is 0.151 mg/kg bodyweight per day, which represents 60.3% of the RfD. The next most highly exposed subgroup, Non-nursing Infants (Less Than One Year Old), the TMRC is 0.148 mg/kg bodyweight per day, which represents 59.1% of the RfD. All other subgroups had TMRCs of less than 44% of the RfD.

The TMRCs or exposure/risk estimates are considered overestimates because it is assumed that 100% of the commodities used in the analysis contain this herbicide either at the maximum legal level or the upper bound residue level. About 90% of the exposure is contributed by potatoes. The use of the entire RAC/food form *potatoes (white), peeled/cooked, not further specified* to represent potato chips is also a source of overestimation. Therefore, given the risk values arrived at by this analysis, it appears that the chronic dietary risk posed by this pesticide on these food uses is minimal.

In 1982 the Agency established an upper limit for hydrazine, a contaminant, at $\leq$15 ppm in technical grade products containing maleic hydrazide. This level alleviates any concern based on calculations of lifetime carcinogenic risks to humans considering both dietary and worker exposure. The Agency continues to require that the hydrazine content of the technical chemical be limited to $\leq$15 ppm because no changes in the use have occurred that would increase the risk since it was originally determined in 1982.

b. Occupational and Residential

There is a potential for mixer/loader/applicator (handlers) exposure via the inhalation and dermal route. A mixer/loader/ applicator risk assessment was discussed in the Registration Standard based on potential developmental toxicity. Since then, additional information and studies have been submitted which demonstrate developmental effects are no longer a concern. Based on the lack of acute toxicological concerns and exposure, the risk posed by this chemical is considered minimal for all workers.

Increased hydrazine levels from the use of maleic hydrazide have been a concern as a pyrolysis product from tobacco. Increased levels of hydrazine are NOT expected; therefore, the risk is no greater than that risk already associated with the use of tobacco.

Data Requirements

There are currently no maleic hydrazide tolerances for animal commodities and the appropriate information concerning animal metabolism, analytical methodology and magnitude of the residue in meat, milk, poultry and eggs for the establishment of tolerances has not been submitted to the Agency at this time. Suitable data have been submitted to enable a reasonable worst case dietary risk assessment to be conducted. These data are derived from feeding studies in which the animals were fed [^{14}C-]maleic hydrazide followed by analysis of meat, milk and tissues for total radioactivity.

The following data requirements remain unfulfilled:
--animal metabolism (Guideline 171-4(b))
--residue analytical method for animal commodities (Guideline 171-4(d))
--magnitude of the residue in animal commodities (Guideline 171-4(j))
--confined rotational crops (Guideline 165-1)
--product chemistry (Guidelines 63-14, and 63-17)
These data are considered confirmatory since the data base is sufficient at this time to make a reasonable upper bound dietary risk assessment.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

Maleic hydrazide is soluble in water (water solubility of 5,000 ppm). The active ingredient in the end-use products is maleic hydrazide - potassium salt which has a high water solubility (550,000 ppm).

Maleic hydrazide was stable to hydrolysis in aqueous buffered solutions at pH 3, 6, and 9 at elevated temperatures of 45°C (61 days) and 80°C (30 days) (MRID 00143322). Maleic hydrazide degraded slowly (< 10% at 28 days) at pH 5, was stable at pH 7, and degraded with an observed half-life of > 30 days at pH 9 in sterile aqueous buffer solutions that were irradiated under artificial light (xenon lamp) (MRIDs 42872301, 42692101, 43141001, 43177301). At 30 days' post-treatment, [^{14}C]maleic hydrazide was the only [^{14}C] compound isolated from the pH 5 and 7 solutions; in the irradiated pH 9 solution, two photodegradates were isolated, maleic acid and succinic acid. Maleic acid and succinic acid were present at concentrations (as maleic hydrazide equivalents) of 0.032 and 0.037 mg/L, respectively, after 30 days irradiation. Photodegradation on sandy soil did not occur. Maleic hydrazide was stable to photolysis after 17 days irradiation (UV lamp, equivalent to 34 days sunlight) (MRID 00141951).

Aerobic soil metabolism data indicate that maleic hydrazide is metabolized rapidly in aerobic sandy loam soil (observed half-life of < 24 hours), with the ultimate degradate being CO_2 (MRID 41896201). Other nonvolatile degradates, maleic acid and maleimide, were identified in small amounts (< 5% of the applied) early in the aerobic soil metabolism of the compound, but did not persist. Maleic hydrazide is moderately persistent under anaerobic soil conditions (half-life 30-60 days; flooding plus nitrogen atmosphere) in loamy sand soil, with mineralization to CO_2 essentially complete after 60 days of anaerobic soil metabolism (MRID 41918201). Two nonvolatile degradates identified in the soil plus floodwater, maleic acid and maleimide, did not persist under anaerobic conditions.

Maleic hydrazide is expected to be mobile, due to its low adsorption to soils. K_{ads} values for parent maleic hydrazide were 0.14 to 2.61 in five unaged soils (silt loam, sandy loam, sandy clay loam, and 2 sandy soils) (MRID 00151952). Column leaching of unaged sandy and clay loam soils yielded all of the radioactivity in the leachate (MRID 00151952).

Based on column leaching studies, aged maleic hydrazide and maleic hydrazide residues were found to be mobile (39.76% of the applied radioactivity was in the leachate) in columns of loamy sand soil, and very mobile (100.79% of the applied radioactivity in the leachate) in columns of sandy soil (MRID 41896202). The degradates maleic acid and maleimide were detected in the leachate from the loamy sand soil column; only maleic hydrazide was detected in the leachate from the sandy soil.

Maleic hydrazide did not persist in the available field dissipation studies. In two acceptable field studies, maleic hydrazide dissipated with observed half-lives of 3 days on bare ground and 5 days in turf plots of sandy loam soil located in California (MRIDs 42790901 and 42744801) and with observed half-lives of < 14 and < 27 days on bare ground and vegetated (mature tobacco) plots, respectively, of loam soil located in North Carolina (MRID 42693301); in general, maleic hydrazide was not detected below the 30-cm soil depth at either location. In an unacceptable field dissipation study that provided supplemental information, maleic hydrazide dissipated with a half-life of 3-7 days in clay loam soil in New Mexico; in the 6- to 12-inch soil depth, maleic hydrazide concentrations were < 0.1 ppm at all sampling intervals, and in the 12- to 18-inch soil depth, maleic hydrazide was not detected (< 0.05 ppm) at any sampling interval (MRID 40034802).

The potential for maleic hydrazide to bioaccumulate in fish is very low, as indicated by the octanol/water partition coefficient of < 0.6 (MRID 00163301).

When maleic hydrazide is aerially or air-blast sprayed, drift from approved use sites could affect non-target crops or areas containing endangered plant species. Therefore, in order to assess the extent of this exposure, the Spray Drift data requirements were imposed in the November 1992 Data Call-In.

b. Environmental Fate Assessment

Available field dissipation and laboratory data indicate that maleic hydrazide is not persistent in the environment. The submitted environmental fate data indicate that mineralization to CO_2 is the major route of dissipation. Small amounts of nonvolatile degradates are produced early in the aerobic soil metabolism of the compound. Maleic hydrazide is moderately persistent under anaerobic soil conditions, but mineralization to CO_2 is essentially complete after 60 days of anaerobic soil metabolism. Hydrolysis, photodegradation, and volatilization do not appear to play a

significant role in the dissipation process. Both parent maleic hydrazide and its minor degradates, maleic acid and maleimide, are mobile, with the highest mobility in sandy soils. Available field data indicate that maleic hydrazide has a half-life of less than two weeks, with little or no leaching observed. The potential for maleic hydrazide to bioaccumulate in fish is very low.

Groundwater Impact

An evaluation of maleic hydrazide using the OPP "New Paradigm" for ground water shows that the Level of Concern (LOC) for mobility is exceeded by this pesticide. However, the LOC for persistence is not exceeded, and for this reason, maleic hydrazide is unlikely to impact groundwater quality.

No further regulation with respect to ground water is needed at this time.

Surface Water Impact

Although available data indicate that maleic hydrazide degrades rapidly under aerobic conditions (observed half-life of < 24 hours) and has a half-life of less than two weeks in the field, maleic hydrazide residues were mobile to very mobile (up to 100% of the applied radioactivity was present in the leachate from sandy soil columns). Its persistence under anaerobic conditions could pose a risk of contamination of surface waters if maleic hydrazide were washed into anaerobic zones by rainfall events that occur soon after application.

Because there is a potential for surface water runoff, the following label advisory is required:

Surface water advisory:

"Under some conditions, maleic hydrazide may have a significant potential for runoff into surface water (primarily via dissolution in runoff water), for several days post-application. Conditions favoring runoff include poorly draining soils or wet soils with readily visible slopes, frequently flooded areas, areas where an intense or sustained rainfall is forecast to occur within 48 hours, areas overlying extremely shallow ground water, and areas overlying tile drainage systems that flow to surface water."

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

Effects to Non-Target Birds

Acute Avian Oral Toxicity:

The data indicate that technical maleic hydrazide and the potassium salt of maleic hydrazide are "practically nontoxic" to avian species on an acute oral basis. The guideline requirement (71-1) for an acute oral toxicity study with avian species is satisfied.

Species	%ai	LD_{50} (mg/kg)	MRID No.	Study Classification
Mallard	90[1]	> 4640	00124742	Core
	34.5[2]	> 2250	00146141	Core

[1]technical maleic hydrazide
[2]potassium salt of maleic hydrazide

Acute Avian Dietary Toxicity:

The data indicate that the technical and the potassium salt of maleic hydrazide are "practically nontoxic" to avian species on a dietary basis. The guideline requirement (71-2) for a dietary toxicity test with avian species is satisfied.

Species	%ai	LC_{50} (ppm)	MRID No.	Study Classification
Mallard	90[1]	> 10,000	00107417	Core
	34.5[2]	> 5620	00147000	Core
Bobwhite quail	90[1]	> 10,000	00126033	Core

[1]technical maleic hydrazide
[2]potassium salt of maleic hydrazide

Avian reproduction

Avian reproduction studies are not required for maleic hydrazide because it is not applied more than once prior to or during the breeding season, and it is practically nontoxic to birds.

(2) Aquatic Data

(a) Effects on Freshwater Fish

The data indicate that the technical and the potassium salt of maleic hydrazide are "practically nontoxic" to coldwater and warmwater fish. The guideline requirement (72-1) for acute toxicity testing with freshwater fish is fulfilled.

