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Prevention, Pesticides and Toxic Substances
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# Reregistration Eligibility Decision for Dimethipin

# Reregistration Eligibility Decision (RED) Document for
# **Dimethipin**

# **List C**

Approved by: _____

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Director
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Date: August 16, 2005

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## Glossary of Terms and Abbreviations

| | |
|---|---|
| ai | Active Ingredient |
| AR | Anticipated Residue |
| CFR | Code of Federal Regulations |
| cPAD | Chronic Population Adjusted Dose |
| CSF | Confidential Statement of Formula |
| CSFII | USDA Continuing Surveys for Food Intake by Individuals |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| DFR | Dislodgeable Foliar Residue |
| DNT | Developmental Neurotoxicity |
| DWLOC | Drinking Water Level of Comparison |
| EC | Emulsifiable Concentrate Formulation |
| EDWC | Estimated Drinking Water Concentration |
| EEC | Estimated Environmental Concentration |
| EPA | Environmental Protection Agency |
| EUP | End-Use Product |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| GENEEC | Tier I Surface Water Computer Model |
| IR | Index Reservoir |
| $LC_{50}$ | 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. |
| LOC | Level of Concern |
| LOAEL | Lowest Observed Adverse Effect Level |
| µg/g | Micrograms Per Gram |
| µg/L | Micrograms Per Liter |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| MUP | Manufacturing-Use Product |
| NA | Not Applicable |
| NAWQA | USGS National Ambient Water Quality Assessment |
| NPDES | National Pollutant Discharge Elimination System |
| NR | Not Required |
| NOAEL | No Observed Adverse Effect Level |
| OPP | EPA Office of Pesticide Programs |
| OPPTS | EPA Office of Prevention, Pesticides and Toxic Substances |
| PAD | Population Adjusted Dose |
| PCA | Percent Crop Area |
| PDP | USDA Pesticide Data Program |
| PHED | Pesticide Handler's Exposure Data |

| | |
|---|---|
| PHI | Preharvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| ppm | Parts Per Million |
| PRZM/EXAMS | Tier II Surface Water Computer Model |
| $Q_1$* | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |
| RAC | Raw Agriculture Commodity |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RQ | Risk Quotient |
| SCI-GROW | Tier I Ground Water Computer Model |
| SAP | Science Advisory Panel |
| SF | Safety Factor |
| SLN | Special Local Need (Registrations Under Section 24©) of FIFRA) |
| TGAI | Technical Grade Active Ingredient |
| TRR | Total Radioactive Residue |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| UF | Uncertainty Factor |
| WPS | Worker Protection Standard |

**Executive Summary**

This document presents the Environmental Protection Agency's (hereafter referred to as the Agency or EPA) decision on the reregistration eligibility of the registered uses of dimethipin [2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetraoxide]. Dimethipin is a plant growth regulator/dessicant, and is used as a defoliant and herbicide on cotton and non-bearing apple tree nursery stock in Washington state. The Agency made its reregistration eligibility determination based on the required data, and the current guidelines for conducting acceptable studies to generate such data. There is clarification needed, and confirmatory studies are required to fulfill all guideline data requirements. However, the Agency has found that currently registered uses of dimethipin are eligible for reregistration.

The Food Quality Protection Act (FQPA) of 1996 requires EPA to consider aggregate risks from non-occupational sources of pesticide exposure, potential increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. FQPA also requires the Agency to determine that "a reasonable certainty of no harm" results in exposure from each pesticide. When a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. There are currently 17 dimethipin tolerances, and 6 of these are proposed for revocation in this document.

Dietary Risk from Food

Acute dietary risk was not assessed as there were no toxicological endpoints attributable to a single exposure. Chronic dietary (food) risks are less than 1% of the chronic Population Adjusted Dose (cPAD) for the general U.S. population and all population subgroups.

Dietary Risk from Water

Acute dietary risk was not assessed as there were no toxicological endpoints attributable to a single exposure. There were no chronic dietary risks of concern for either surface or groundwater sources of drinking water.

Occupational Risk

There are no occupational risks of concern for dimethipin, as all Margins of Exposure (MOEs) were greater than 100, indicating that risks are below EPA's level of concern. No post-application scenarios were assessed because no dermal endpoints were identified; therefore post-application worker risks are assumed to be not of concern.

Residential Risk

There are no residential uses; thus a residential assessment was not conducted.

Chronic Aggregate Risk.

The chronic aggregate risk assessment addresses exposure to dimethipin residues in food and water. There are no residential uses of dimethipin; hence residential exposure is not included in this aggregate assessment. The chronic Drinking Water Level of Comparison (DWLOCs) are greater than the Estimated Drinking Water Concentrations (EDWCs) indicating that chronic dietary (food and water) risks are below EPA's Level of Concern (LOC).

Cumulative Risk

EPA has not made a common mechanism of toxicity finding for dimethipin. Also, dimethipin does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has not assumed that dimethipin shares a common mechanism of toxicity with other compounds. Thus, a cumulative assessment was not conducted.

Ecological Risk

There are few scenarios with LOC exceedances for small mammals, and all of these exceedances are slight. Despite the lack of plant toxicity data there is an assumption that dimethipin may be harmful to terrestrial plants, due to its herbicidal properties. In addition, there were no chronic avian data available to the Agency for its assessment. EPA has determined that no risk mitigation is appropriate for environmental concerns at this time, but the Agency is calling in the chronic data to confirm.

Endangered Species

The screening level ecological risk assessment indicates that dimethipin has the potential for causing acute risk of concern to endangered small mammals that forage on grasses, broadleaf plants, and insects. There is potential for direct effects on terrestrial plants, should exposure to listed species occur. No direct acute risks of concern were seen for aquatic organisms or birds in the preliminary assessment. In addition, there is a presumption of no direct acute effects for large mammals. The Agency cannot at this time make a clear "no effect" finding for indirect effects or for direct chronic effects.

Next Steps

The Agency is issuing this Reregistration Eligibility Decision (RED) document for dimethipin as announced in a Notice of Availability published in the *Federal Register*. The Agency is providing a 30-day public comment period for stakeholders to respond to this risk management decision. If substantive information is received during the comment period that indicates a need to refine any of EPA's assumptions or need for additional risk mitigation, then this decision will be modified as appropriate through an amendment to the RED.

In the future, EPA will issue a generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient dimethipin. EPA will also issue a product specific DCI for data necessary to complete product reregistration for products containing dimethipin.

## I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 3, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://epa.gov/pesticides/cumulative/.

Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for dimethipin. The Agency has found no information indicating dimethipin shares a common mechanism of toxicity with other substances. Dimethipin does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration

eligibility, EPA has not assumed that dimethipin shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests dimethipin shares a common mechanism of toxicity with other compounds, additional testing would be required and a cumulative assessment would be necessary.

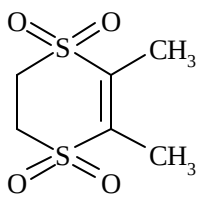
This document presents EPA's human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for dimethipin. The document consists of six sections: Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides a profile of the use and usage of the chemical; Section III gives an overview of the human health and environmental effects risk assessments based on data, public comments, and other information received; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes potential label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The preliminary and revised risk assessments for dimethipin are available in the Public Docket, under docket number OPP-2004-0380 and on the Agency's web page, http://www.epa.gov/edockets.

## II. Chemical Overview

### A. Regulatory History

Dimethipin has been registered in the United States since 1982 for use as a cotton growth regulator/dessicant, defoliant, and post-emergent herbicide. In June 1998 it was registered for herbicidal use under a Section 24(c) or Special Local Need (SLN) in Washington state for nonbearing apple nursery stock. Crompton Manufacturing Company has been the technical registrant since 1989, with Uniroyal Chemical preceeding them as the technical registrant. The Agency conducted a review of the scientific data underlying pesticide registrations and identified missing or inadequate studies. Subsequent Data Call-Ins (DCIs) were issued in 1989, 1991, and 1995. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data submitted to date.

### B. Chemical Identification



**Common Name**: Dimethipin

**Trade Name**: Harvade®

**Chemical Name**: [2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetraoxide]

**CAS Registry Number:** 55290-64-7

**OPP Chemical Code**: 118901

**Moleculer Weight**: 210.26

**Empirical Formula**: $C_6H_{10}O_4S_2$

**Basic Manufacturers**: Crompton Manufacturing Company

Dimethipin is a white powder or solid with a sweet, molasses-like scent. It has a melting point of 162-167˚ C. Dimethipin is stable in neutral and acidic aqueous solutions; however, stability decreases with increasing pH. Dimethipin is practically insoluble in water, but is soluble in most organic solvents. Dimethipin is not particularly volatile due to its low vapor pressure of $<3.81 \times 10^{-7}$ mm Hg at 24˚C (Merck Index, 11th Edition).

There are currently four products containing dimethipin registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). There is one SLN in Washington state for non-bearing apple nursery stock. This RED evaluates risk from all currently registered uses.

### C. Use Profile

The following is information on the currently registered uses including an overview of use sites and application methods. A detailed table of the uses of dimethipin eligible for reregistration is contained in Appendix A.

**Type of Pesticide**: Cotton growth regulator, defoliant and dessicant; herbicide

**Summary of Use:** Dimethipin is a cotton growth regulator/dessicant, used as a pre-harvest defoliant, and herbicide on cotton and non-bearing apple trees.

**Target Organisms**: Morning glory, sicklepod

**Mode of Action**: Dimethipin functions by stressing the plant's stomatal system causing it to lose water and resulting in leaf abscission.

