



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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

SUBJECT: Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

FROM: Debra Edwards, Director
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Office of Pesticide Programs

TO: Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.¹ These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

¹ Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

Attachment A:
Organophosphates included in the OP Cumulative Assessment

| Chemical | Decision Document | Status |
|-----------------------|--------------------------|---|
| Acephate | IRED | IRED completed 9/2001 |
| Azinphos-methyl (AZM) | IRED | IRED completed 10/2001 |
| Bensulide | IRED | IRED completed 9/2000 |
| Cadusafos | TRED | TRED completed 9/2000 |
| Chlorethoxyphos | TRED | TRED completed 9/2000 |
| Chlorpyrifos | IRED | IRED completed 9/2001 |
| Coumaphos | TRED | TRED completed 2/2000 |
| DDVP (Dichlorvos) | IRED | IRED completed 6/2006 |
| Diazinon | IRED | IRED completed 7/2002 |
| Dicrotophos | IRED | IRED completed 4/2002 |
| Dimethoate | IRED | IRED completed 6/2006 |
| Disulfoton | IRED | IRED completed 3/2002 |
| Ethoprop | IRED | IRED completed 9/2001 IRED addendum completed 2/2006 |
| Fenitrothion | TRED | TRED completed 10/2000 |
| Malathion | RED | RED completed 8/2006 |
| Methamidophos | IRED | IRED completed 4/2002 |
| Methidathion | IRED | IRED completed 4/2002 |
| Methyl Parathion | IRED | IRED completed 5/2003 |
| Naled | IRED | IRED completed 1/2002 |
| Oxydemeton-methyl | IRED | IRED completed 8/2002 |
| Phorate | IRED | IRED completed 3/2001 |
| Phosalone | TRED | TRED completed 1/2001 |
| Phosmet | IRED | IRED completed 10/2001 |
| Phostebupirim | TRED | TRED completed 12/2000 |
| Pirimiphos-methyl | IRED | IRED completed 6/2001 |
| Profenofos | IRED | IRED completed 9/2000 |
| Propetamphos | IRED | IRED completed 12/2000 |
| Terbufos | IRED | IRED completed 9/2001 |
| Tetrachlorvinphos | TRED | TRED completed 12/2002 |
| Tribufos | IRED | IRED completed 12/2000 |
| Trichlorfon | TRED | TRED completed 9/2001 |



Interim Reregistration Eligibility Decision (IRED)

Bensulide



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide bensulide. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on June 16, 1999. Additionally, the Agency held a Technical Briefing on June 16, 1999, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on June 16, 1999, and closed on August 16, 1999.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of bensulide. The EPA is now publishing its interim reregistration eligibility and risk management decision for the current uses of bensulide and its associated human health and environmental risks. The tolerance reassessment decision for bensulide will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The Agency's decision on the individual chemical bensulide can be found in the attached document entitled, "Interim Reregistration Eligibility Decision for Bensulide."

A Notice of Availability for this Interim Reregistration Eligibility Decision for Bensulide is published in the *Federal Register*. To obtain a copy of the Interim RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the Interim RED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/op>.

The Interim RED is based on the updated technical information found in the bensulide public docket. The docket not only includes background information and comments on the Agency's

preliminary risk assessments, it also now includes the Agency's revised risk assessments for bensulide (revised as of June 16, 1999 and updated in two February, 2000 addenda), and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For bensulide, a proposal was submitted by Gowan Company, the technical registrant. Comments on mitigation or mitigation suggestions were submitted by an environmental organization, an agricultural extension agent, and various golf course organizations.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

Please note that the bensulide risk assessment and the attached Interim RED concern only this particular organophosphate. This Interim RED presents the Agency's reregistration decision except for the decision on tolerance reassessment. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing the risk assessments for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks that have already been attributed to current uses of bensulide. The Agency will issue the final tolerance reassessment decision for bensulide once the cumulative assessment for all of the organophosphates is complete.

This document contains generic and product-specific Data Call-In (DCI) notices that outline further data requirements for this chemical. Registrants must respond to the DCIs issued by the Agency within 90 days of receipt of this letter.

End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV. of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V. of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Jacqueline McQueen at (703) 308-8164.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

**Interim Reregistration Eligibility Decision
for
Bensulide**

TABLE OF CONTENTS

| | |
|---|-----|
| BENSULIDE TEAM | i |
| GLOSSARY OF TERMS AND ABBREVIATIONS | iii |
| EXECUTIVE SUMMARY | 1 |
| I. INTRODUCTION | 4 |
| II. CHEMICAL OVERVIEW | 6 |
| A. Regulatory History | 6 |
| B. Chemical Identification | 6 |
| C. Use Profile | 7 |
| D. Estimated Usage of Pesticide | 8 |
| III. SUMMARY OF BENSULIDE RISK ASSESSMENT | 9 |
| A. Human Health Risk Assessment | 10 |
| 1. Dietary Risk from Food | 10 |
| a. Toxicity | 10 |
| b. FQPA Safety Factor | 11 |
| c. Population Adjusted Dose (PAD) | 11 |
| d. Exposure Assumptions | 11 |
| e. Food Risk Characterization | 12 |
| 2. Dietary Risk from Drinking Water | 13 |
| a. Surface Water | 13 |
| b. Ground Water | 13 |
| c. Drinking Water Levels of Comparison (DWLOCs) | 14 |
| 3. Occupational and Residential Risk | 16 |
| a. Toxicity | 16 |
| b. Exposure | 17 |
| c. Occupational & Residential Handler Risk Summary | 19 |
| 1) Agricultural Handler Risk | 19 |
| 2) Golf Course & Other Professional Turf Use Risk | 21 |
| 3) Post-Application Occupational Risk | 25 |
| 4) Residential (Homeowner) Handler Risk | 26 |
| 5) Residential Post-Application Risk | 27 |
| 4. Aggregate Risk | 28 |