Species	%ai	LC_{50} (ppm)	MRID No.	Study Classification
Rainbow trout	90[1]	1435	00124740	Core
	34.5[2]	> 1000	00146142	Core
Bluegill	90[1]	1608	00124739	Core

[1]technical maleic hydrazide
[2]potassium salt of maleic hydrazide

(b) Effects on Freshwater Invertebrates

These data indicate that technical maleic hydrazide and the potassium salt are "practically nontoxic" to freshwater invertebrates. The guideline requirement (72-2) for an acute toxicity study with freshwater invertebrates is satisfied.

Species	%ai	LC_{50} (ppm)	MRID No.	Study Classification
Daphnia magna	90[1]	107.5	00124741	Core
	34.5[2]	> 1000	00146143	Core

[1]technical maleic hydrazide
[2]potassium salt of maleic hydrazide

(3) Non-Target Insects Data

The data indicate that maleic hydrazide is practically nontoxic to the honey bee. The guideline requirement (141-1) for an acute-contact toxicity study with the honey bee is satisfied.

Species	% ai	LD_{50} (µg/bee)	MRID/ Fiche No.	Study Classification
Honey bee	N/A	> 36.26	00018842	Scientifically sound

(4) Non-Target Plants Data

Tier I and II plant testing is complete. The guideline requirement (122-1) for seed germination/seedling emergence/vegetative vigor is satisfied. The guideline requirement (123-2) for aquatic plant growth also is satisfied.

The acceptable Tier I and II phytotoxicity data on maleic hydrazide are indicated below.

Species	% ai	Results (mg/l)	MRID No.	Study Classification
Selenastrum capricornutum	72.5[1]	NOEC > 9.84 (the highest level tested)	41318001	Core
Seed germination	30.2[2]	(see next page)[3]	41289301	Core
Seed emergence		(see next page)[4]	41289301	Core
Vegetative vigor		(see next page)[5]	41289302	Core
Anabaena flos-aquae	98.9	EC_{50} > 95 NOEC = 95 LOEC = 60	43006901	Core
Nitzschia palea		EC_{50} > 97.8 NOEC = 97.8 LOEC = 60.4	43006902	Core
Skeletonema costatum		EC_{50} > 102 NOEC > 102 LOEC = 102	43006903	Core
Lemna gibba		EC_{50} = 114 NOEC = 38.6 LOEC = 23.7	43006904	Core

[1]technical maleic hydrazide
[2]potassium salt of maleic hydrazide

[3]**Tier II seed germination test results (lowest observed EC values, lbs ai/acre; rl = radicle length, pg = percent germination)**:

Plant	EC_{25}	EC_{50}	NOEC
Soybean	> 6.00 (rl,pg)	> 6.00 (rl,pg)	> 6.00
Lettuce	2.01 (rl)	> 6.00 (rl)	1.50
Carrot	0.62 (rl)	> 6.00 (rl)	3.00
Tomato	1.23 (rl)	> 6.00 (rl)	1.50
Cucumber	> 6.00 (rl)	> 6.00 (rl)	3.00
Cabbage	> 6.00 (rl,pg)	> 6.00 (rl,pg)	6.00
Oat	0.79 (rl)	4.59 (rl)	0.75
Ryegrass	0.97 (rl)	> 6.00 (rl)	3.00
Corn	1.06 (rl)	> 6.00 (rl)	0.60
Onion	0.68 (rl)	> 6.00 (rl)	3.00

4**Tier II vegetative vigor test results (lowest observed EC values, lbs ai/acre; pr = % plant phytotoxicity, ph = plant height, dw = dry weight)**:

Plant	EC_{25}	EC_{50}	NOEC
Soybean	2.31 (pr)	> 6.00 (ph)	0.38
Lettuce	2.22 (ph,dw)	4.47 (dw)	0.75
Carrot	4.73 (pr)	> 6.00 (ph)	0.75
Tomato	4.71 (pr,ph)	> 6.00 (ph)	1.50
Cucumber	4.63 (pr,ph)	> 6.00 (ph)	1.50
Cabbage	1.10 (pr,dw)	3.48 (dw)	0.75
Oat	1.95 (ph,dw)	3.97 (dw)	1.50
Ryegrass	4.87 (ph)	7.61 (ph)	3.00
Corn	4.01 (ph)	> 6.00 (ph)	1.50
Onion	1.44 (ph)	4.45 (ph)	0.38

5**Tier II seedling emergence test results (lowest observed EC values, lbs ai/acre; ph = plant height, dw = dry weight)**:

Plant	EC_{25}	EC_{50}	NOEC
Soybean	1.09 (ph)	2.72	0.75
Lettuce	2.77 (ph)	> 6.00	1.50
Carrot	> 6.00 (ph)	> 6.00	6.00
Tomato	1.03 (dw)	2.28	0.75
Cucumber	> 6.00 (ph)	> 6.00	6.00
Cabbage	1.07 (dw)	4.40	0.75
Oat	1.35 (ph)	4.70	< 0.38
Ryegrass	2.52 (ph)	> 6.00	1.50
Corn	3.02 (ph)	5.40	1.50
Onion	0.53 (ph)	4.60	0.38

b. Ecological Effects Risk Assessment

(1) Terrestrial Organisms

Risks to Birds:

Wildlife may be exposed to maleic hydrazide when consuming contaminated food items, such as grasses, seeds, fruits, and insects. Actual residue data on potential food items are not available, but estimates of maximum expected terrestrial residues, based on maximum application rates can be calculated according to Hoerger and Kenaga (1972). Based on these estimates, use patterns with application rates less than or equal to 9 lbs ai/acre are not considered to present a potential risk to birds.

The following maximum residues are expected from maximum applications of maleic hydrazide on fallow lands (9 lbs ai/acre) and turf and rights-of-way (6 lbs ai/acre):

Site	Estimated Residue (ppm)			
	9 lbs ai/acre[1]		6 lbs ai/acre[2]	
	Max.	Typical	Max.	Typical
Short grass	2050	1068	1425	742
Tall grass	980	819	650	543
Leaves, Leafy crops	1060	297	750	210
Forage, Small insects	510	290	345	196
Seed pods, Large insects	105	26	71	18
Fruits	63	13	42	9

[1]applies to a single application for control of nightshade on fallow lands
[2]applies to rights-of-way, turf, and lawns

Risk to birds is assessed by comparing these estimated residues with multiples of the dietary LC_{50} value. If residues are $ 0.5 LC_{50}, a "high risk" to avian species is presumed. If residues are $ 0.2 LC_{50}, a "restricted use" trigger is exceeded; this is a level at which risk can be reduced by restricted-use labeling. Lastly an "endangered species" concern is triggered if residues are $ 0.1 LC_{50}. However, when the estimated residue levels are relatively low and the LC_{50} exceeds 5000 ppm ("practically nontoxic") with no dose-related mortality, the Agency presumes no undue risk to either endangered or nonendangered birds. Therefore because the avian LC_{50} values for maleic hydrazide and its salt are > 5620 and > 10,000 ppm, respectively, no risk to birds is anticipated from the present uses of maleic hydrazide (See following table).

Use site	Max. appl. rate (lbs ai/ acre)	Level of concern[1] (ppm)	Relevant EEC[2] (ppm)
Fallow land	9	HR = > 5000 RU = > 2000 ES = > 1000	819 819 819
Rights-of-way, Commercial turf, Lawns	6	HR = > 5000 RU = > 2000 ES = > 1000	742 742 742
Tobacco, Trees, Shrubs, Ivy	4.5	HR = > 5000 RU = > 2000 ES = > 1000	154 154 154
Onions, Potatoes	2-3	SR = > 5000 RU = > 2000 ES = > 1000	105 105 105
Broadleaf trees	unknown (injected)	as above	unknown
Ornamentals, Citrus, Ivy, Iceplant	unknown (apply to drip pt.)	as above	unknown

[1]High Risk (HR) = 0.5 LC_{50}; Restricted Use (RU) = 0.2 LC_{50}; Endangered Species (ES) = 0.1 LC_{50}
[2]where EEC = typical expected residues on potential food items, based on the maximum application rate for that use site

The Agency cannot fully evaluate the risk to birds from applying maleic hydrazide to ornamental trees and shrubs, ivy, iceplant, and young citrus trees when the application rate is not specified. Spraying to the drip point may contaminate insects and expose birds feeding on insects. However, risk is probably minimal because maleic hydrazide is practically nontoxic to birds. Applications to broadleaf trees by injection are not likely to pose a risk.

Risks to Mammals:

Risk to small mammals is assessed by estimating dietary LC_{50} value from acute oral toxicity testing with the laboratory rat. The LD_{50} values to male and female rats are greater than 5000 mg/kg for both technical maleic hydrazide and the potassium salt. These values are assumed to be applicable to other small mammals, including a representative herbivore (meadow vole), granivore (deer mouse), and insectivore (Least shrew). Body weights and daily food consumption for these species were obtained from Davis and Golly (1963).

The following LC_{50} values were estimated:

Species	**Body wt. (g)**	**Food eaten/ day (g)**	**Expected foods**	**LC_{50}[1]** (ppm)
Meadow vole	46	28.1	grasses	> 8185
Deer mouse	13	2.1	seeds, insects	> 30,952
Least shrew	5	5.5	insects	> 4545

[1]Where LC_{50} = LD_{50} x body weight ÷ daily food consumption

The LOCs for assessing risk to nonendangered and endangered mammals are the same as those indicated for birds (0.5, 0.2, and 0.1 x LC_{50}). Applying the same approach as for birds of presuming that a trigger is not exceeded when residues are relatively low and an LC_{50} value exceeds 5000 ppm or thereabouts, minimal risk is anticipated to nonendangered or endangered mammals (see following table).

Use site	Max. appl. rate (lbs ai/ acre)	Level of concern[1] (ppm)	Relevant EEC[2] (ppm) MV[3]	DM	LS
Fallow land	9	HR = > 5000 RU = > 2000 ES = > 1000	819 819 819	290 290 290	290 290 290
Rights-of-way, Turf, Lawns	6	HR = > 5000 RU = > 2000 ES = > 1000	742 742 742	196 196 196	196 196 196
Tobacco, Trees, Shrubs, Ivy	4.5	HR = > 5000 RU = > 2000 ES = > 1000	154 154 154	147 147 147	147 147 147
Onions, Potatoes	2-3	HR = > 5000 RU = > 2000 ES = > 1000	121 121 121	99 99 99	99 99 99
Broadleaf trees	unknown (injected)	as above	unknown		
Ornamental, Citrus, Ivy, Iceplant	unknown (apply to drip pt.)	as above	unknown		

[1]High Risk (HR) = 0.5 LC_{50}; Restricted Use (RU) = 0.2 LC_{50}; Endangered Species (ES) = 0.1 LC_{50}
[2]EEC = typical expected residues on potential food items
[3]MV = meadow vole; DM = deer mouse; LS = Least shrew

(2) Aquatic Organisms

Foliar applications of maleic hydrazide by ground or air could result in a potential risk to aquatic organisms from runoff and drift into water bodies. The maximum aquatic concentrations of maleic hydrazide are estimated below. They are based on runoff from ground applications and both runoff and drift from aerial and air-blast applications.