**Use Sites**: Cotton, non-bearing apple nursery stock

**Tolerances:** There are seventeen dimethipin tolerances for cotton seeds and hulls, cattle, horse, goat, and sheep meat and meat byproducts, as well as the fat of horses, goats, sheep, hogs, and cattle.

**Use Classification:** General use

**Formulation Types:** Dimethipin is formulated as a flowable and emulsifiable concentrate

**Application Methods:** Dimethipin can be applied aerially, with a ground boom sprayer, or a high pressure handwand.

**Application Rates:** Dimethipin is labeled for use on cotton at a maximum seasonal rate of 0.56 lbs ai/A, however 0.31 lbs ai/A is most commonly used. For non-bearing apple trees, the maximum application rate is 0.077 lbs ai/A.

**Application Timing:** For cotton defoliation: apply 7-14 days prior to anticipated harvest, at 70% of boll opening, when the last boll to be harvested is no more than four nodes above the last cracked boll showing fiber, when the last boll to be harvested is hard to cut through and seed coat is light brown, or when there is no active growth and lower leaves have a purple tinge. For herbicide use: apply when the young weeds are at least 4 inches tall and the cotton is at least 10 inches tall. For crop maturation: apply at 30% boll opening and if necessary apply a follow-up treatment of a harvest aid product according to its label directions. For non-bearing apple nursery stock: apply after the terminal bud has set, and preferably after a light frost. Apply a second application 6 to 7 days after the first, if necessary. Do not use on apple trees that bear fruit for harvest within one year of application.

### D. Estimated Usage of Pesticide

Dimethipin is used on approximately 5% of the cotton crop nationally. The predominant usage is in Alabama, North Carolina, Georgia, and Mississippi.

## III. Summary of Dimethipin Risk Assessments

The following is a summary of EPA's human health and ecological risk findings and conclusions for dimethipin, as presented fully in the documents "Dimethipin: HED Chapter of the Reregistration Eligibility Decision Document (RED)" written by S. Stanton, J. Liccione, D. Drew and S. Tadayon, (8/26/04) and "Environmental Fate and Ecological Risk Assessment for the Reregistration of Dimethipin" written by L. Liu, and J. Felkel (11/18/04).

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket http://epa.gov/edockets (docket number OPP-2004-0380) and may also be accessed on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

### A. Human Health Risk Assessment

#### 1. Toxicity

The Agency has determined that the toxicity database for dimethipin is adequate for this assessment. Further details on the toxicity of dimethipin can be found in the Dimethipin: HED Chapter of the Reregistration Eligibility Decision Document (RED).

#### a. Toxicity Profile

*Acute:* Dimethipin has moderate (Category II) acute toxicity via the oral and inhalation routes, and low (Category III) acute toxicity via the dermal route. It is not an eye or skin irritant or a dermal sensitizer. The acute toxicity for dimethipin is listed in Table 1.

**Table 1. Acute Toxicity Data for Dimethipin.**

| Guideline No./ Study Type | MRID Number | Results | Toxicity Category |
|---|---|---|---|
| 870.1100 Acute Oral Toxicity | 42429601 | $LD_{50}$ = 458 mg/kg--male<br>$LD_{50}$ = 546 mg/kg–female | II |
| 870.1200 Acute Dermal Toxicity | 42429602 | $LD_{50}$>5000 mg/kg | III |
| 870.1300 Acute Inhalation Toxicity | 42429603 | $LC_{50}$ = 1.2 mg/L | II |
| 870.2400 Acute Eye Irritation | 85642 (Accession # 070237H) | Non-irritant | IV |
| 870.2500 Acute Dermal Irritation | 42429604 | Non-irritant | IV |
| 870.2600 Skin Sensitization | 42429605 | Not a sensitizer | – |

*Chronic:* Data from long-term studies indicate that organ effects and decreased weight gain are the primary effects of exposure to dimethipin. Observed organ effects include toxicity in the kidney, lungs, duodenum and testes of male rats and toxicity in the liver kidney, glandular stomach, heart and aortic artery of female rats. Dimethipin is not mutagenic, neurotoxic, and it does not cause developmental or reproductive effects. In a 104-week dietary study in the rat, effects were observed in males treated with 77.6 mg/kg/day (mid-dose) and 161 mg/kg/day (high-dose), and in females treated with 50.3 mg/kg/day (mid-dose) and 103 mg/kg/day (high-dose).

Toxicity occurred in the gastrointestinal tract illustrated by a higher frequency and severity of epithelial hyperplasia in the nonglandular stomach in high-dose male rats, mineralization in the glandular stomach of mid- and high-dose female rats, epithelial hyperplasia of the duodenum in mid- and high-dose males and high-dose females, and crypt abscesses in the duodenum of mid-and high-dose male rats. In addition, testicular lesions occurred in male rats fed the mid and high-doses, and epididymal hypospermia occurred in high-dose males. Effects occurring only in females included cardiovascular toxicity (mid- and high-doses) and brain degeneration (high-doses). The NOAEL in males is 2.18 mg/kg/day and in females is 1.75 mg/kg/day.

### b. Food Quality Protection Act Safety Factor (FQPA SF)

The Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor, to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures. FQPA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

*FQPA Special Safety Factor:* After evaluating hazard data for dimethipin, EPA reduced the 10X FQPA special safety factor. The toxicity database for dimethipin includes acceptable developmental and reproductive toxicity studies. No quantitative or qualitative sensitivity was observed in the rat and rabbit developmental studies or in the 2-generation reproduction study in the rat. Based on the lack of evidence of pre- and/or postnatal susceptibility following exposure to dimethipin, and considering the lack of residual uncertainties for pre- and/or postnatal toxicity, the 10X FQPA special safety factor was reduced to 1X.

*Database Uncertainty Factor:* The toxicological database is complete, and there is no database uncertainty factor for dimethipin.

### c. Carcinogenicity

The Agency has classified dimethipin as a possible human carcinogen (Group C), based on evidence of lung adenomas and carcinomas in the male CD-1 mouse. The Agency concluded that the original rat study was not conducted at a high enough dose and recommended that a new study be

conducted. The results of the new study indicated no evidence of carcinogenicity in the rat. Calculation of a Q1* was not recommended for dimethipin, based on the weight-of-evidence (i.e., tumors at the Highest Dose Tested (HDT) in only one sex, strain, species and only one experiment; and weak mutagenicity of dimethipin).

### d. Toxicological Endpoints and Doses for Risk Assessment

No endpoints (effects) of concern attributable to a single exposure (dose) were identified in any of the dimethipin studies; therefore an acute reference dose (RfD) was not established. In addition, no dermal endpoint was identified from the studies reviewed. The short- and intermediate-term, and chronic toxicological endpoints used in the human health risk assessment for dimethipin are listed in Table 2. The safety factors used to account for interspecies extrapolation, and intraspecies variability, are described in Table 2 as well. There were no concerns with special susceptibility to infants and children (FQPA 10X reduced), nor were there database uncertainties.

**Table 2: Summary of Toxicological Doses and Endpoints for Dimethipin for Use in Human Risk Assessments**

| Exposure Scenario | Dose Used in Risk Assessment, UF (mg/kg/day) | Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Chronic Dietary (all populations) | NOAEL = 2.18<br><br>UF = 100 (10x for intraspecies variation, 10x for interspecies extrapolation)<br><br>Chronic RfD = 0.0218 | FQPA SF= 1X<br>cPAD = 0.0218 mg/kg/day | Oral Chronic Toxicity/Carcinogenicity Study in the Rat MRID# 43897601<br><br>LOAEL = 50.3 mg/kg/day, based on toxicity in the kidney, lungs, duodenum, and testes of male rats and depressed body weight gain and toxicity in the liver, kidney, glandular stomach, heart, and aortic artery of female rats. |
| Occupational Inhalation Short-Term (1 - 30 days) | NOAEL = 20 | FQPA SF= 1X<br><br>LOC: MOE = 100 (10x for intraspecies variation, 10x for interspecies extrapolation) | Oral Developmental Study in the Rabbit MRID#93089033<br><br>LOAEL = 40 mg/kg/day, based on decreased body weight gain. |
| Occupational Inhalation Intermediate-Term (1 - 6 months) | NOAEL = 11.8 | FQPA SF= 1X<br><br>LOC: MOE = 100 (10x for intraspecies variation, 10x for interspecies extrapolation) | Two-Generation Reproduction Study in the Rat MRID#93089034<br><br>LOAEL = 31.2-120.3 mg/kg/day, based on decreased body weight/body weight gain in F0 & F1 females. |
| Cancer (oral, inhalation) | Classification: Class C - quantification not recommended. | | |

## 2. Dietary Exposure and Risk from Food

### a. Exposure Assumptions

There was no acute dietary assessment conducted for dimethipin because no acute endpoints were identified in any studies. The refined chronic dietary exposure assessment was conducted using the Lifeline ™ Model Version 2.0 and the Dietary Exposure Evaluation Model (DEEM-FCID™), Version 2.03. DEEM-FCID and Lifeline use food consumption data from the United States Department of Agriculture (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998 and determine exposure and risk estimates resulting from food intake for the general U.S. population and various population subgroups. Risk is expressed as a percent of the cPAD.

The chronic dietary risk assessment is conservative because 100% crop treated was assumed, along with default processing factors, and tolerance-level residues for all commodities except for the liver of cattle, goats, hogs, and sheep.