Application method	Max. appl. rate (lbs ai/acre)	Expected aquatic concentrations (ppm) at water depths of 0.5- 6 feet			
		0.5'	1'	3'	6'
Ground	9	3.303	1.653	0.549	0.274
Air blast	6	1.541	0.771	0.256	0.128
Aerial	3	0.770	0.385	0.128	0.064

Risk to nonendangered or endangered aquatic organisms is expected to be minimal because anticipated aquatic concentrations of maleic hydrazide are much lower than lethal concentrations to fish or aquatic invertebrates (LC_{50} values ranging from 107.5 ppm to > 1000 ppm), Since the potential for risk to aquatic organisms from ground applications at 6-9 lbs ai/acre or from aerial applications at 3 lbs ai/acre is minimal, risk at lower application rates is also expected to be minimal.

(3) Non-Target Insects

Maleic hydrazide applications to tobacco are made during flowering, at which time honey bees might be exposed to the pesticide. However, with an LD_{50} value greater than 36.26 µg/bee, maleic hydrazide is considered "practically nontoxic" to honey bees. Therefore, minimal risk to honey bees is anticipated.

(4) Non-Target Plants

LOCs have been exceeded for terrestrial and semi-aquatic plants; however, the LOC has not been exceeded for aquatic plants. Exposure of terrestrial and semi-aquatic plants to maleic hydrazide is based on expected runoff from an application by ground and from runoff and drift for aerial and air-blast applications. Direct applications by ground on rights-of-way also are a concern, because endangered and other nontarget plants growing in rights-of-way will be directly exposed to the pesticide spray. No refined modeling was done.

It should be noted that maleic hydrazide is a growth inhibitor, and thus it would not be expected to kill many nontarget

plants. However, inhibiting growth might affect reproduction (e.g., inhibit flowering or seed production) which would adversely impact nontarget plant populations.

Summary of risk to terrestrial, semi-aquatic, and aquatic plants

Use site	Max. appl. rate (lbs ai/acre)	Toxicity results[1]	Relevant EEC[2]			
			Direct appl. (lbs ai/ acre)	Adjacent to site (lbs ai/ acre)	Wet area away (lbs ai/ acre)	Aquatic site (ppm)
Fallow land	9	EC_{25} = 0.53 EC_{50} = > 9.84	-	0.45	4.5*	3.3
Rights-of-way, Commercial turf, Lawns	6	EC_{25} = 0.53 EC_{25} = 1.10 EC_{50} = > 9.84	6*	0.3-0.48 0.3	2.1-3.0* 0.3	2.2
Tobacco, Ivy, Trees, Shrubs	4.5	EC_{25} = 0.53 EC_{50} = > 9.84	-	0.23	2.3*	1.6
Onions, Potatoes	2-3	EC_{25} = 0.53 EC_{25} = 0.53 EC_{25} = 1.10 EC_{50} = > 9.84	-	0.15 0.24[3] 0.15[4]	1.5* 1.05[3,*] 0.15[4]	1.1

[1] a) terrestrial plants - lowest EC_{25} value (onion seedling emergence (se) [plant height] = 0.53 lbs ai/acre) from seed germination (sg) and seedling emergence (se) tests for runoff and runoff + drift; lowest EC_{25} value (cabbage [dry weight] = 1.10 lbs ai/acre) for vegetative vigor tests for drift only; b) aquatic plants - lowest EC_{50} value from aquatic plant studies (*Selanastrum* EC_{50} = > 9.84 mg/l, the highest level tested).

[2]EEC values are based on runoff from ground applications, except where noted for aerial application to onions and potatoes; the aquatic site EEC is for a 0.5-ft deep water body.

*Exceeds the New Ecorisk Paradigm level of concern for risk to non-target plants (i.e., EEC > LOC)

[3]EEC value for aerial application (runoff + drift)
[4]EEC value for aerial application (drift only)

Terrestrial and Semi-Aquatic Plants

The following use sites were used in the evaluation of risk:

(1) Fallow land; Maximum application rate = 9 lb a.i./A
(2) Rights-of-way, commercial turf, lawn; Maximum application rate = 6 lb a.i./A
(3) Tobacco, Ivy, Trees, Shrubs; Maximum application rate = 4.5 lb a.i./A
(4) Onions, Potatoes; Maximum application rate = 2-3 lb a.i./A

Semi-aquatic plant LOCs were exceeded from runoff onto wet areas (i.e., moist, saturated, or flooded soils) for all use sites noted above and terrestrial plant LOCs were exceeded by direct application to rights-of-way (see Tables below). Risk exists for both nonendangered and endangered terrestrial plants if runoff exceeds the nontarget-plant EC_{25} values for seed germination and seedling emergence test results. EEC values are based on runoff from ground applications, except where noted for aerial application to onions and potatoes.

Risk to semi-aquatic plants (plants growing in wet, off-site areas away from treated sites) is shown below.

Use Site	Toxicity results[1]	Relevant EEC Semi-Aquatic Plants (lbs a.i./A)	Risk Quotient (EEC/EC_{25})
Fallow land	EC_{25} = 0.53	4.5	8.5
Rights-of-way,Commercial turf, Lawns	EC_{25} = 0.53	3.0	5.7
Tobacco, Ivy, Trees, Shrubs	EC_{25} = 0.53	2.3	4.3
Onions, Potatoes	EC_{25} = 0.53 EC_{25} = 0.53	1.5[2] 1.05[3]	2.8 2.0

[1] lowest EC_{25} value (onion seedling emergence, plant height)
[2]EEC value from runoff (ground application).
[3]EEC value from runoff and drift (aerial application)

A risk exists for semi-aquatic plants, i.e., plants growing in wet, off-site areas away from treated sites. A risk exists to plants in such wet areas from applications as low as 2 lbs ai/acre. Therefore, almost all registered uses of maleic hydrazide are likely to pose a risk to semi-aquatic plants growing on off-site wet areas.

Risk to terrestrial non-target plants inhabiting rights-of-way is expected from direct applications of 6 lbs ai/acre.

Use Site	Toxicity Results[1]	Relevant EEC for Direct application (lbs a.i./A)	Risk Quotient (EEC/EC_{25})
Rights-of-way	EC_{25} = 0.53	6.0	11.3

[1] lowest EC_{25} value (onion seedling emergence, plant height)

A high risk to plants inhabiting rights-of-way also is expected from direct applications of 6 lbs ai/acre. No risk to terrestrial plants is expected in areas adjacent to treated sites. In the seed germination/seedling emergence studies, the lowest EC_{25} value was 0.53 lbs ai/acre for onions. EC_{25} values for carrots, oats, and ryegrass also were less than 1 lb ai/acre.

Aquatic plants

The lowest EC_{50} value for aquatic plants is presumed to be 9.84 mg/l (the highest level tested) for *Selanastrum capricornutum*. Because the estimated aquatic concentrations for even a 0.5-ft. deep water body (0.7-3.3 ppm) are less than the LOC for aquatic plants (> 9.84 ppm), no risk to nonendangered or endangered aquatic plants is expected.

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 maleic hydrazide and the potassium salt of maleic hydrazide active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing maleic hydrazide and the potassium salt of maleic hydrazide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of maleic hydrazide and the potassium salt of maleic hydrazide, 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 maleic hydrazide and the potassium salt of maleic hydrazide and to determine that maleic hydrazide and the potassium salt of maleic hydrazide can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing maleic hydrazide and the potassium salt of maleic hydrazide as the active ingredients 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 all uses of maleic hydrazide and the potassium salt of maleic hydrazide 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 maleic hydrazide and the potassium salt of maleic hydrazide, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients maleic hydrazide and the potassium salt of maleic hydrazide, the Agency has sufficient information on the health effects of maleic hydrazide and the potassium salt of maleic hydrazide and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing maleic hydrazide and the potassium salt of maleic hydrazide for all uses are eligible for reregistration.

The Agency has determined that maleic hydrazide and the potassium salt of maleic hydrazide products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that the current uses of maleic hydrazide and the potassium salt of maleic hydrazide are eligible for reregistration. These uses are listed in Appendix A. Uses eligible for reregistration do **not** include cranberries. Use on cranberries is neither registered nor supported; although a tolerance exists for residues of maleic hydrazide on cranberries, that tolerance will be revoked. (See Tolerance Reassessment below.)

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for maleic hydrazide and the potassium salt of maleic hydrazide. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

There are no current tolerances for maleic hydrazide in animal commodities. On receipt of the required data from animal feeding studies, tolerances for maleic hydrazide in animal commodities will be determined.

Sufficient data for determining an upper bound estimate of human dietary exposure from consumption of animal commodities has been provided. Simulated cattle and poultry feeding studies, in which [^{14}C]maleic hydrazide is fed and total ^{14}C determined, indicate that in cattle appropriate levels of maleic hydrazide for upper bound dietary risk assessment purposes would be 0.2 ppm in milk; 0.8 ppm in liver; 4 ppm in kidney; and 0.4 ppm in muscle and fat. In poultry, appropriate levels of maleic hydrazide for upper bound dietary risk assessment purposes would be 0.3 ppm in meat and meat by-products; 0.07 ppm in skin, fat and eggs.

Tolerances Listed Under 40 CFR §180.175(a):

The tolerances listed in 40 CFR §180.175(a) are for residues of maleic hydrazide per se in or on onions (dry bulb) and potatoes. Sufficient data are available to ascertain the adequacy of the established tolerances listed in the 40 CFR for these plant commodities (Table A).

The commodity definition of the tolerance for dry bulb onions is not in accordance with the definition listed in the Commodity Index Report dated 10/28/92; see Table A for the modification.

Tolerances Listed Under 40 CFR §180.175(b):

The tolerance [with regional registration as defined in §180.l(n)] listed in 40 CFR §180.175(b) is for residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) per se in or on cranberries.

Sufficient magnitude of the residue, but not nature of the residue, data are available to ascertain the adequacy of the established tolerance listed in 40 CFR §180.175(b) for cranberries. However, the registrant is not supporting uses of maleic hydrazide on this commodity, and cranberries are not currently registered on end-use product labels. If no other party intends to support uses on cranberries, the established tolerance with regional registration of 15 ppm for residues of maleic hydrazide in or on cranberries will be revoked (Table A).