Although dimethipin is used solely on cotton, and in some parts of the country, on nonbearing apple trees, cotton seed, cotton meal and cotton gin byproducts may be part of the diet of livestock. Although feeding study data indicate that there is no expectation of finite residues in the fat, meat, or meat byproducts of cattle, goat, horses, hogs or sheep, the tolerances for dimethipin in livestock meat and meat byproducts are being retained in order to harmonize with the established Codex maximum residue limits (MRLs). The U.S. tolerances for dimethipin in the fat of cattle, goat, horses, hogs and sheep are being revoked as there is no expectation of finite residues in these commodities and there are no Codex MRLs established.

The chronic analysis could be refined through the use of anticipated residues for these livestock commodities, average residues for cottonseed based on field trial data, and percent crop treated data.

### b. Population Adjusted Dose (PAD)

The Population Adjusted Dose (PAD) is a modification of the RfD that takes into account the FQPA SF. The chronic PAD (cPAD) is an estimate of the daily exposure of the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse health effects over a lifetime. For chronic assessments, the risk is expressed as a percentage of the cPAD. The Agency is concerned when estimated dietary risk exceeds 100% of the cPAD.

### c. Dietary Risk from Food

**Acute**, There is no acute endpoint and therefore, an acute dietary risk assessment was not conducted.

**Chronic**, The chronic dietary risk from food alone is below the Agency's level of concern. Chronic dietary exposure from food comprises less than 1% of the cPAD for the U.S. population and all

population sub-groups, even the most highly exposed group, children 3-5 years old (see Table 3). Cotton is the only crop considered in the dietary assessment including secondary residues in livestock from the consumption of cotton feed items. The bold text in Table 3 represents the population sub-group with the highest exposure.

**Table 3. Chronic Dietary Exposure and Risk Estimates for Dimethipin**

| Population Subgroup | cPAD (mg/kg/day) | Exposure (mg/kg/day) | | %cPAD | |
|---|---|---|---|---|---|
| | | Lifeline | DEEM-FCID | Lifeline | DEEM-FCID |
| General U.S. Population | 0.0218 | 0 | 0.00004 | <1.0 | <1.0 |
| All Infants (< 1 year old) | | 0 | 0.000015 | <1.0 | <1.0 |
| Children 1-2 years old | | 0.0001 | 0.000078 | <1.0 | <1.0 |
| **Children 3-5 years old** | | **0.0001** | **0.000085** | **<1.0** | **<1.0** |

### 3. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses modeling (or monitoring data, if available and of sufficient quality), to estimate those exposures. In assessing drinking water risks, EPA compares model results to concentrations that would be acceptable in drinking water from a human health perspective (e.g, DWLOCs). The DWLOC is the maximum concentration in drinking water that, when considered together with dietary (food) exposure, does not exceed a level of concern. If the estimated drinking water concentrations (EDWCs) in water are less than the DWLOCs, EPA does not have concern for exposure through drinking water. If the EDWCs are greater than DWLOCs, EPA will conduct further analysis to characterize the potential dietary risk from drinking water. Risks from exposure to dimethipin in drinking water are further discussed in this document's section entitled "Aggregate Exposure and Risk."

No major environmental degradates were identified, thus parent dimethipin is the compound of concern for drinking water. The high mobility and persistence of dimethipin could result in exposure through leaching into ground water and surface water. The Screening Concentration in Ground Water (SCI-GROW) model was used to assess the concentrations of dimethipin in ground water, and the FQPA Index Reservoir Screening Tool (FIRST) model assessed the surface water concentrations of dimethipin.

#### a. Surface Water

The Tier I screening model, FIRST was used to estimate dimethipin residues in surface water used for drinking water. It provides high-end values for the concentrations that might be found in a small drinking water reservoir.

There are no concerns for exposure to dimethipin through surface water. The estimated chronic concentration is 7.3 ppb. Acute DWLOCs were not calculated, since an acute endpoint of concern has not been identified for dimethipin. The calculated chronic DWLOCs for the U.S. population and various population subgroups are between 217 ppb (infants and children) and 762 ppb (adults). The estimated chronic concentration in surface water of 7.3 ppb is well below the calculated DWLOCs and, therefore, not of concern.

### b. Ground Water

There were no available ground water monitoring data for the Agency to review. As a result, modeling was used to estimate impacts from dimethipin use on ground water quality. Estimated ground water concentrations are based on the SCI-GROW model, which is a Tier 1 model that provides high-end concentration estimates. The SCI-GROW model generates a single Estimated Drinking Water Concentration (EDWC) of a pesticide in ground water used for drinking water and provides an estimated ground water screening concentration for use in determining potential risk to human health from drinking water contaminated with a pesticide.

For the chronic assessment, a Tier I drinking water analysis was completed. Dimethipin's Koc was 1, which is very low and outside the range of Koc values used in the development of SCI-GROW. When the model was run using the Koc of 1, an EDWC of 423 ppb resulted. This EDWC significantly overestimated ground water concentrations, in part, because of the limitations of the SCI-GROW model. Based on input from M. Barrett, the developer of SCI-GROW, the model was run again with a Koc of 10. The Agency believes the Koc of 10 is more representative of the concentration of dimethipin in groundwater, resulting in an EDWC of 99 ppb compared to a DWLOC of 762. Table 4 displays the modeled EDWC values for surface and ground water arising from the Tier I assessment.

**Table 4. Surface and Ground Water Estimated Drinking Water Concentrations (EDWCs)**

| Water Segment | Duration | EDWC (ppb) |
|---|---|---|
| Surface Water | Chronic | 7.3 |
| Ground Water | All Duration | 99 |

## 4. Residential and Other Non-Occupational Exposure

There are no residential or other non-occupational uses of dimethipin.

## 5. Aggregate Exposure and Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include

exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. In the case of dimethipin, there are no residential or non-occupational sources of exposure, so the aggregate assessment included dietary risks only. Furthermore, no acute assessment was done because there were no acute endpoints of concern identified.

### a. Chronic Aggregate Risk

The chronic aggregate risk assessment for dimethipin includes food and drinking water. Dimethipin residues on food items account for less than 1% of the cPAD for all population subgroups. The Agency used the LifeLine food exposure estimates to calculate chronic DWLOCs for the U.S. population and various population subgroups. The calculated DWLOCS ranged from 762 ppb for adults to 217 ppb for infants and children. The chronic surface water EDWC (7.3 ppb) and chronic ground water EDWC (99 ppb) are well below the calculated DWLOCs for chronic exposure to dimethipin for the U.S. population and each population subgroup. Based on these comparisons, the Agency is reasonably certain that the chronic aggregate risk associated with the use of dimethipin does not exceed our level of concern for the overall U.S. population or population subgroups, including infants and children. (see Table 5).

**Table 5. DWLOCs for Chronic Aggregate Risk**

| Population Subgroup | Estimated Drinking Water Concentration (EDWC) of Dimethipin (ppb) | | Chronic DWLOC (ppb) |
|---|---|---|---|
| | Groundwater | Surface Water | |
| U.S. Population | 99 | 7.3 | 762 |
| Infants <1 | 99 | 7.3 | 218 |

### 6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, flagging in cotton fields, applying a pesticide, or re-entering treated sites. Occupational handlers of dimethipin include: mixers/loaders, flaggers, and applicators to cotton and non-bearing apple nurseries. Occupational risk for these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL).

MOEs are the ratio of estimated exposure to an established dose level NOAEL. Dimethipin MOEs are determined by a comparison of specific exposure scenario estimates to the inhalation NOAEL of 20 mg/kg/day from a rabbit developmental study for short-term assessment, or 11.8 mg/kg/day from a rat two-generation reproduction study for intermediate-term assessment. No dermal endpoint was identified in any of the available studies, thus only inhalation risk was assessed. For

dimethipin users, an MOE of 100 or greater has been determined to be adequately protective (for both short- and intermediate-term exposure) based on the standard uncertainty factors of 10x for interspecies extrapolation and 10x for intraspecies variability. Long-term worker exposure is not expected for dimethipin and thus was not assessed.

For more information on the assumptions and calculations of potential risk of dimethipin to workers, see the Occupational Exposure Assessment (Section 2.2.2), 6/8/04, or the Dimethipin HED Chapter of the Reregistration Eligibility Decision Document (RED) (Section 9) dated 8/26/04.

### a. Occupational Toxicity

Table 6 below provides a listing of the toxicological endpoints used in the dimethipin occupational risk assessment.

**Table 6: Summary of Toxicological Endpoints for the Occupational Risk Assessment**

| Exposure Scenario | Dose used in Risk Assessment (mg/kg/day) | Level of Concern/ MOE | Study and Toxicological Effects |
|---|---|---|---|
| Short-Term (1-30 days) Inhalation | NOAEL= 20 | MOE = 100 | Developmental toxicity study in rabbits LOAEL = 40 mg/kg/day based on decreases in maternal body weight gain. MRID#:93089033 |
| Intermediate-Term (1-6 months) Inhalation | NOAEL= 11.8 | MOE = 100 | Two-generation reproduction study in rats LOAEL = 31.2 - 120.3 mg/kg/day based on decreased body weight/body weight gain in F0 & F1 females. MRID#:93089034 |
| Cancer | Classification: Class C (possible carcinogen) calculation of a Q1* was not recommended | | |

### b. Occupational Handler Exposure

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle dimethipin during the usual uses associated with the pesticide. Based on the use patterns, the following 7 major occupational handler exposure scenarios were identified:

*(1) mixing/loading liquids for aerial applications;*
*(2) mixing/loading liquids for groundboom applications;*
*(3) mixing/loading liquids for high-pressure handwand applications;*
*(4) applying aerially using sprays;*
*(5) applying using groundboom equipment;*
*(6) applying using high-pressure handwand; and*
*(7) flagging for sprays application.*

For more detail on the assumptions and calculations of potential risk of dimethipin to workers, see the Occupational Exposure Assessment (section 2.1) dated June 8, 2004.

### c. Summary of Handler Risk Estimates

Short- and intermediate-term inhalation MOE estimates for all occupational handler scenarios are greater than 100 at either baseline level of protection (i.e. long sleeve, long pants, socks, shoes, and no respirator) or using engineering controls (i.e. closed cockpit for fixed wing aircraft). Baseline personal protective equipment (PPE) is sufficient for all exposure scenarios except the aerial spray application which requires a closed cockpit. Short-term MOEs range from 1,500 to 1,300,000, and intermediate-term MOEs range from 880 to 770,000. Therefore, short- and intermediate-term occupational risk are not of concern. Table 7 below provides a listing of the short- and intermediate-term risk estimates for handlers.

**Table 7: Summary of Occupational Handler Risk for Dimethipin (Baseline PPE)**

| Exposure Scenario (Scenario # referenced above) | Crop | Application Rate lb ai/A | Daily Area Treated A or gal/day | Short-Term Inhalation MOE | Intermediate-Term Inhalation MOE |
|---|---|---|---|---|---|
| Mixer/Loader | | | | | |
| Mixing/Loading Liquids for Aerial Application (1) | Cotton | 0.56 | 1200 | 1500 | 880 |
| Mixing/Loading Liquids for Groundboom application (2) | | | 200 | 8900 | 5300 |
| Mixing/Loading Liquids for High-Pressure Hand Wand (3) | Apple | 0.00077/gal | 1000 gals | 1300000 | 770000 |
| Applicator | | | | | |
| Sprays for Aerial Application (4) (closed cockpit) | Cotton | 0.56 | 1200 | 26000 | 15000 |
| Sprays for Groundboom Application (5) | | | 200 | 14000 | 8500 |
| Spray for High Pressure Hand Wand Application (6) | Apple | 0.00077/gal | 1000 gals | 20000 | 12000 |
| Flagger | | | | | |
| Flagging for Sprays Application (7) | Cotton | 0.56 | 350 | 17000 | 10000 |

### d. Occupational Post-Application Risk

EPA did not assess post-application dermal exposure risks to agricultural workers following treatments to cotton or non-bearing apple nursery stock, since no short- or intermediate-term dermal endpoint of concern was identified and long-term dermal exposures are not expected. Also, since post-application inhalation exposure is expected to be negligible, a risk assessment for this route was not conducted.

Access to pesticide-treated areas is limited after an application while the pesticide may still present a hazard. In the absence of specific data to determine the appropriate length of the restricted-entry interval (REI), it is established based on the acute dermal toxicity and eye and skin irritation potential of the active ingredient. The dimethipin technical material has been classified in Toxicity Category III for acute dermal toxicity and Toxicity Category IV for primary eye and skin irritation potential. In accordance with the Worker Protection Standard (WPS), a 12-hour REI is indicated for chemicals classified under Toxicity Category III or IV. In the Worker Protection Standard (WPS), an REI is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in any task or activity would not result in exposures which are of concern. Thus, EPA has determined that dimethipin-only products would be eligible for a 12 hour REI (currently dimethipin labels have a 48 hour REI).

#### e. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), and the Agency's Office of Pesticide Program's Incident Data System (IDS), the National Pesticide Information Center (NPIC), the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR) and the California Pesticide Illness Surveillance Program. Only one incident of an oral ingestion of dimethipin was reported to the PCC, which involved a forty-three year old man who ingested the product (Harvade) and reported throat irritation and itching. No further information on the disposition of the case was reported.

There were no dimethipin exposures reported in the Incident Data Systems (1992 to present), NPIC (1984-1991), NIOSH SENSOR (1998-2002) or California Pesticide Illness Surveillance Program (1982-2002) data bases. The absence of reported incidences serves to reinforce the occupational risk assessment conclusions.

## B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for dimethipin is presented below. Dimethipin has the following registered uses which result in environmental exposures: cotton defoliation and post-emergence herbicide. More detailed information associated with the environmental risk from the use of dimethipin can be found in the "Environmental Fate and Ecological Risk Assessment for the Reregistration of Dimethipin," dated November 18, 2004. The complete environmental risk assessment may be accessed in the OPP Public Docket (OPP-2004-0380) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

### 1. Environmental Exposure

#### a. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure associated with dimethipin use. However, EPA does intend to issue a DCI as part of this RED to require submission of additional data for the parent compound to address areas of uncertainty. Studies on vegetative vigor, plant and aquatic toxicity, and chronic avian toxicity will help to refine the environmental risk assessments and provide the Agency with necessary data. These data are expected to confirm the conclusions of this environmental risk assessment.

The environmental fate of dimethipin varies somewhat based on the site-specific properties of the soil to which it is applied, but generally, dimethipin is persistent in soil, with a half-life ranging from several weeks to several months. Dimethipin is practically insoluble in water, and stable to hydrolysis and photolysis in soil. The aqueous photolysis half-lives for dimethipin, at a pH of 5, 7, and 9 are approximately 60, 224, and 72 days respectively. The aerobic soil half-life is approximately 400 days in sandy loam, and the anaerobic aquatic half-life is estimated to be 2 years.

Dimethipin has very high mobility in all soils, according to available laboratory mobility studies. In a terrestrial field dissipation study conducted on cotton in Georgia, dimethipin was detected at depths of 75-90 cm below the soil surface (MRID 43216001). A second terrestrial field dissipation study conducted on cotton in Mississippi resulted in dimethipin detections at 60–75 cm soil depth (MRID 43216002).

Dimethipin is mobile in soils and it has the potential to enter surface water by runoff and enter groundwater by leaching. However, no ground or surface water monitoring data are available at this time, and the U.S. Geological Survey's National Ambient Water Quality Assessment (NAWQA) program is not currently analyzing for dimethipin Additional information on the environmental fate of dimethipin can be found in the drinking water section of this document and in the supporting documents referenced in Appendix C.

### b. Aquatic Organism Exposure

For exposure to fish and aquatic invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. The Agency used Tier I surface water modeling to derive estimated environmental concentrations (EECs) for the concentration of dimethipin residues in surface water. The modeling results used in risk calculations for dimethipin are detailed in the Environmental Fate and Effects Division chapter: Environmental Fate and Ecological Risk Assessment for the Reregistration of Dimethipin, dated November 18, 2004.

Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk

assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

The Tier 1 model GENEEC2 was used to estimate surface water concentrations of dimethipin. Exposures are typically calculated for invertebrates and fish. Fish serve as surrogates for aquatic-phase amphibians. The GENEEC2 model was run for two different crops, cotton and apple/non-bearing nursery stock, using the proposed maximum label application rates (0.56 lbs ai/A and 0.077 lbs ai/A, respectively) with aerial application.

Exposure to non-target aquatic plants may occur through runoff or spray drift from adjacent treated sites.

| Table 8. Tier I Estimated Environmental Concentrations (EECs) of Dimethipin in Surface Water | | | | | |
|---|---|---|---|---|---|
| Crop/Scenario | EECs of Dimethipin in Surface Water (ppb) | | | | |
| | App. Rate | Peak, 24-Hour | 96-hour Average | 21-day Average | 60-day Average |
| Cotton | 0.56 lbs ai/A | 33.89 | 33.88 | 33.83 | 33.7 |
| Non-Bearing Apple Nursery Stock | 0.08 lbs ai/A | 4.66 | 4.66 | 4.65 | 4.63 |

### c. Terrestrial Organism Exposure

The Agency assessed exposure to terrestrial organisms by first predicting the amount of dimethipin residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items are based on the Fletcher nomogram, which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994), and the current maximum application rate for dimethipin. Thus, EPA modeled the maximum residues of dimethipin on cotton and nonbearing apple nurseries, immediately following application at the maximum application rates, which are 0.56 lbs ai/A on cotton for post-emergence herbicidal usage, and 0.077 lbs. ai/A on non-bearing apple nurseries. The Agency assumed no dilution due to the growth of the plants or degradation of dimethipin. EPA's estimates of dimethipin residues on various wild animal food items are summarized in Table 9. EPA used these EECs and standard food consumption values to estimate dietary exposure levels for dimethipin to birds and mammals.

| Table 9. Maximum Residue EECs on Avian and Mammalian Food Items (ppm) Following a Single Application of Dimethipin at 0.56 lbs ai/A for Cotton and 0.077 lbs ai/A for Apples | | |
|---|---|---|
| Crop and Food Group Classification | Acute EECs (ppm) | |
| | Cotton | Non-Bearing Apple Nursery Stock |
| Short grass | 134 | 18 |
| Tall grass | 62 | 8 |
| Broadleaf/forage plants and small insects | 76 | 10 |
| Fruits/pods/seeds/large insects | 8 | 1.16 |

The terrestrial EECs used to determine the chronic risk quotients (RQs) were estimated using the ELL-FATE model, which calculates the decay of a chemical applied to foliar surfaces for single and/or multiple applications. Pesticide food residues are based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario. A 35-day foliar dissipation half-life was assumed due to a lack of data on dissipation from foliar surfaces, which is the default value.

### d. Non-target Terrestrial Plant Exposure

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff and spray drift. In the case of dimethipin, it is applied by ground boom and aerially to cotton, and hand-held spray applicator for non-bearing apple nursery stock**.** Due to the lack of acceptable studies on plant toxicity, exposure modeling was not conducted for non-target terrestrial plants.