Tolerances Listed Under 40 CFR §185.3900:

The food additive tolerance listed in 40 CFR §185.3900 is for residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) per se present as a result of the

application of a pesticide formulation containing maleic hydrazide to the growing potato plant.

Sufficient data are available to ascertain the adequacy of the established tolerance listed in 40 CFR §185.3900 for potato chips. The Agency has required that the established food additive tolerance for potato chips be increased from 160 to 200 ppm (Table A).

New Tolerances Needed:

The Agency has required that food/feed additive tolerances be established for the following processed commodities: "potatoes, granules" (200 ppm); and "potatoes, waste from processing" (200 ppm) (Table A). In response, The Maleic Hydrazide Task Force II has submitted petitions for the tolerance changes requested above.

TABLE A. TOLERANCE REASSESSMENT SUMMARY

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.175(a)			
Onions, dry bulb	15.0	Same	*Onions, dry bulb (only)*
Potatoes	50.0	Same	
Tolerance listed under 180.175(b)			
Cranberries	15.0	Revoke	Cranberry uses are not registered
Tolerance listed under 185.3900			
Potato chips	160	200	Increased tolerance needed
Potatoes, granules	N/A	200	New tolerance needed
Tolerance listed under 186.3900			
Potatoes, waste from processing	N/A	200	New tolerance needed

CODEX HARMONIZATION

Codex Maximum Residue Limits (MRLs) for the sum of free and conjugated maleic hydrazide expressed as maleic hydrazide are established at 15 mg/kg in or on bulb onions and 50 mg/kg in or on potatoes. These limits are numerically equivalent to established U.S. tolerances but the U.S. tolerances are established for maleic hydrazide (without specifying the free or conjugated form). Although the U.S tolerances and Codex MRLs are expressed differently, they are compatible

because the tolerance enforcement analytical method includes a destructive distillation step that ensures the quantification of maleic hydrazide, whether it is conjugated or free.

TABLE B. CODEX MRLS AND APPLICABLE U.S. TOLERANCES.

Commodity	MRL (Step) (mg/kg)	Reassessed U.S. Tolerance (ppm)
Onion, bulb	15 (CXL)	15.0
Potato	50 (CXL)	50.0

2. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant species to maleic hydrazide. Based on the conclusions discussed in the preceding sections of this risk assessment, applications of maleic hydrazide, even at low application rates, pose a significant risk to endangered plant species inhabiting treated rights-of-way. A risk from runoff of maleic hydrazide also occurs to endangered plant species growing in wetter areas away from treated sites.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would 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 Program in the Federal Register in 1994 and by 1995 have enforceable county-specific bulletins available. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

3. Labeling Rationale

End Use Product

The environmental fate and ecological risk assessment identified a potential risk to non-target terrestrial and semi-aquatic plants from exposure to runoff from sites treated with maleic hydrazide. Based on this assessment, the Agency is requiring a surface water advisory. In addition, to mitigate the exposure of non-target plants at the sites where the highest application rates are used, the Agency is requiring that the number of applications to fallow land, rights-of way, turf, and lawns be limited to 1 per year.

Currently, there are some maleic hydrazide end-use products which fail to provide guidance about the rate of application per a given area, only instructing the user to spray to drip-point. To reduce possible misuse of this product, the Agency is requiring that these labels clearly indicate the maximum application rates per acre.

Spray drift management labeling statements may be required in a future notice that is currently being prepared by the Agency. This future labeling may be required for all maleic hydrazide products with aerial application, in order to inform the user of recommended practices to minimize spray drift from the target site.

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 maleic hydrazide for the above eligible uses has been reviewed and determined to be substantially complete. The data for the following guidelines are outstanding but are considered confirmatory data: Guidelines 171-4(b), Nature of residue in animals; 171-4(d), Residue analytical method in animals; 171-4(j), Magnitude of the residue in animal; 165-1, Confined rotational crop; 201-1, Droplet size spectrum; and 202-1, Drift field evaluation. These additional generic data requirements are not part of the target database for maleic hydrazide and do not affect the reregistration eligibility of maleic hydrazide.

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.

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.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

The labels of all maleic hydrazide end-use products must be revised to bear the following statement:

Surface Water Advisory

"Under some conditions, maleic hydrazide may have a significant potential for runoff into surface water (primarily via dissolution in runoff water), for several days post-application. Conditions favoring runoff include poorly draining soils or wet soils with readily visible slopes, frequently flooded areas, areas where an intense or sustained rainfall is forecast to occur within 48 hours, areas overlying extremely shallow ground water, and areas overlying tile drainage systems that flow to surface water."

Application Rates

Application rates must be provided for all uses. In instances where labels indicates to spray to "drip-point," labels must clearly state the maximum application rate per an acre.

For fallow land, lawns, turf and rights of way uses, labels must indicate that the number of applications are limited to one per year.

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; State of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Tex.	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
ONION				Use Group: TERRESTRIAL FOOD CROP								
Low volume spray (concentrate)., Foliar., Aircraft.	SC/L	NA		UC	*	NS		NS	NS 0.5			C46, C93
Low volume spray (concentrate)., Preharvest., Aircraft.	SC/L	NA	1.995 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/L	NA	1.547 lb (AE)	A	*	NS		NS	NS NS			G74, GM3
	SC/L	NA	1.969 lb (AE)	A	*	NS		NS	NS NS			GM3
	SC/S	NA	1.998 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/S	NA	1.998 lb (AE)	A	*	NS		NS	NS NS			C46, G74, GM3
Spray., Foliar., Ground.	SC/L	NA		UC	*	NS		NS	NS 0.5			C46, C93
Spray., Preharvest., Ground.	SC/L	NA	1.995 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/L	NA	1.547 lb (AE)	A	*	NS		NS	NS NS			G74, GM3
	SC/L	NA	1.969 lb (AE)	A	*	NS		NS	NS NS			GM3
	SC/S	NA	1.998 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/S	NA	1.998 lb (AE)	A	*	NS		NS	NS NS			C46, G74, GM3
POTATO, WHITE/IRISH				Use Group: TERRESTRIAL FOOD+FEED CROP								
Low volume spray (concentrate)., Foliar., Aircraft.	SC/L	NA		UC	*	NS		NS	NS 0.5			C46, C93
	SC/L	NA	3 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/L	NA	2.25 lb (AE)	A	*	NS		NS	NS NS			G74, GM3
	SC/L	NA	2.993 lb (AE)	A	*	NS		NS	NS NS			GM3
	SC/S	NA	9 lb (AE) 3 3 lb (AE)	A A	* *	NS		NS	NS NS			C46
	SC/S	NA	3 lb (AE)	A	*	NS		NS	NS NS			C46, G74, GM3
Spray., Foliar., Ground.	SC/L	NA		UC	*	NS		NS	NS 0.5			C46, C93
	SC/L	NA	3 lb (AE)	A	*	NS		NS	NS NS			C46
	SC/L	NA	2.25 lb (AE)	A	*	NS		NS	NS NS			G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
POTATO, WHITE/IRISH (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	SC/L	NA	2.993 lb (AE) A	*	NS	NS	NS	NS			GM3
	SC/S	NA	9 lb (AE) 3 A 3 lb (AE) A	* *	NS	NS	NS	NS			C46
	SC/S	NA	3 lb (AE) A	*	NS	NS	NS	NS			C46, G74, GM3
NON-FOOD/NON-FEED											
AGRICULTURAL FALLOW/IDLELAND				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Postharvest., Boom sprayer.	SC/L	NA	9 lb (AE) A	*	NS	NS	NS	NS	AZ, CA		C46, GI6, GM3
Spray., Postharvest., Sprayer.	SC/S	NA	9 lb (AE) A	*	NS	NS	NS	NS	AZ, CA		C46, GI6
AIRPORTS/LANDING FIELDS				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Fall., Airblast.	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	4.455 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.5 lb (AE) A	*	1/Y	NS	NS	NS			GM3
	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Tractor-mounted sprayer.	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
AIRPORTS/LANDING FIELDS (con't)				Use Group:	TERRESTRIAL NON-FOOD CROP (con't)						
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Spring., Airblast.	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Sprayer.	SC/L	NA	3.3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			GM3
	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Tractor-mounted sprayer.	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
CITRUS FRUITS				Use Group:	TERRESTRIAL NON-FOOD CROP						
Spray., Nonbearing., Sprayer.	SC/L	NA	UC	*	NS	NS	42	NS	FL		G74, GM3
	SC/L	NA	UC	*	NS	NS	42	NS	FL		GM3
COMMERCIAL/INDUSTRIAL LAWNS				Use Group:	TERRESTRIAL NON-FOOD CROP						
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
COMMERCIAL/INDUSTRIAL LAWNS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
Spray., Spring., Sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
ELDERBERRY				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Early summer., Sprayer.	SC/L	NA	UC	*	1/Y		NS	NS	NS		C46, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
Spray., Spring., Sprayer.	SC/L	NA	UC	*	1/Y		NS	NS	NS		C46, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
GOLF COURSE TURF				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Fall., Airblast.	SC/L	NA	4.05 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
	SC/S	NA	3.75 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	4.455 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		GM3
	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Fall., Tractor-mounted sprayer.	SC/L	NA	4.05 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Spring., Airblast.	SC/L	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
GOLF COURSE TURF (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	SC/S	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
	SC/S	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Sprayer.	SC/L	NA	3.3 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		GM3
	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Tractor-mounted sprayer.	SC/L	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
INDUSTRIAL AREAS (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
Spray., Fall., Sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
Spray., Spring., Sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
MULBERRY				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Early summer., Sprayer.	SC/L	NA		UC	*	1/Y	NS	NS	NS		C46, GM3
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
Spray., Spring., Compressed air sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
Spray., Spring., Hose-end sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		GM3
Spray., Spring., Sprayer.	SC/L	NA		UC	*	1/Y	NS	NS	NS		C46, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
Spray., Summer., Compressed air sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
Spray., Summer., Hose-end sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		GM3
Spray., Summer., Sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Dormant., Sprayer.	SC/L	NA	6.008 lb (AE) A		*	1/Y	NS	NS	NS		GM3
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A		*	NS	NS	NS	NS		G74, GM3
Spray., Fall., Airblast.	SC/L	NA	3.758 lb (AE) A		*	1/Y	NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A		*	1/Y	NS	NS	NS		C46, G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A		*	1/Y	NS	NS	NS		C46, GM3
	SC/L	NA	3.758 lb (AE) A		*	1/Y	NS	NS	NS		G74, GM3
	SC/L	NA	4.995 lb (AE) A		*	NS	NS	NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
	SC/S	NA	4.5 lb (AE) A		*	1/Y	NS	NS	NS		C46, G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	6.6 lb (AE) A		*	1/Y	NS	NS	NS		C46, G74, GM3
	SC/L	NA	1.2 lb (AE) A		*	1/Y	NS	NS	NS		G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	SC/L	NA	5.063 lb (AE) A	*	1/Y		NS	NS	NS		GM3
	SC/L	NA	4.995 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Fall., Tractor-mounted sprayer.	SC/L	NA	3.758 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
Spray., Spring., Airblast.	SC/L	NA	2.993 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	2.993 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Sprayer.	SC/L	NA	6.6 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
	SC/L	NA	1.2 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		GM3
	SC/L	NA	4.005 lb (AE) A	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Spring., Tractor-mounted sprayer.	SC/L	NA	2.993 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y		NS	NS	NS		C46, G74, GM3
Tree injection treatment., When needed., Tree injection equipment.	SC/L	NA	UC	*	NS		NS	NS	NS		C46
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Fall., Airblast.	SC/L	NA	4.05 lb (AE) A	*	1/Y		NS	NS	NS		G74, GM3

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	4.455 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.5 lb (AE) A	*	1/Y	NS	NS	NS			GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Tractor-mounted sprayer.	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Airblast.	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Sprayer.	SC/L	NA	3.3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Tractor-mounted sprayer.	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Early summer., Sprayer.	SC/L	NA		UC *	1/Y		NS	NS	NS		C46, GM3
	SC/S	NA		UC *	1/Y		NS	NS	NS		C46
Spray., Spring., Compressed air sprayer.	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/S	NA		UC *	NS		NS	NS	NS		C46, G74, GM3
Spray., Spring., Hose-end sprayer.	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/L	NA		UC *	NS		NS	NS	NS		GM3
Spray., Spring., Sprayer.	SC/L	NA		UC *	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/S	NA		UC *	1/Y		NS	NS	NS		C46
	SC/S	NA		UC *	NS		NS	NS	NS		C46, G74, GM3
Spray., Summer., Compressed air sprayer.	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/S	NA		UC *	NS		NS	NS	NS		C46, G74, GM3
Spray., Summer., Hose-end sprayer.	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/L	NA		UC *	NS		NS	NS	NS		GM3
Spray., Summer., Sprayer.	SC/L	NA		UC *	NS		NS	NS	NS		G74, GM3
	SC/S	NA		UC *	NS		NS	NS	NS		C46, G74, GM3
ORNAMENTAL LAWNS AND TURF				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Dormant., Airblast.	SC/L	NA	1.2 lb (AE)	A *	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE)	A *	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Dormant., Boom sprayer.	SC/L	NA	1.2 lb (AE)	A *	1/Y		NS	NS	NS		G74, GM3
	SC/S	NA	4.5 lb (AE)	A *	1/Y		NS	NS	NS		C46, G74, GM3
Spray., Dormant., Sprayer.	SC/L	NA	6.6 lb (AE)	A *	1/Y		NS	NS	NS		C46, G74, GM3
	SC/L	NA	1.2 lb (AE)	A *	1/Y		NS	NS	NS		G74, GM3
	SC/L	NA	6.008 lb (AE)	A *	1/Y		NS	NS	NS		GM3

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USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL LAWNS AND TURF (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	SC/S	NA	4.5 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Dormant., Tractor-mounted sprayer.	SC/L	NA	1.2 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	4.5 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Air carrier sprayer.	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Fall., Airblast.	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Sprayer.	SC/L	NA	4.455 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	5.063 lb (AE) A	*	1/Y	NS	NS	NS			GM3
	SC/L	NA	4.995 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Fall., Tractor-mounted sprayer.	SC/L	NA	4.05 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3.75 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Air carrier sprayer.	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3
Spray., Spring., Airblast.	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/S	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			C46, G74, GM3
Spray., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A	*	1/Y	NS	NS	NS			C46, GM3
	SC/L	NA	3 lb (AE) A	*	1/Y	NS	NS	NS			G74, GM3
	SC/L	NA	4.005 lb (AE) A	*	NS	NS	NS	NS			G74, GM3

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USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL LAWNS AND TURF (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
	SC/S	NA	3 lb (AE)	A	*	1/Y	NS	NS	NS		C46, G74, GM3
Spray., Spring., Sprayer.	SC/L	NA	3.3 lb (AE)	A	*	1/Y	NS	NS	NS		C46, G74, GM3
	SC/L	NA	3 lb (AE)	A	*	1/Y	NS	NS	NS		G74, GM3
	SC/L	NA	3.938 lb (AE)	A	*	1/Y	NS	NS	NS		GM3
	SC/L	NA	4.005 lb (AE)	A	*	NS	NS	NS	NS		G74, GM3
	SC/S	NA	3 lb (AE)	A	*	1/Y	NS	NS	NS		C46, G74, GM3
Spray., Spring., Tractor-mounted sprayer.	SC/L	NA	3 lb (AE)	A	*	1/Y	NS	NS	NS		G74, GM3
	SC/S	NA	3 lb (AE)	A	*	1/Y	NS	NS	NS		C46, G74, GM3
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Early summer., Sprayer.	SC/L	NA		UC	*	1/Y	NS	NS	NS		C46, GM3
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
Spray., Spring., Compressed air sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/S	NA		UC	*	NS	NS	NS	NS		C46, G74, GM3
Spray., Spring., Hose-end sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		GM3
Spray., Spring., Sprayer.	SC/L	NA		UC	*	1/Y	NS	NS	NS		C46, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y	NS	NS	NS		C46
	SC/S	NA		UC	*	NS	NS	NS	NS		C46, G74, GM3
Spray., Summer., Compressed air sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/S	NA		UC	*	NS	NS	NS	NS		C46, G74, GM3
Spray., Summer., Hose-end sprayer.	SC/L	NA		UC	*	NS	NS	NS	NS		G74, GM3
	SC/L	NA		UC	*	NS	NS	NS	NS		GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				Use Group:	TERRESTRIAL NON-FOOD CROP (con't)						
Spray., Summer., Sprayer.	SC/L	NA		UC	*	NS		NS NS	NS		G74, GM3
	SC/S	NA		UC	*	NS		NS NS	NS		C46, G74, GM3
RECREATIONAL AREAS				Use Group:	TERRESTRIAL NON-FOOD CROP						
Tree injection treatment., When needed., Tree injection equipment.	SC/L	NA		UC	*	NS		NS NS	NS		C46
RESIDENTIAL LAWNS				Use Group:	OUTDOOR RESIDENTIAL						
Edging treatment., Dormant., Sprayer.	SC/L	NA	6.008 lb (AE) A		*	1/Y		NS NS	NS		GM3
Edging treatment., Fall., Boom sprayer.	SC/L	NA	6 lb (AE) A		*	1/Y		NS NS	NS		C46, GM3
Edging treatment., Fall., Sprayer.	SC/L	NA	5.063 lb (AE) A		*	1/Y		NS NS	NS		GM3
	SC/L	NA	.1172 lb (AE) 1K sq.ft		*	NS		NS NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y		NS NS	NS		C46
Edging treatment., Spring., Boom sprayer.	SC/L	NA	6 lb (AE) A		*	1/Y		NS NS	NS		C46, GM3
Edging treatment., Spring., Compressed air sprayer.	SC/L	NA	.08789 lb (AE) 1K sq.ft		*	1/Y		NS NS	NS		G74, GM3
	SC/S	NA	4.5 tbsp (AE) 1K sq.ft		*	1/Y		NS NS	NS		C46, G74, GM3
Edging treatment., Spring., Hose-end sprayer.	SC/L	NA	4.402 lb (AE) A		*	1/Y		NS NS	NS		C46, G74, GM3
	SC/L	NA	4.002 lb (AE) A		*	1/Y		NS NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y		NS NS	NS		C46, G74, GM3
Edging treatment., Spring., Sprayer.	SC/L	NA	3.938 lb (AE) A		*	1/Y		NS NS	NS		GM3
	SC/L	NA	.09375 lb (AE) 1K sq.ft		*	NS		NS NS	NS		G74, GM3
	SC/S	NA		UC	*	1/Y		NS NS	NS		C46
	SC/S	NA	.75 lb (AE) A		*	1/Y		NS NS	NS		C46, G74, GM3

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
SMALL FRUITS				Use Group:	TERRESTRIAL NON-FOOD CROP						
Spray., Early summer., Sprayer.	SC/L	NA	UC	*	1/Y	NS	NS	NS			C46, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
Spray., Spring., Sprayer.	SC/L	NA	UC	*	1/Y	NS	NS	NS			C46, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
SUBTROPICAL/TROPICAL FRUIT				Use Group:	TERRESTRIAL NON-FOOD CROP						
Spray., Early summer., Sprayer.	SC/L	NA	UC	*	1/Y	NS	NS	NS			C46, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
Spray., Spring., Sprayer.	SC/L	NA	UC	*	1/Y	NS	NS	NS			C46, GM3
	SC/S	NA	UC	*	1/Y	NS	NS	NS			C46
TOBACCO				Use Group:	TERRESTRIAL NON-FOOD CROP						
Low volume spray (concentrate)., Foliar., Aircraft.	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)
Spray., Foliar., Animal-drawn sprayer.	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			H01(7)
Spray., Foliar., Compressed air sprayer.	EC	NA	.1186 lb (AE) 667 plants	*	1/C	NS	NS	NS			C46, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			G74, GM3, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			GM3, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			H01(7)
	SC/S	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, G74, GM3, H01(7)
	SC/S	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)
Spray., Foliar., Sprayer.	EC	NA	2.106 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C	NS	NS	NS			C46, H01(7)

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
TOBACCO (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	SC/S	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		C46, H01(7)
Spray., Foliar., Tractor-mounted sprayer.	SC/L	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		C46, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		G74, GM3, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		GM3, H01(7)
	SC/L	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		H01(7)
	SC/S	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		C46, G74, GM3, H01(7)
	SC/S	NA	4.5 lb (AE) A	*	1/C		NS	NS	NS		C46, H01(7)
WALNUT (ENGLISH/BLACK)				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., Early summer., Sprayer.	SC/L	NA	UC	*	1/Y		NS	NS	NS		C46, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
Spray., Spring., Compressed air sprayer.	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3
Spray., Spring., Hose-end sprayer.	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3
	SC/L	NA	UC	*	NS		NS	NS	NS		GM3
Spray., Spring., Sprayer.	SC/L	NA	UC	*	1/Y		NS	NS	NS		C46, GM3
	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3
	SC/S	NA	UC	*	1/Y		NS	NS	NS		C46
Spray., Summer., Compressed air sprayer.	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3
Spray., Summer., Hose-end sprayer.	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3
	SC/L	NA	UC	*	NS		NS	NS	NS		GM3
Spray., Summer., Sprayer.	SC/L	NA	UC	*	NS		NS	NS	NS		G74, GM3