## 2. Environmental Effects (Hazard)

### a. Toxicity to Aquatic Organisms

Freshwater and Estuarine/Marine Fish

The available acute toxicity data, outlined in Table 10 below, indicate that dimethipin is slightly toxic to freshwater fish on an acute basis, based on an $LC_{50}$ value of 20.9 ppm for bluegill sunfish.

Chronic data for freshwater fish show that larval survival was the most sensitive endpoint for dimethipin. The toxicity endpoints for aquatic species are listed in Table 10.

**Table 10. Dimethipin Toxicity Reference Values (TRVs) for Aquatic Organisms**

| Exposure Scenario | Species | Exposure Duration | Toxicity Reference Value (ppm ai) | Reference |
|---|---|---|---|---|
| **Freshwater Fish** | | | | |
| Acute | Bluegill sunfish | 96 hours | $LC_{50}$ = 20.9 ppm ai | MRID 41945902 |
| Chronic | Fathead minnow | 31 days | NOAEC = 12 ppm ai | MRID 00126069 |
| **Freshwater Invertebrates** | | | | |
| Acute | *Daphnia magna* | 48 hours | $LC_{50}$ = 20 ppm ai | 00086315 LeBlanc 1977 |
| Chronic | *Daphnia magna* | 21 days | NOAEC (length) = 0.61 ppm ai | MRID 00128803 |
| **Estuarine/Marine Fish** | | | | |
| Acute | Sheepshead minnow | 96 hours | $LC_{50}$ = 17.8 ppm ai | MRID 41663901 |
| Chronic | no data; an extrapolated NOAEC value based on the acute-to-chronic ratio in freshwater fish is 10.2 ppm ai[1] | | | |
| **Estuarine/Marine Invertebrates** | | | | |
| Acute | Mysid shrimp | 48 hour | $LC_{50}$ = 13.9 ppm ai | MRID 41663902 |

| Table 10. Dimethipin Toxicity Reference Values (TRVs) for Aquatic Organisms | | | | |
|---|---|---|---|---|
| **Exposure Scenario** | **Species** | **Exposure Duration** | **Toxicity Reference Value (ppm ai)** | **Reference** |
| Chronic | no data; an extrapolated NOAEC value based on the acute-to-chronic ratio in freshwater invertebrates is 0.42 ppm ai[2] | | | |
| **Aquatic Plants** | | | | |
| Acute | *Lemna gibba* | 14 days | $EC_{50}$ = 2.1 ppm ai<br>NOAEC = 0.8 ppm ai | MRID 42627104 |
| 1 Acute-to-Chronic ratio for freshwater fish is 20.9: 12 = 1.7; 17.8 ppm/1.7 =10.2 ppm<br>2 Acute-to-Chronic ratio for freshwater invertebrates is 20: 0.61 = 32.8; 13.9 ppm/32.8 = 0.42 ppm | | | | |

Freshwater and Estuarine/Marine Invertebrates

Acute data on technical dimethipin show that it is slightly toxic to freshwater invertebrates (daphnid $LC_{50}$ of 20 ppm) and estuarine/marine invertebrates (mysid shrimp $LC_{50}$ of 13.9 ppm). Table 10 above displays the acute and chronic toxicity endpoints for freshwater invertebrates.

Aquatic Plants

The $EC_{50}$ value of 2.1 ppm ai in duckweed suggests that dimethipin is acutely toxic to freshwater plants (macrophytes).

### b. Toxicity to Terrestrial Organisms

Birds

Dimethipin is classified as slightly toxic to birds on an acute oral basis, since the $LD_{50}$ value is between 501 mg/kg and 2,000 mg/kg (see Table 11). Additionally, with $LC_{50}$ values >5,000 ppm, dimethipin is classified as slightly-to-practically nontoxic to birds on a subacute dietary basis. An $LC_{50}$ is a statistically estimated measure (concentration) expected to be lethal to 50% of the test population. Table 11 summarizes the data that support the acute toxicity endpoints used in assessing the risks to birds.

| Table 11. Summary of Toxicity Endpoints for Birds | | | | | |
|---|---|---|---|---|---|
| **Toxicity Study** | **Test Species** | **% ai** | **Endpoint** | **Toxicity Category** | **MRID#** |
| **Acute (single dose administered by gelatin capsule)** | | | | | |
| Avian Oral | Mallard Ducks (Anus platyrhynchos) | 98.64 | $LD_{50}$ 880 mg ai/kg | *Slightly Toxic* | 41955901 |
| **Subchronic (5-Day dietary exposure followed by 3-day observation period)** | | | | | |
| Avian Dietary | Mallard Ducks (Anus platyrhynchos) | 98.64 | $LC_{50}$ >5,000 ppm ai | *Practically non-toxic* | 41955902 |
| **Chronic (reproductive):** NOT ASSESSED DUE TO LACK OF DATA | | | | | |

Mammals

Dimethipin is classified as moderately toxic to small mammals on an acute oral basis with an $LD_{50}$ value of 458 mg/kg (see Table 12). Chronic toxicity data for mammals from the 2-generation rat reproduction study indicate decreased body weight in pups with a NOAEL of 200 ppm. Table 12 discusses the data that support the acute toxicity and chronic endpoints used in assessing the risks to mammals.

**Table 12. Summary of Toxicity Endpoints for Mammals**

| Species | Test Type | Toxicity Value | Affected Endpoints | Identification Number |
|---|---|---|---|---|
| Rat | Acute Oral Toxicity | $LD_{50}$ = 458 mg/kg (♂)<br>$LD_{50}$ = 546 mg/kg (♀) | Mortality | MRID 42429601 |
| Rat | 2-Generation Reproductive study<br><br>Dietary exposure to 0, 50, 200, or 800 ppm | Parental systemic NOAEL for ♀ = 200 ppm; NOAEL for ♂ ≥ 800 ppm<br><br>Reproductive toxicity NOAEL for ♀ and ♂ ≥ 800 ppm<br><br>Offspring toxicity NOAEL for ♀ and ♂ = 200 ppm | Decreased body weight | MRID 93089034 |

Non-Target Insects

Available data from a honey bee acute toxicity study indicated that technical dimethipin is practically non-toxic to the honey bee (with an $LD_{50}$ greater than 100 micrograms per bee; MRID# 41264606).

Non-Target Terrestrial Plants

No acceptable data for terrestrial plants have been submitted to the Agency. However, dimethipin is an herbicide, therefore plant toxicity is expected.

### 3. Ecological Risk Estimation (RQs)

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to EECs based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of dimethipin products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose ($LD_{50}$) or the median lethal concentration ($LC_{50}$). These RQ values are then compared to the Agency's levels of concern (LOCs), given in Table 13, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to

that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

**Table 13. EPA's Levels of Concern and Associated Risk Presumptions**

| Risk Presumption | LOC Terrestrial Animals | LOC Aquatic Animals | LOC Plants |
|---|---|---|---|
| *Acute Risk* - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification. | 0.5 | 0.5 | 1 |
| *Acute Restricted Use* - there is potential for acute risk, but may be mitigated through restricted use classification. | 0.2 | 0.1 | N/A |
| *Acute Endangered Species* - endangered species may be adversely affected; regulatory action may be warranted. | 0.1 | 0.05 | 1 |
| *Chronic Risk* - there is potential for chronic risk; regulatory action may be warranted. | 1 | 1 | N/A |

### a. Risk to Aquatic Organisms

Fish and Aquatic Invertebrates

No acute or chronic risks are predicted for freshwater fish, estuarine fish, and aquatic invertebrates.

Aquatic Plants

Aquatic plant toxicity dose response data were available for four aquatic plant species. Acute RQ values for aquatic plants are well below the LOC for acute risk for both cotton and non-bearing apple nursery stock crop applications. Based on the screening level assessment, it appears unlikely that adverse effects in aquatic plants would be observed at the current labeled rates of dimethipin. Methods are not currently available to assess chronic risks to aquatic plants.

### b. Risk to Non-target Terrestrial Organisms

Birds

Acute RQs from two applications of dimethipin (for a seasonal maximum application of 0.56 lbs ai/A) range from less than 0.0002 to less than 0.03. There are no exceedances for any acute LOCs for birds. Chronic RQs for birds could not be estimated due to a lack of chronic avian data.

Mammals

There are no exceedances for acute mammalian LOCs when dimethipin is applied to non-bearing apple nursery stock. For application on cotton, RQs range from 0.001 (1000g granivore, seeds) to 0.28 (15g mammal, short grass). For acute restricted use risk, the RQ exceeds the LOC (0.2) for a 15g mammal feeding on short grass. All chronic RQs for mammals are below the LOC of 1 for dimethipin application to cotton (including endangered species).

**Table 14. Acute Risk Quotient (RQ) Calculations for Mammalian Consumption of Plant and Insect Forage Material**

| Crop and Forage Item | Maximum EEC (ppm) | Acute $LD_{50}$ (mg/kg bw/d) | Weight of Mammal | | |
|---|---|---|---|---|---|
| | | | 15 g | 35 g | 1000 g |
| | | | Acute Risk Quotients [1] | | |
| Cotton | | | | | |
| Short grass | 134.4 | 458 | **0.28** | **0.19** | 0.04 |
| Tall grass | 61.6 | | **0.13** | 0.09 | 0.02 |
| Broadleaf/forage plants and small insects | 75.6 | | **0.16** | **0.11** | 0.02 |
| Fruits/pods/large insects | 8.4 | | 0.02 | 0.01 | 0 |
| Seeds (granivore) | 8.4 | | 0.004 | 0.003 | 0.001 |
| Apple/nonbearing nursery stock | | | | | |
| Short grass | 18.48 | 458 | 0.04 | 0.03 | 0.01 |
| Tall grass | 8.47 | | 0.02 | 0.01 | 0.003 |
| Broadleaf/forage plants and small insects | 10.4 | | 0.02 | 0.01 | 0.003 |
| Fruits/pods/large insects | 1.16 | | 0.002 | 0.002 | 0.004 |
| Seeds (granivore) | 1.16 | | 0.0005 | 0.0004 | 0.0001 |

[1] $RQ = \frac{\text{EEC (ppm)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$

Note: RQs in bold print signify an exceedence of the acute restricted use LOC for risk to mammals, and the endangered species LOC.