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
EC : EMULSIFIABLE CONCENTRATE
SC/L : SOLUBLE CONCENTRATE/LIQUID
SC/S : SOLUBLE CONCENTRATE/SOLID

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

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C93 : Do not apply directly to water.
G74 : Do not feed treated foliage to livestock or graze treated areas.
GI6 : Do not graze or feed forage or hay from treated areas to livestock.
GM3 : Do not pasture or use treated crop for feed, food, forage or bedding purposes.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AZ : Arizona
CA : California
FL : Florida

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 Maleic Hydrazide covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Maleic Hydrazide 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 Maleic Hydrazide

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY[1]			
	Registrant: Uniroyal Chemical Co.		
	Product(s): 97% T (EPA Reg. No. 400-97)		
61-1	**Chemical Identity**	**A B C K**	**41186001**
61-2A	**Start. Mat. & Mnfg. Process**	**A B C K**	**40985301**
61-2B	**Formation of Impurities**	**A B C K**	**41186002**
62-1	**Preliminary Analysis**	**A B C K**	**41186003**
62-2	**Certification of limits**	**A B C K**	**41186004**
62-3	**Analytical Method**	**A B C K**	**41186003, 41186005**
63-2	**Color**	**A B C K**	**40985302**
63-3	**Physical State**	**A B C K**	**40985302**
63-4	**Odor**	**A B C K**	**40985302**
63-5	**Melting Point**	**A B C K**	**40985302**
63-7	**Density**	**A B C K**	**40985303**
63-8	**Solubility**	**A B C K**	**40985304**
63-9	**Vapor Pressure**	**A B C K**	**40985305**
63-10	**Dissociation Constant**	**A B C K**	**40985306**

[1] The product chemistry submissions are presented in this table separately for each of the 3 technical producers: Uniroyal Chemical Co., Fair Products, Inc. and Drexel Chemical Co.

Data Supporting Guideline Requirements for the Reregistration of Maleic Hydrazide

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	Octanol/Water Partition	A B C K	40985307
63-12	pH	A B C K	40985308
63-13	Stability	A B C K	40993001
63-14	Oxidizing/Reducing Action	A B C K	41484401
63-16	Explodability	A B C K	40985309, 40985310
63-17	Storage stability	A B C K	41278001, 41471501
63-20	Corrosion characteristics	A B C K	41222101, 41278002, 41471502

REQUIREMENT		USE PATTERN	CITATION(S)
	Registrant: Drexel Chemical Company		
	Product(s): 95% T and 97% T (EPA Reg. Nos. 19713-25 and 19713-26)		
61-1	**Chemical Identity**	**A B C K**	**41132901, 41132903**
61-2A	**Start. Mat. & Mnfg. Process**	**A B C K**	**41132901, 41132903**
61-2B	**Formation of Impurities**	**A B C K**	**41132901, 41132903, 41336902, 41336904**
62-1	**Preliminary Analysis**	**A B C K**	**41336901, 41667801**
62-2	**Certification of limits**	**A B C K**	**41132901, 41132903, 41336901**
62-3	**Analytical Method**	**A B C K**	**41185402, 41185403**
63-2	**Color**	**A B C K**	**41132902, 41132904**
63-3	**Physical State**	**A B C K**	**41132902, 41132904**
63-4	**Odor**	**A B C K**	**41132902, 41132904**
63-5	**Melting Point**	**A B C K**	**41132902, 41132904**
63-7	**Density**	**A B C K**	**41132902, 41132904**
63-8	**Solubility**	**A B C K**	**41132902, 41132904, 41336903, 41336905, 42308501**
63-10	**Dissociation Constant**	**A B C K**	**41165401**
63-11	**Octanol/Water Partition**	**A B C K**	**41132902, 41132904**
63-12	**pH**	**A B C K**	**41132902, 41132904**
63-13	**Stability**	**A B C K**	**41132902, 41132904, 42240101, 42413701**
63-14	**Oxidizing/Reducing Action**	**A B C K**	**41132902, 41132904**
63-17	**Storage stability**	**A B C K**	**41667801**
63-20	**Corrosion characteristics**	**A B C K**	**41667801**

REQUIREMENT		USE PATTERN	CITATION(S)
	Registrant: Fair Products, Inc.		
	Product(s): 96% (EPA Reg. No. 51873-10)		
61-1	Chemical Identity	A B C K	40975901, 41229602
61-2A	Start. Mat. & Mnfg. Process	A B C K	40975901, 41229602, 41233201
61-2B	Formation of Impurities	A B C K	40975901, 41229602, 41233201
62-1	Preliminary Analysis	A B C K	40975901, 41280701
62-2	Certification of limits	A B C K	40975901, 41229602
62-3	Analytical Method	A B C K	41185402, 41185403
63-2	Color	A B C K	41233201
63-3	Physical State	A B C K	41233201
63-4	Odor	A B C K	41233201
63-5	Melting Point	A B C K	41233201
63-7	Density	A B C K	41233201
63-8	Solubility	A B C K	41233201
63-10	Dissociation Constant	A B C K	41165401
63-11	Octanol/Water Partition	A B C K	41165401
63-12	pH	A B C K	41165401
63-13	Stability	A B C K	41267701, 42005601
63-17	Storage stability	A B C K	42005601
63-20	Corrosion characteristics	A B C K	42005601

Data Supporting Guideline Requirements for the Reregistration of Maleic Hydrazide

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A C K O	00124742, 00146141
71-2A	Avian Dietary - Quail	A C K O	00126033
71-2B	Avian Dietary - Duck	A C K O	00107417, 00147000
72-1A	Fish Toxicity Bluegill	A C K O	00124739
72-1C	Fish Toxicity Rainbow Trout	A C K O	00124740, 00146142
72-2A	Invertebrate Toxicity	A C K O	00124741
72-2B	Invertebrate Toxicity - TEP	A C K O	00146143
123-1A	Seed Germination/Seedling Emergence	A C K O	41289301
123-1B	Vegetative Vigor	A C K O	41289302
123-2	Aquatic Plant Growth	A C K O	41318001, 43006901, 43006902, 43006903, 43006904
141-1	Honey Bee Acute Contact	A C K O	00018842
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A B C K	00079657
81-2	Acute Dermal Toxicity - Rabbit/Rat	A B C K	00079658
81-3	Acute Inhalation Toxicity - Rat	A B C K	41185401
81-4	Primary Eye Irritation - Rabbit	A B C K	00079661
81-5	Primary Dermal Irritation - Rabbit	A B C K	00079660
81-6	Dermal Sensitization - Guinea Pig	A B C K	41289101

Data Supporting Guideline Requirements for the Reregistration of Maleic Hydrazide

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	21-Day Dermal - Rabbit/Rat	A B C K	41289102
83-1A	Chronic Feeding Toxicity - Rodent	A B	42570101, 42770401
83-1B	Chronic Feeding Toxicity - Non-Rodent	A B	42214101, 42248101
83-2A	Oncogenicity - Rat	A B	42570101, 42770401
83-2B	Oncogenicity - Mouse	A B	00097886, 00098466
83-3A	Developmental Toxicity - Rat	A B	41458201, 41702901, 40874202, 41055903
83-3B	Developmental Toxicity - Rabbit	A B	00128721, 40985311
83-4	2-Generation Reproduction - Rat	A B	00128720
84-2A	Gene Mutation (Ames Test)	A B C K	41149001
84-2B	Structural Chromosomal Aberration	A B C K	41147302, 41660001, 41719101
84-4	Other Genotoxic Effects	A B C K	41176601, 41176602, 41147303
85-1	General Metabolism	A B	41571701, 41679701, 42432301
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A B C K	00143322
161-2	Photodegradation - Water	A B C	42692101, 42872301
161-3	Photodegradation - Soil	A B C	00151951
162-1	Aerobic Soil Metabolism	A B C K	41896201
162-2	Anaerobic Soil Metabolism	A B C	41918201
163-1	Leaching/Adsorption/Desorption	A B C K	00151952, 41896202
164-1	Terrestrial Field Dissipation	A B C K	42693301, 42736901, 42744801, 42790901

REQUIREMENT		USE PATTERN	CITATION(S)
165-1	Confined Rotational Crop	A B C	00122390, 41937801
165-4	Bioaccumulation in Fish	A B C	00163301
165-5	Bioaccumulation - Aquatic NonTarget	A B C	00163301
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A B	00106979, 00121599, 00122399, 00125641, 41488201, 41488202, 42654901
171-4B	Nature of Residue - Livestock	B	42567801, 42641501
171-4C & 171-4D	Residue Analytical Method - Plants & - Animals	A B	00058579, 00087400, 00100749, 00101295, 00106267, 00106979, 00106983, 00112750, 00122366, 00125636, 42125301, 42382101, 42654901
171-4E	Storage Stability	A B	00058587, 42567804, 42567805, 42567806, 42641501, 42905801
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	00106979, 42567802, 42567803
171-4K	Crop Field Trials		
	Root and Tuber Vegetable Group		
	- Potatoes	A B	00086764, 00106979, 00121603, 00122361, 00122364, 42567804
	Bulb Vegetable Group		
	- Onions (dry bulb)	A	00058587, 00106979, 00121605, 00122363, 00141353, 42567805
	Small Fruits and Berries Group		

Data Supporting Guideline Requirements for the Reregistration of Maleic Hydrazide

REQUIREMENT		USE PATTERN	CITATION(S)
	- Cranberries		00100749, 00101298
	Nonbearing Orchard Crops		
	- Citrus Fruits	A	00101296
	Miscellaneous Commodities		
	- Tobacco	C	00087392, 00125636, 00165460, 41055901, 41055902, 41294301
171-4L	Processed Food		
	-Processed Potatoes	A B	42567806

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

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID	CITATION
00058579	Harris, W.D. (1951) Residue Determinations of Maleic hydrazide in Milk and Grass. (Unpublished study received Apr 4, 1952 under 400-38; submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 231189-D)
00058587	Uniroyal Chemical (1951) Maleic hydrazide Residue. (Unpublished study received Dec 22, 1952 under 400-38; CDL:231189-L)
00079657	Shapiro, R. (1977) Acute Oral Toxicity: Report No. T-235. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-G)
00079658	Shapiro, R. (1977) Acute Dermal Toxicity: Report No. T-242. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-H)
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42641501	Johnston, A.; Jackson, R.; Hall, B.; et al. (1993) Chromatographic Analysis of Samples from Hens following Administration of (carbon 14)-Maleic Hydrazide: Lab Project Number: 8492: 381635. Unpublished study prepared by Inveresk Research International. 156 p.
42654901	McGuire, G. (1993) Response to EPA Requests as Detailed in U.S. EPA Memorandum on Radiovalidation Study (Maleic Hydrazide), Supplemental: Lab Project Number: 354418: 3798. Unpublished study prepared by Inveresk Research International, Ltd. 13 p.
42692101	Schocken, M. (1993) Response to EPA's Comments Regarding the Maleic Hydrazide Aqueous Photolysis Study Conducted by Springborn Labs., Inc.: Supplemental Information: Lab Project Number: 41-0890-6119-720: 91-5-3766. Unpublished study prepared by Springborn Labs., Inc. 7 p.
42693301	Dykeman, R. (1993) Determination of the Dissipation of Residues of Maleic Hydrazide in a North Carolina Tobacco Field: Lab Project Number: MHTF-9005: 44-875-614-545. Unpublished study prepared by Inveresk Research International, Ltd. in assistance with American Agricultural Services, Inc. and Compliance Services International. 679 p.
42736901	Dykeman, R. (1993) Determination of the Dissipation of Residues of Maleic Hydrazide in a Washington State Potato Field Treated with Super Sprout Stop: A Supplemental: Lab Project Number: MHTF-9004. Unpublished study prepared by Inveresk Research International, Ltd. 674 p.
42744801	Dykeman, R. (1993) Determination of the Dissipation of Residues of Maleic Hydrazide in a California Turf Soil Treated with Royal SLO-GRO: Lab Project Number: MHTF-9006. Unpublished study prepared by Inveresk Research International, Ltd. in assistance with Research for Hire and Compliance Services International. 731 p.
42770401	Perry, C. (1993) Maleic Hydrazide: 104 Week Dietary Combined Chronic Toxicity/Oncogenicity Study in Rats with 52 Week Interim Kill: Addendum: Lab Project Number: 437944: IRI 437944. Unpublished study prepared by Inveresk Research International Lab. 973 p.
42790901	Dykeman, R. (1993) Determination of the Dissipation of Residues of Maleic Hydrazide in a California Turf Soil Treated with Royal Slo-Gro: Amendment 1

BIBLIOGRAPHY

MRID	CITATION
	to Study Report: Lab Project Number: MHTF-9006. Unpublished study prepared by Inveresk Research Intl., Research for Hire and Compliance Services Intl. 24 p.
42872301	Fackler, P. (1993) Maleic Hydrazide--Determination of Aqueous Photolysis Rate Constant and Half-Life: Amended Final Report: Lab Project Number: 91-5-3766: 41.0890.6119.720. Unpublished study prepared by Springborn Labs, Inc. 55 p.
42905801	Jacobson, S. (1993) Determination of the Magnitude of Residues of Maleic Hydrazide in Processed Fractions of Potatoes Treated with Super Sprout Stop: Amendment 1 to: Lab Project Number: MHTF-9002: MHTF-9002-M01: 8983. Unpublished study prepared by Inveresk Research International, Ltd. 24 p.
43006901	Davis, J. (1993) Maleic Hydrazide (Potassium Salt): Acute Toxicity to the Freshwater Blue-Green Alga, Anabaena flos-aquae, Under Static Test Conditions: Lab Project Number: J9306001G. Unpublished study prepared by Toxikon Environmental Sciences. 55 p.
43006902	Davis, J. (1993) Maleic Hydrazide (Potassium Salt): Acute Toxicity to the Freshwater Diatom, Nitzschia palea, Under Static Test Conditions: Lab Project Number: J9306001F. Unpublished study prepared by Toxikon Environmental Sciences. 53 p.
43006903	Davis, J. (1993) Maleic Hydrazide (Potassium Salt): Acute Toxicity to the Saltwater Diatom, Skeletonema costatum, Under Static Test Conditions: Lab Project Number: J9306001E. Unpublished study prepared by Toxikon Environmental Sciences. 53 p.
43006904	Davis, J. (1993) Maleic Hydrazide (Potassium Salt): Toxicity to Duckweed, Lemna gibba G3, Under Static Test Conditions: Lab Project Number: J9306001D. Unpublished study prepared by Toxikon Environmental Sciences. 54 p.
43177301	Shocken, M.J. (1994) Maleic Hydrazide-Identification of Photolytic Degradation Products: Supplemental Information: Lab Project I.D.: 94-2-5161; Sponsor Project No. 9364. Supplemental letter reports prepared by Springborn Laboratories, Inc. 5 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Maleic Hydrazide. Its purpose is to provide a path to more detailed information if needed. These accompanying documents are part of the Administrative Record for Maleic Hydrazide 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. Maleic Hydrazide RED Fact Sheet

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

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.

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F. Physical Format Requirements & Number of Copies 9

G. Special Requirements for Submitting Data to the Docket 10

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 complete 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 multiple volumes is permissible so long as the entire study is paginated 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 petitions 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 Divison

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 transmittal 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

Page 1 of X
(X is the total number of pages in the study)

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:_____

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:_____

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

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***

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	***LINES***	***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 _____

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_____

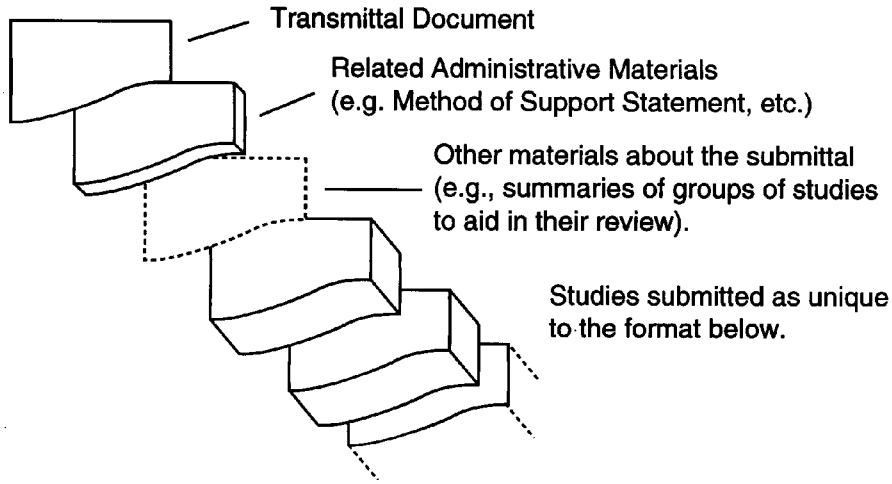
Example 3.

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.

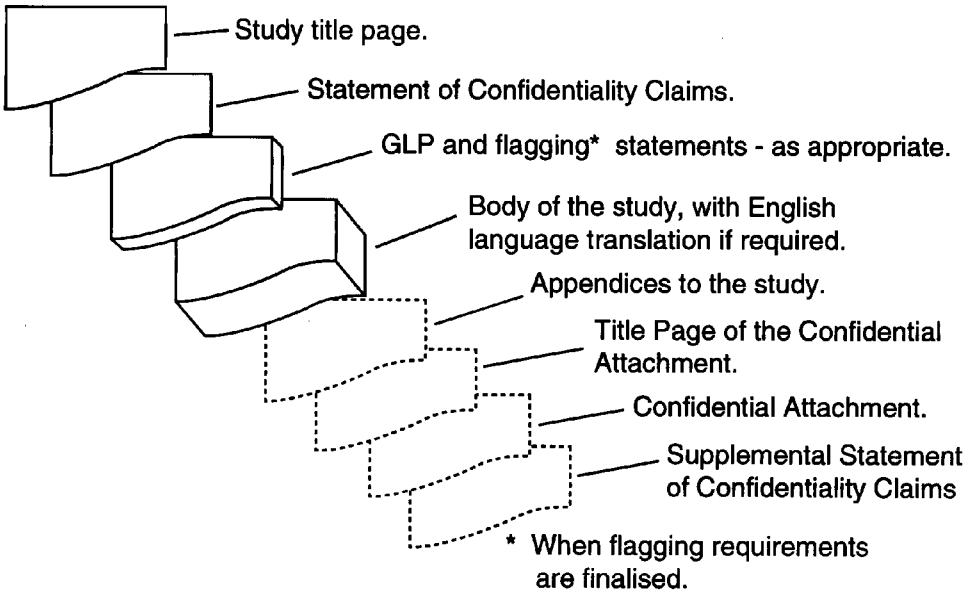
Submitter_____

ATTACHMENT 7.

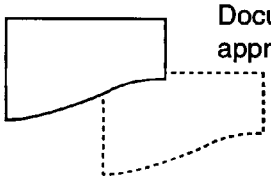
FORMAT OF THE SUBMITTAL PACKAGE



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.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

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 Reqistrant'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

MALEIC HYDRAZIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 maleic hydrazide. 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 3), (4) the EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) a list of registrants receiving this DCI (Attachment 6), (7) the Cost Share and Data Compensation Forms in replying to this Maleic Hydrazide Generic Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for maleic hydrazide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on maleic hydrazide are needed. These data are needed to fully complete the reregistration of all eligible maleic hydrazide 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 at (703) 308-8077.

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

Susanne Cerrelli, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Maleic Hydrazide

MALEIC HYDRAZIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of maleic hydrazide, please contact at (703) 308-8077.

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. or Veronica Dutch at (703) 308-8585.

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

Veronica Dutch
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: **Maleic Hydrazide**

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.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS 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.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS 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

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

EPA'S BATCHING OF PRODUCTS CONTAINING MALEIC HYDRAZIDE 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 maleic hydrazide (1,2-Dihydro-3,6-pyridazinedione and 1,2-Dihydro-3,6-pyridazinedione, potassium salt) 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 batch for the active ingredient maleic hydrazide.

Table 1.