Non-Target Insects

Available data from a honeybee acute contact toxicity study indicated that technical dimethipin is practically nontoxic to the honeybee (with an $LD_{50}$ >100 ug/bee) and its uses on cotton and non-bearing apple nursery stock are predicted to pose minimal risk to non-target insects.

Non-Target Terrestrial Plants

There is insufficient toxicity data to evaluate risk to non-target terrestrial plants from use of dimethipin. Dimethipin is used as an herbicide in terrestrial settings, therefore risk to terrestrial plants from dimethipin is probable.

### c. Ecological Incidents

No ecological incidents reports have been received for dimethipin.

### d. Endangered Species Concerns

The Agency's screening level ecological assessment for dimethipin resulted in a determination that dimethipin will have no direct acute effects on threatened and endangered avian, and aquatic species from its use on cotton and non-bearing apple nursery stock. Additionally, no direct acute effects are expected for large (≥1000g) mammals, as well as no chronic effects for mammals or aquatic animals.

Using the data available, RQs for 15g mammals feeding on short grass, tall grass, and broadleaf plants and small insects exceed the acute endangered risk LOC of 0.1. Additionally, the RQs exceed the acute endangered risk LOC for 35g mammals feeding on short grass and broadleaf plants and small insects. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the ESA. The LOC exceedences for these endangered animals are based on the maximum application rate of 0.56 lb ai/A on cotton, 0.077 lb ai/A on nonbearing apple nursery stock, and a 35-day half-life default value in the exposure analysis.

There is a potential for direct effects on terrestrial plants, should exposure to listed species occur (since dimethipin is a defoliant). Chronic risks have not been assessed for avian species based on the lack of available chronic data. Additionally, there is a potential for indirect effects on any listed species that is either dependent upon mammals < 1000 grams and /or dependent upon terrestrial plants, and occurs within areas where exposure is sufficient to produce adverse effects on small mammals and/or terrestrial plants. There have been no previous consultations with the Services on endangered species concerns from the use of dimethipin.

### e. Risk Characterization

The screening level risk assessment for dimethipin is conservative, conducted with the maximum application rate of 0.56 lb ai/A for cotton and 0.077 lb ai/A for nonbearing apple nursery stock. In addition, the default foliar half life of 35 days was used for residues of dimethipin.

Freshwater fish and aquatic invertebrates do not appear to be at acute or chronic risk from exposure to dimethipin. Similarly, there is no risk of concern for aquatic plants for the crop scenarios considered.

The LOC for acute restricted use (LOC 0.2) is exceeded for 15g mammals feeding on short grass. The assessment assumed that small 15g mammals were consuming 100% of their diet from short grass. The small mammals were the only category that exceeded the restricted use LOC. There are no exceedances for acute mammal LOCs for application of dimethipin to nonbearing apple nursery stock. None of the chronic LOCs are exceeded for application of dimethipin to cotton or nonbearing apple nursery stock.

There are no acute risks to birds, yet chronic risk for birds cannot be precluded as there are no chronic data available. For terrestrial plants, there is insufficient data to evaluate risk; yet, dimethipin's herbicidal properties indicate that risk is probable.

## IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

### A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient 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 dimethipin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing dimethipin.

The Agency has completed its assessment of the dietary, occupational, and ecological risk associated with the use of pesticide products containing the active ingredient dimethipin. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of dimethipin to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that dimethipin containing products are eligible for reregistration. Appendix A summarizes the uses of dimethipin that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of dimethipin, and lists the submitted studies that the Agency found acceptable.

### B. Public Comments and Responses

Through the Agency's public participation process, EPA provides the opportunity for stakeholders and the public to engage in the regulatory process for dimethipin. However, during the public comment period on the risk assessments, which closed on April 26, 2005, the Agency received no comments.

The RED and technical supporting documents for dimethipin are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket number OPP-2004-0380. The public may access EPA Dockets at http://www.epa.gov/edockets. In addition, the dimethipin RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

## C. Regulatory Position

### 1. Food Quality Protection Act Findings

#### a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to dimethipin is within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for dimethipin meet FQPA safety standards.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of dimethipin, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and the possibility of increased dietary exposure due to the specific consumption patterns of infants and children. The FQPA Safety Factor has been reduced to 1X for dimethipin because: 1) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure; 2) no residual uncertainties; and 3) the dietary exposure assessments do not underestimate the potential exposures to infants and children.

#### b. Determination of Safety to the U.S. Population Including Infants and Children

The Agency has determined that the established tolerances for dimethipin meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population, infants and children or any subgroup from the use of dimethipin. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of

dimethipin. As discussed in Chapter 3, the total acute dietary (food and water) risk was not assessed, since no appropriate acute endpoint was identified. Chronic aggregate risks, which included drinking water and food, do not exceed levels of concern. Estimated aggregate exposure was less than 1% of the cPAD for all U.S. population subgroups.

#### c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, dimethipin may be subject to additional screening and/or testing.

#### d. Cumulative Risks

Risks summarized in this document are those that result only from the use of dimethipin. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not assumed that dimethipin shares a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

### 2. Tolerance Reassessment Summary

#### a. Tolerances Currently Listed Under 40 CFR §180.406

The existing tolerances for residues of dimethipin (2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetraoxide) are established under 40 CFR §180.406. The Agency plans to revoke the tolerances on cotton hulls, and the fat of cattle, goat, hog, horse, and sheep (see Table 15).

**Table 15. Tolerance Reassessment Summary for Dimethipin**

| Commodity | Current Tolerance (ppm) | Range of Residues (ppm) | Tolerance Reassessment (ppm) | Comment |
|---|---|---|---|---|
| **Tolerances Listed Under 40 CFR §180.406(a):** | | | | |
| Cotton, undelinted seed | 0.5 | <0.10-0.260 | 0.5 | |
| Cotton, hulls | 0.7 | average processing factor = 0.95x | Revoke | No tolerance for cotton hulls is necessary because residues do not concentrate. |
| Cattle, fat | 0.02 | <0.01 at a 9.6x dosing level | Revoke | The available feeding study data, reflecting exaggerated dosing levels, indicate that there is no expectation of finite residues. However, tolerances should be maintained, except for fat, to harmonize with CODEX MRLs. Tolerances for fat should be revoked as there are no CODEX MRLs for fat. |
| Cattle, meat | 0.02 | | 0.02 | |
| Cattle, meat byproducts | 0.02 | | 0.02 | |
| Goat, fat | 0.02 | | Revoke | |
| Goat, meat | 0.02 | | 0.02 | |
| Goat, meat byproducts | 0.02 | | 0.02 | |
| Hog, fat | 0.02 | | Revoke | |
| Hog, meat | 0.02 | | 0.02 | |
| Hog, meat byproducts | 0.02 | | 0.02 | |
| Horse, fat | 0.02 | | Revoke | |
| Horse, meat | 0.02 | | 0.02 | |
| Horse, meat byproducts | 0.02 | | 0.02 | |
| Sheep, fat | 0.02 | | Revoke | |
| Sheep, meat | 0.02 | | 0.02 | |
| Sheep, meat byproducts | 0.02 | | 0.02 | |
| **Tolerances to be Established Under 40 CFR 180.406(a):** | | | | |
| Cotton, gin byproducts | -- | -- | TBD | |

### b. Codex Harmonization

Results from feeding studies, reflecting exaggerated dosing levels, indicate that there is no expectation of finite residues in the fat, meat, or meat byproducts of cattle, goats, horses, hogs or sheep. However, the Agency recommends that the tolerances for dimethipin in livestock meat and meat byproducts be retained in order to reflect those established by the Codex MRLs. The U.S. tolerances for livestock meat and meat byproducts are 0.02 and the Codex MRLs for livestock meat and meat byproducts are established at 0.01 ppm. The Agency recommends that tolerances for dimethipin in the fat of cattle, goats, horses, hogs and sheep be revoked as there is no expectation of

finite residues in these commodities and there are no Codex MRLs established. There is no U.S. tolerance for dimethipin in milk as there is no expectation of finite residues.

## D. Regulatory Rationale

The Agency has determined that dimethipin is eligible for reregistration. At this time, the Agency has not identified risks that require mitigation for the reregistration of dimethipin.

### 1. Endangered Species Considerations

From the screening level assessment, there were no direct acute or chronic risks noted for any aquatic animal or aquatic plant. In addition, no direct acute risks were identified for endangered birds. The screening level assessment for dimethipin resulted in acute endangered species risks above EPA's level of concern for 15g mammals feeding on short grass, tall grass, and broadleaf plants and small insects. In addition, the RQ exceeded the LOC for 35g mammals feeding on short grass and broadleaf plants and small insects. There are no chronic risks above EPA's level of concern for listed mammals. Chronic risks have not been assessed for avian species based on the lack of available chronic data. There is a potential for direct effects on terrestrial plants, should exposure to listed species occur. In addition, there is a potential for indirect effects on any listed species that is either dependent upon mammals < 1000 grams and /or dependent upon terrestrial plants, and occurs within areas where exposure is sufficient to produce adverse effects on small mammals and/or terrestrial plants.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of dimethipin, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary. EPA is not requiring specific dimethipin

label language at the present time relative to threatened and endangered species. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

### 2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of dimethipin, as summarized in this document, the Agency concludes that no additional drift mitigation measures are needed for dimethipin. In the future, dimethipin product labels may need to be revised to include additional or different drift label statements.

## V. What Registrants Need to Do

The Agency has determined that dimethipin is eligible for reregistration provided that additional data are submitted to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring, product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data that the Agency intends to require for dimethipin to be eligible for reregistration.

### A. Manufacturing Use Products

#### 1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dimethipin for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

**Table 16. Data Requirements for the Reregistration Eligibility Decision on Dimethipin**

| Guideline Study Name | New OPPTS Guideline No. | Old Guideline No. |
|---|---|---|
| Crop Field Trials (Cotton Gin Byproducts Group) | 860.1500 | 171-4K |
| Confined Accumulation in Rotational Crops | 860.1850 | 165-1 |
| Storage Stability Data - Plant Commodities | 860.1380 | 171-4E |

| Table 16. Data Requirements for the Reregistration Eligibility Decision on Dimethipin | | |
|---|---|---|
| **Guideline Study Name** | **New OPPTS Guideline No.** | **Old Guideline No.** |
| Avian Reproduction Tests (Bobwhite Quail and Mallard Duck) | 850.2300 | 71-4A, 71-4B |
| Early-Life Stage Freshwater Fish | 850.1400 | 72-4A |
| Fish Life Cycle Study | 850.1500 | 72-5 |
| Seedling Germination and Seedling Emergence, Tier II | 850.4225 | 123-1A |
| Vegetative Vigor, Tier II | 850.4250 | 123-1B |

The Agency is also asking for some clarification on the following three previously submitted studies:

1) Prenatal Developmental Toxicity (Teratogenicity), Rat: Data must be submitted on test material stability, homogeneity, and concentration in the dosing medium.

2) Prenatal Developmental Toxicity (Teratogenicity), Rabbit: Data must be submitted on test material stability, homogeneity, and concentration in the dosing medium.

3) Chronic Feeding Toxicity Study, Non-Rodent: Data must be submitted on historical controls, and diet homogeneity and stability.

### 2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. Based on the review of the available data, the EPA has determined that dimethipin is eligible for a 12 hour REI on all product labels except for those containing other active ingredients with more restrictive REIs.

## 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 Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

### 2. Labeling for End-Use Products

Currently, there are no required labeling changes for dimethipin.

## VI. Appendices

| **Appendix A. Food/Feed Use Patterns Subject to Reregistration for Dimethipin** | | | | | |
|---|---|---|---|---|---|
| Site<br>Application Type<br>Application Timing<br>Application Equipment | Maximum Single Application Rate (lb ai/A) | Maximum Number of Applications Per Year | Maximum Yearly Rate (lb ai/A) | Preharvest Interval (Days) | Limitations |
| <u>*Cotton*</u> | | | <u>*Use Directions*</u>*:*<br>*Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.*<br>*Do not apply through any type of irrigation system.*<br>*Do not apply when drift is likely to occur.*<br>*Do not apply when wind velocity is 10 mph or greater.*<br>*Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.*<br>*Do not contaminate water, food, or feed by storage or disposal.*<br>*Rotational/ plant back crop restriction.* | | |
| Spray<br>After boll-opening<br>Aircraft/Ground | 0.31 | 2 | NS | 7-14 | Geographic Allowable: CA |
| Broadcast/Low volume spray (concentrate)/Spray<br>Ground<br>Fixed boom | 0.31 | 2 | NS | 7-14 | Geographic Allowable: AL, AR, FL, GA, KS, LA, MO, MS, NC, NM, OK (eastern), SC, TN, TX (eastern including the Rio Grande) |

| | | | | | |
|---|---|---|---|---|---|
| Spray<br>Pre-harvest Defoliant<br>Aircraft/Ground | 0.38 | 2 | 0.56 | 7-14 | Geographic Allowable: AL, AR, FL, GA, KS, LA, MO, MS, NC, OK (eastern), SC, TN, TX (eastern including the Rio Grande), VA |
| Spray<br>Post-Emergent Herbicide<br>Aircraft/Ground | 0.56 | 2 | 0.54 - 0.56 | 7-14 | Geographic Allowable: AL, AR, FL, GA, LA, MO, MS, NC, OK (eastern), SC, TN, TX (eastern including the Rio Grande), VA |
| <u>*NonBearing Apple Nursery Stock*</u> | | | <u>*Use Directions:*</u><br>*Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.*<br>*Do not apply through any type of irrigation system.*<br>*Do not apply when drift is likely to occur.*<br>*Do not apply when wind velocity is 10 mph or greater.*<br>*Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.*<br>*Do not contaminate water, food, or feed by storage or disposal.*<br>*Rotational/ plant back crop restriction.* | | |
| Spray | 0.08 | NS | NS | 5 | Geographic Allowable: WA-24(c) |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dimethipin

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---|---|---|---|---|
| | **PRODUCT CHEMISTRY** | | | |
| **New Guideline Number** | **Old Guideline Number** | | | |
| 830.1550 | 61-1 | Product Identity and Composition | AB | 41943801, CSF 12/17/92 |
| 830.1600<br>830.1620<br>830.1650 | 61-2A | Starting Material & Manufacturing. Process | AB | 42282701,41943802 |
| 830.1670 | 61-2B | Formation of Impurities | AB | 41943803 |
| 830.1700 | 62-1 | Preliminary Analysis | AB | 40361401, 41457601, 41967001 |
| 830.1750 | 62-2 | Certification of Limits | AB | 41967002, CSF 12/17/92 |
| 830.1800 | 62-3 | Analytical Method | AB | 41967003 |
| 830.6302 | 63-2 | Color | AB | 40410302 |
| 830.6303 | 63-3 | Physical State | AB | 40410302 |
| 830.6304 | 63-4 | Odor | AB | 40410302 |
| 830.6313 | 63-13 | Stability to Normal and Elevated Temperature, Metals and Metal Ions | AB | 40410302, 41655605, 41655606 |
| 830.7200 | 63-5 | Melting Point/ Melting Range | AB | 41655601, 40410302 |
| 830.7300 | 63-7 | Density | AB | 40410302, 41655602 |
| 830.7840 | 63-8 | Water Solubility | AB | 41967004, 41967005, 40410302 |
| 830.7950 | 63-9 | Vapor Pressure | AB | 40410302, 43898701 |
| 830.7370 | 63-10 | Dissociation Constant | AB | 41655603 |
| 830.7550 | 63-11 | Octanol/Water Partition Coefficient | AB | 42282702, 40410302 |
| 830.7000 | 63-12 | pH | AB | 40410302, 41655604 |
| | **ECOLOGICAL EFFECTS** | | | |
| 850.2100 | 71-1A | Avian Acute Oral Toxicity - Quail/Duck | AB | 41955901 |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dimethipin

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---|---|---|---|---|
| 850.2200 | 71-2A | Avian Dietary Toxicity - Quail | AB | 41945901- Supplemental |
| 850.2200 | 71-2B | Avian Dietary Toxicity - Duck | AB | 41955902 |
| 850.2300 | 71-4A | Avian Reproduction- Quail | AB | DATA GAP |
| 850.2300 | 71-4B | Avian Reproduction- Duck | AB | DATA GAP |
| 850.1075 | 72-1A | Freshwater Fish Acute Toxicity Bluegill | AB | 41945902 |
| 850.1075 | 72-1C | Freshwater Fish Acute Toxicity Rainbow Trout | AB | 41945903 |
| 850.1010 | 72-2A | Freshwater Invertebrate Acute Toxicity | AB | 41945904, 00086315 |
| 850.1010 | 72-2B | Freshwater Invertebrate Acute Toxicity (Formulated Product) | | 46063401-Supplemental |
| 850.1075 | 72-3A | Estuarine/Marine Toxicity - Fish | AB | 41663901 |
| 850.1025 | 72-3B | Estuarine/Marine Toxicity - Mollusk | AB | 42643101, 41666501 - Supplemental |
| 850.1035 | 72-3C | Estuarine/Marine Toxicity - Shrimp | AB | 41663902 |
| 850.1350 | 72-4B | Freshwater Aquatic Invertebrate- Life Cycle | AB | 128803 |
| 850.1500 | 72-4B | Fish Life Cycle Study | AB | DATA GAP |
| 850.1400 | 72-4A | Freshwater Fish- Early Life Stage | AB | DATA GAP, 00126069 -Supplemental |
| 850.3020 | 141-1 | Honey Bee Acute Contact (Formulated Product) | AB | 41264606 |
| 850.4225 | 123-1A | Seed Germ/Seedling Emergence | AB | DATA GAP |
| 850.4250 | 123-1B | Vegetative Vigor | AB | DATA GAP |
| 850.4400 | 123-2 | Aquatic Plant Growth, Tier 2 | AB | 41264605, 42627103, 42627102, 42627101, 42627104 |
| **TOXICOLOGY** | | | | |
| 870.1100 | 81-1 | Acute Oral Toxicity-Rat | AB | 42429601 |
| 870.1200 | 81-2 | Acute Dermal Toxicity-Rabbit | AB | 42429602 |
| 870.1300 | 81-3 | Acute Inhalation Toxicity-Rat | AB | 42429603 |
| 870.2400 | 81-4 | Primary Eye Irritation-Rabbit | AB | 70236 |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dimethipin