Batch	Registration Number	% Active Ingredient	Form
1	400-97	1,2-dihydro-3,6-pyridazinedione … 97.0%	powder
	19713-25	1,2-dihydro-3,6-pyridazinedione … 97.0%	powder
	19713-26	1,2-dihydro-3,6-pyridazinedione … 97.0%	powder
	51873-10	1,2-dihydro-3,6-pyridazinedione … 96.0%	powder
2	400-84	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.7%	liquid
	400-94	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.7%	liquid
	51873-2	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.7%	liquid
	51873-8	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.7%	liquid
3	19713-20	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.6%	liquid
	19713-294	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.6%	liquid
4	2155-105	1,2-dihydro-3,6-pyridazinedione, potassium salt … 30.2%	liquid
	19713-1	1,2-dihydro-3,6-pyridazinedione, potassium salt … 30.2%	liquid
	19713-2	1,2-dihydro-3,6-pyridazinedione, potassium salt … 30.2%	liquid
	19713-17	1,2-dihydro-3,6-pyridazinedione, potassium salt … 27.8%	liquid
	19713-293	1,2-dihydro-3,6-pyridazinedione, potassium salt … 30.2%	liquid
	51873-9	1,2-dihydro-3,6-pyridazinedione, potassium salt … 30.2%	liquid
5	19713-361	1,2-dihydro-3,6-pyridazinedione, potassium salt … 80.0%	powder
	19713-371	1,2-dihydro-3,6-pyridazinedione, potassium salt … 80.0%	powder
	19713-372	1,2-dihydro-3,6-pyridazinedione, potassium salt … 80.0%	powder
6	19713-105	1,2-dihydro-3,6-pyridazinedione, potassium salt … 11.1% N-decanol … 38.3%	liquid
	51873-6	1,2-dihydro-3,6-pyridazinedione, potassium salt … 11.1% N-decanol … 38.3%	liquid

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.

Unbatched Products		
Reg. No.	% Active Ingredient	Form
400-165	1,2-dihydro-3,6-pyridazinedione, potassium salt … 80.0%	powder
400-424	1,2-dihydro-3,6-pyridazinedione, potassium salt … 33.3%	liquid
2155-104	1,2-dihydro-3,6-pyridazinedione, potassium salt … 21.7%	liquid
48211-76	1,2-dihydro-3,6-pyridazinedione, potassium salt … 8.0%	liquid

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 $>$ 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 $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ 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 $\geq$ 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 ≤ 2 or ≥ 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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	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.

EPA	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

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 3-31-96

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:

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)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA-738-F-94-009
June 1994

R.E.D. FACTS

Maleic Hydrazide

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 Case 0381, technical maleic hydrazide and maleic hydrazide potassium salt, referred to as maleic hydrazide.

Use Profile

Maleic hydrazide is a plant growth regulator (sprout inhibitor) and herbicide, that acts by inhibiting cell division in plants. It is used to control sprouting of potatoes and onions, suckers in tobacco, and growth of weeds, grasses and trees in/along lawns, turf, ornamental plants, non-bearing citrus, utility and highway rights-of-way, airports and industrial land. Most of the maleic hydrazide used in the U.S. is applied to tobacco (86-88%), followed by potatoes (11-12%).

Formulations include an emulsifiable concentrate and soluble concentrate/liquid and solid. Maleic hydrazide is applied by aircraft or ground spray equipment. Current use practice limitations prohibit treating crops within 7 days of harvest, and grazing or feeding forage or hay from treated areas to livestock.

Regulatory History

Maleic hydrazide was first synthesized in 1895 but its ability to regulate plant growth was not discovered until 1949. It was first registered as a plant growth regulator in 1952. In October 1976, maleic hydrazide went into Special Review (then called Rebuttable Presumption Against Registration or RPAR) because it met the risk criteria for oncogenic, mutagenic and reproductive effects.

A Data Call-In notice issued in August 1980 resulted in suspension of the diethanolamine salt of maleic hydrazide (DEA-MH) when its manufacturers did not submit the required data. All DEA-MH registrations now are cancelled.

Based on other data submitted, EPA determined that the oncogenicity and reproductive effects triggers were not supported, and that only weak evidence supported the mutagenicity trigger. In concluding the RPAR in June 1982, EPA allowed continued use of maleic hydrazide and its potassium salt (K-MH), but established an upper limit of 15 ppm for the contaminant hydrazine (associated with tumor induction) in technical grade maleic hydrazide. At this level, lifetime cancer risks for both dietary and worker exposure are not of concern.

The Registration Standard issued in June 1988 (NTIS #PB88-236849) continued to limit hydrazine in the technical product to 15 ppm. A Data Call-In issued in November 1992 required additional ecological effects and environmental fate data. Currently, 26 maleic hydrazide products remain registered including 4 technical grade/manufacturing-use product(s).

Human Health Assessment

Toxicity

In acute toxicity studies using laboratory animals, maleic hydrazide is practically non-toxic by the oral, dermal and inhalation routes and has been placed in Toxicity Category IV (the lowest of four levels) for these effects. It causes slight irritation to the eyes (Toxicity Category III) and skin (Toxicity Category IV), and is not a skin sensitizer.

Maleic hydrazide does not appear to cause any adverse developmental or reproductive effects of concern. The potassium salt (K-MH) was not found to be carcinogenic and has been classified as a "Group E" carcinogen--a chemical that is not considered to be a human carcinogen.

Maleic hydrazide and its potassium salt appear to be genotoxic (that is, they have the potential to affect DNA repair processes) at high doses in some mutagenicity tests. However, when all the available mutagenicity studies are considered together with the results of all the other toxicological studies on maleic hydrazide and its potassium salt, especially the negative cancer studies, the potential genotoxic hazard is considered negligible.

Dietary Exposure

People may be exposed to residues of maleic hydrazide in the diet when consuming potatoes, potato chips and other potato products made from potato granules; onions; and meat, milk, poultry and eggs.

Tolerances or maximum residue limits are established, and have been reassessed, for residues of maleic hydrazide in or on potatoes, potato chips, potato granules, potato waste (from processing), onions and cranberries (please see 40 CFR 180.175, 185.3900, and 186.3900). The potato and onion tolerances are acceptable, but an increased tolerance is needed for potato chips and new, food/feed additive tolerances are needed for potato granules and potato waste. The cranberry use is not on any currently registered product labels and is not supported for reregistration by its manufacturer. Unless another party decides to support this use, the tolerance should be revoked.

Tolerances are needed but have not yet been established for meat, milk, poultry or eggs. Animal feeding studies are being required in order to set these tolerances. Also, a confined rotational crop study is required to determine whether tolerances are needed for winter wheat planted as a rotational crop in fields treated with maleic hydrazide.

Compatible international Codex Maximum Residue Levels (MRLs) are established for potatoes and onions.

Based on reassessed tolerance levels for cranberries, onions, potatoes, potato chips, potato granules and potato waste, and based on upper bound residue levels for meat, milk, poultry and eggs, EPA estimates that the overall U.S. population is exposed to about 29.5% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Most of this exposure (27.5% of the RfD) is contributed by potatoes. For children age 1-6 and non-nursing infants, the two most highly exposed subgroups, the TMRC represents about 60% of the RfD. These TMRCs are overestimates, however; and actual chronic dietary risk (of decreased body weight gain) posed by maleic hydrazide is minimal.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to maleic hydrazide via the inhalation and dermal route. However, based on the lack of toxicological concerns with maleic hydrazide, the risk is considered minimal for all workers.

Smokers and others near them may be exposed to maleic hydrazide and the contaminant hydrazine as pyrolysis products from tobacco. However, increased levels of hydrazine are not expected, so the risk is no greater than that already associated with the use of tobacco.

Human Risk Assessment

Maleic hydrazide is of low acute toxicity. It has been shown to cause genotoxic effects in some mutagenicity studies. However, in view of several negative cancer studies, its genotoxic hazard is considered negligible. The contaminant hydrazine has been shown to induce tumors. However, EPA has set an upper limit of $\leq$15 ppm hydrazine in technical grade maleic hydrazide products. This level alleviates any concern of lifetime cancer risk to humans considering both dietary and worker exposure.

Environmental Assessment

Environmental Fate

Maleic hydrazide is mobile, especially in sandy soils, but not persistent in the environment. It therefore is not likely to impact groundwater quality. It could contaminate surface waters, however, if it is washed into anaerobic soil zones by rainfall soon after application. EPA is requiring a surface water label advisory to address this concern.

When maleic hydrazide is aerially or air-blast sprayed, drift from use sites could affect non-target crops or endangered plant species.

Ecological Effects

In acute toxicity studies, maleic hydrazide is "practically nontoxic" to birds, fish, invertebrates and honey bees. It is considered to pose minimal risks to birds, mammals, aquatic organisms, non-target insects and aquatic plants.

Maleic hydrazide may pose risks of concern to non-target terrestrial and semi-aquatic plants as a result of runoff from ground application, and runoff and drift from aerial and air-blast applications.

Ecological Effects Risk Assessment

Maleic hydrazide does not pose risks to ground water but it has the potential to contaminate surface water. It also may drift from target use sites when it is aerially or air-blast applied. EPA is requiring that a surface water advisory statement and spray drift management information be added to maleic hydrazide end-use product labels to address these concerns.

Maleic hydrazide poses minimal acute risks to birds, mammals, aquatic species, insects and non-target aquatic plants, but exceeds levels of concern for non-target semi-aquatic and terrestrial plants. To mitigate exposure to non-target plants, EPA is requiring that the number of applications to fallow land, rights-of-way, turf and lawns be limited to one per year.

EPA has concerns about the exposure of endangered plant species to maleic hydrazide. These concerns will be addressed through implementation of the Endangered Species Protection Program.

Additional Data Required

EPA is requiring the following additional generic data for maleic hydrazide to confirm its regulatory assessments and conclusions:

Nature of the residue in animals;

Analytical method for residue in animals;

Magnitude of the residue in animal commodities;

Confined rotational crop;

Droplet size spectrum; and

Drift field evaluation.

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

Worker Protection Standard (WPS) - All maleic hydrazide products within the scope of the Worker Protection Standard (WPS) for Agricultural Pesticides (see PR Notice 93-7) must, within the timeframes listed in PR Notices 93-7 and 93-11, revise their labeling to be consistent with the WPS, as directed in those notices and the requirements of the RED.

Surface Water Advisory - All end-use labels must be revised to bear the following statement:

> "Under some conditions, maleic hydrazide may have a significant potential for runoff into surface water (primarily via dissolution in runoff water), for several days post-application. Conditions favoring runoff include poorly draining soils or wet soils with readily visible slopes, frequently flooded areas, areas where an intense or sustained rainfall is forecast to occur within 48 hours, areas overlying extremely shallow ground water, and areas overlying tile drainage systems that flow to surface water."

Application Rates - Application rates must be provided for all uses. In instances where labels indicate to spray to "drip-point," labels must clearly state the maximum application rate per acre. For fallow land, lawns, turf and rights of way uses, labels must indicate that the number of applications is limited to one per year.

Regulatory Conclusion

The use of currently registered pesticide products containing maleic hydrazide and the potassium salt of maleic hydrazide in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these currently registered products are eligible for reregistration. (The cranberry use of maleic hydrazide, which is not on any currently registered product labels, is not among the uses eligible for reregistration.)

Eligible maleic hydrazide 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 maleic hydrazide will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for maleic hydrazide 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 maleic hydrazide 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 maleic hydrazide RED, or reregistration of individual products containing maleic hydrazide, 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.