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---|---|---|---|---|
| 870.2500 | 81-5 | Primary Skin Irritation | AB | 42429604 |
| 870.2600 | 81-6 | Dermal Sensitization | AB | 42429605 |
| 870.3100 | 82-1A | 90-Day Oral Toxicity - Rat | AB | 43065901 |
| 870.3200 | 82-2 | 21/28-Day Dermal Toxicity- Rat | AB | 41944901 |
| 870.4100 | 83-1B | Chronic Feeding Toxicity - Non-Rodent (Dog) | AB | 93089030, 9389008**Upgradeable |
| 870.4200 | 83-2A | Carcinogenicity - Rat | AB | 43897601 |
| 870.4200 | 83-2B | Carcinogenicity - Mouse | AB | 93089031, 93089008 |
| 870.3700A | 83-3A | Developmental Toxicity - Rat | AB | 93089032, 93089009 **Upgradeable |
| 870.3700B | 83-3B | Developmental Toxicity - Rabbit | | 93089033, 93089010, 44988701**Upgradeable |
| 870.3800 | 83-4 | 2-Generation Reproduction - Rat | AB | 93089034, 93089011 |
| 870.5100 | 84-2 | Bacterial Reverse Gene Mutation Assay Test | | 93089035, 93089012 |
| 870.5140 | 84-2A | Gene Mutation (Ames Test) | AB | 133302 |
| 870.5300 | 84-2 | Gene Mutations in Somatic Cells in Culture (In Vitro), Mammalian | AB | 93089041, 93089029 |
| 870.5375 | 84-2B | In-Vitro Mammalian Cytogenetics Tests (Structural Chromosomal Aberration) | AB | 40479602, 133302 |
| 870.5395 | 84-2 | In-Vitro Mammalian Cytogenetics Tests (Erythrocyte Micronucleus Assay) | AB | 40479602, 41708201 |
| 870.5900 | 84-2 | In-Vitro Sister Chromatid Exchange Assay | AB | 93089036, 93089015, 42282705 |
| 870.5550 | 84-4 | Other Genotoxic Effects | AB | 40479601, 93089016 |
| 870.7485 | 85-1 | General Metabolism | AB | 41323301, 41323302, 41612401 |
| **ENVIRONMENTAL FATE** | | | | |
| None | 160-5 | Chemical Identity | | 41943801 |
| 835.2120 | 161-1 | Hydrolysis | AB | 80106- Supplemental |
| 835.2240 | 161-2 | Photodegradation - Water | AB | 41967101-Supplemental |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dimethipin

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---|---|---|---|---|
| 835.2410 | 161-3 | Photodegradation - Soil | AB | 42237601-Supplemental |
| 835.2370 | 161-4 | Photodegradation in Air | AB | N/A |
| 835.4100 | 162-1 | Aerobic Soil Metabolism | AB | 42429606-Supplemental |
| 835.4200 | 162-2 | Anaerobic Soil Metabolism | AB | N/A |
| 835.4400 | 162-3 | Anaerobic Aquatic Metabolism | AB | 42673501- Supplemental |
| 835.4300 | 162-4 | Aerobic Aquatic Metabolism | AB | N/A |
| 835.1410 | 163-2 | Laboratory Volatility | AB | N/A |
| 835.8100 | 163-3 | Field Volatility | AB | N/A |
| 835.1240<br>835.1230 | 163-1 | Leaching/Adsorption/Desorption | AB | 41660901-Supplemental |
| 835.6100 | 164-1 | Terrestrial Field Dissipation | AB | 43216001, 43216002 |
| 835.6200 | 164-2 | Aquatic Field Dissipation | AB | N/A |
| 850.1700 | 165-4 | Accumulation in Fish | AB | N/A |
| 850.2000 | 165-5 | Accumulation Aquatic Non-Target Organisms | AB | N/A |
| **RESIDUE CHEMISTRY** | | | | |
| 860.1300 | 171-4A | Nature of Residue - Plants | AB | 43436901, 00136860, 00085669 93089025 93089038 42467002, 42920903, 43109801, 43979103 |
| 860.1300 | 171-4B | Nature of Residue - Livestock | AB | 42706001, 43086701, 43922101 |
| 860.1340 | 171-4C | Residue Analytical Method - Plants/Animals | AB | 43109801* Method should be forwarded to FDA, 42920903, 93089038, 42467002,00085669 00136860 93089025 43109801[1] 43979103[2] |
| 860.1340 | 171-4D | Residue Analytical Method- Animal | AB | 43966401, 44147201, 44147202 |
| 860.1360 | 171-4M | Multiresidue Method | AB | 43096501 |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dimethipin

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---|---|---|---|---|
| 860.1380 | 171-4E | Storage Stability Data -Plant Commodities | AB | DATA GAP- 42712701, 43931401 *Storage stability data are required to support the field rotational crop studies |
| | | Storage Stability Data-Livestock Commodities | AB | 43966401, 44190001 |
| 860.1480 | 171-4J | Magnitude of Residues -Meat/Milk/Poultry /Egg | AB | 43966401,44147201,44147202 |
| 860.1500 | 171-4K | Crop Field Trials (Cotton, seed, gin byproducts) | AB | DATA GAP- 42467001, 42920901, 43184101* Crop field trial data for cotton gin byproducts must be submitted |
| 860.1520 | 171-4L | Magnitude of Residue in Processed Food/Feed | AB | 00080098, 00085666, 93089026, 93089039, 42920902 |
| 860.1850 | 165-1 | Confined Accumulation in Rotational Crops | AB | DATA GAP- 42666301, 42757801, 43768201, 43768202, 43931301* Additional storage stability data information comparing the chromatographic profiles of stored samples with those from the original analysis is required to support the supplemental confined rotational crop data |
| 860.1900 | 165-2 | Field Accumulation in Rotational Crops | AB | 43979101, 43979102 |

## Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/reregistration

These documents include:

HED Documents:

1. Dimethipin: HED Chapter of the Reregistration Eligibility Decision Document (RED). August 26, 2004.
2. Dimethipin: Residue Chemistry Considerations for Reregistration Eligibility Decision. July 22, 2004.
3. Dimethipin Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision. August 18, 2004.
4. Tier I Estimated Environmental Concentrations of Dimethipin, for use in Human Health Risk Assessment. June 24, 2004.
5. Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Dimethipin. June 8, 2004.
6. Dimethipin. HED Product Chemistry Chapter for Reregistration Eligibility Decision. March 25, 2004.
7. Dimethipin. Report of the Health Effects Division (HED) Risk Assessment Review Committee (RARC). August 5, 2004.

EFED Documents:

1. Environmental Fate and Ecological Effects Risk Assessment for the Reregistration of Dimethipin. November 18, 2004.
2. Reregistration Environmental Risk Assessment for Dimethipin. November 18, 2004.

## Appendix D. Citations Considered To Be Part of The Data Base Supporting The Interim Reregistration Decision (BIBLIOGRAPHY)

## GUIDE TO APPENDIX D

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 (1999), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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## Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Dimethipin RED for a list of studies that the Agency plans to require.

## Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

## Appendix G. EPA'S Batching of Dimethipin Products for Meeting Acute Toxicity Data Requirements For Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing dimethipin as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

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

Four products were found which contain dimethipin as the active ingredient. These products have not been placed into batch group based on the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

| No Batch | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 400-432 | 90.0 |
| | 400-155 | 48.0 |
| | 400-505 | 32.7 |
| | 400-398 | 22.4 |

## Appendix H. List of Registrants Sent this Data Call-In

Company Number: 400
Company Name: Crompton Manufacturing Company Inc.
Address: 74 Amity Road, Bethany, CT 06524-3402
Contact: Dr. Allen Blem

## Appendix I. List of Available Related Documents and Electronically Available Forms

**Pesticide Registration Forms are available at the following EPA internet site:**

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

**Instructions**

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

| | | |
|---|---|---|
| 8570-1 | Application for Pesticide Registration/Amendment | http://www.epa.gov/opprd001/forms/8570-1.pdf |
| 8570-4 | Confidential Statement of Formula | http://www.epa.gov/opprd001/forms/8570-4.pdf |
| 8570-5 | Notice of Supplemental Registration of Distribution of a Registered Pesticide Product_ | http://www.epa.gov/opprd001/forms/8570-5.pdf |
| 8570-17 | Application for an Experimental Use Permit | http://www.epa.gov/opprd001/forms/8570-17.pdf |
| 8570-25 | Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need | http://www.epa.gov/opprd001/forms/8570-25.pdf |

| | | |
|---|---|---|
| 8570-27 | Formulator's Exemption Statement | http://www.epa.gov/opprd001/forms/8570-27.pdf |
| 8570-28 | Certification of Compliance with Data Gap Procedures | http://www.epa.gov/opprd001/forms/8570-28.pdf |
| 8570-30 | Pesticide Registration Maintenance Fee Filing | http://www.epa.gov/opprd001/forms/8570-30.pdf |
| 8570-32 | Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | http://www.epa.gov/opprd001/forms/8570-32.pdf |
| 8570-34 | Certification with Respect to Citations of Data (PR Notice 98-5) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf |
| 8570-35 | Data Matrix (PR Notice 98-5) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf |
| 8570-36 | Summary of the Physical/Chemical Properties (PR Notice 98-1) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf |
| 8570-37 | Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf |

**Pesticide Registration Kit** www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
c. Biopesticides and Pollution Prevention Division (BPPD) Contacts
d. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.