| | | |
|-----|--|----|
| B. | Environmental Risk Assessment | 29 |
| 1. | Environmental Fate and Transport | 30 |
| 2. | Risk to Birds and Mammals | 30 |
| 3. | Risk to Aquatic Species | 31 |
| IV. | INTERIM RISK MANAGEMENT AND REREGISTRATION DECISION | 32 |
| A. | Determination of Interim Reregistration Eligibility | 32 |
| B. | Summary of Phase 5 Comments and Responses | 33 |
| C. | Regulatory Position | 34 |
| 1. | FQPA Assessment | 34 |
| a. | “Risk Cup” Determination | 34 |
| b. | Tolerance Summary | 35 |
| 2. | Endocrine Disruptor Effects | 36 |
| 3. | Required Label Modifications | 37 |
| a. | Agricultural and Turf Uses: Occupational and Ecological Risk Mitigation | 37 |
| b. | Homeowner Use: Homeowner and Ecological Risk Mitigation | 38 |
| D. | Regulatory Rationale | 38 |
| 1. | Human Health Risk Mitigation | 38 |
| a. | Dietary Mitigation | 38 |
| 1) | Acute Dietary (Food) | 38 |
| 2) | Chronic Dietary (Food) | 39 |
| 3) | Drinking Water | 39 |
| b. | Occupational Risk Mitigation | 39 |
| 1) | Agricultural Uses | 39 |
| 2) | Golf Course and Professional Turf Uses | 40 |
| c. | Homeowner Risk Mitigation | 41 |
| 1) | Handler Risk | 41 |
| 2) | Post-Application Risk | 42 |
| 2. | Environmental Risk Mitigation | 42 |
| E. | Other Labeling Requirements | 43 |
| 1. | Endangered Species Statement | 43 |
| 2. | Spray Drift Management | 43 |
| V. | WHAT REGISTRANTS MUST DO | 44 |
| A. | Manufacturing Use Products | 44 |
| 1. | Additional Generic Data Requirements | 44 |
| 2. | Labeling Requirements for Manufacturing Use Products | 45 |
| B. | End-Use Products | 45 |
| 1. | Additional Generic Data Requirements | 45 |

| | | |
|-------------|--|-----|
| 2. | Labeling Requirements for End-Use Products | 45 |
| C. | Existing Stocks | 46 |
| D. | Required Labeling Changes Summary Table | 47 |
| VI. | RELATED DOCUMENTS AND HOW TO ACCESS THEM | 57 |
| VII. | APPENDICES | 59 |
| Appendix A. | TABLE OF USE PATTERNS ELIGIBLE FOR INTERIM REREGISTRATION | 61 |
| Appendix B. | TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE INTERIM REREGISTRATION DECISION | 71 |
| Appendix C. | TECHNICAL SUPPORT DOCUMENTS | 79 |
| Appendix D. | CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE INTERIM REREGISTRATION DECISION (BIBLIOGRAPHY) | 81 |
| Appendix E. | GENERIC DATA CALL-IN | 101 |
| Appendix F. | PRODUCT SPECIFIC DATA CALL-IN | 105 |
| Appendix G. | EPA'S BATCHING OF BENSULIDE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION | 113 |
| Appendix H. | LIST OF REGISTRANTS SENT THIS DATA CALL-IN | 119 |
| Appendix I. | LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS | 121 |

BENSULIDE TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|--------|--|
| AE | Acid Equivalent |
| a.i. | Active Ingredient |
| AGDCI | Agricultural Data Call-In |
| ai | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| AR | Anticipated Residue |
| ARC | Anticipated Residue Contribution |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| CI | Cation |
| CNS | Central Nervous System |
| cPAD | Chronic Population Adjusted Dose |
| CSF | Confidential Statement of Formula |
| CFR | Code of Federal Regulations |
| CSFII | USDA Continuing Surveys for Food Intake by Individuals |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| DFR | Dislodgeable Foliar Residue |
| DRES | Dietary Risk Evaluation System |
| DWEL | Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur. |
| DWLOC | Drinking Water Level of Comparison. |
| EC | Emulsifiable Concentrate Formulation |
| EEC | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem. |
| EP | End-Use Product |
| EPA | U.S. Environmental Protection Agency |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| G | Granular Formulation |
| GENEEC | Tier I Surface Water Computer Model |
| GLC | Gas Liquid Chromatography |
| GLN | Guideline Number |

GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|------------------|--|
| GM | Geometric Mean |
| GRAS | Generally Recognized as Safe as Designated by FDA |
| HA | Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur. |
| HAFT | Highest Average Field Trial |
| HDT | Highest Dose Tested |
| 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. |
| LEL | Lowest Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOAEL | Lowest Observed Adverse Effect Level |
| MATC | Maximum Acceptable Toxicant Concentration |
| MCLG | Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act. |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MP | Manufacturing-Use Product |
| MPI | Maximum Permissible Intake |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| NA | Not Applicable |
| N/A | Not Applicable |
| NAWQA | USGS National Water Quality Assessment |
| NOEC | No Observable Effect Concentration |
| NOEL | No Observed Effect Level |
| NOAEL | No Observed Adverse Effect Level |
| NPDES | National Pollutant Discharge Elimination System |
| NR | Not Required |
| OP | Organophosphate |

GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|------------------|--|
| OPP | EPA Office of Pesticide Programs |
| OPPTS | EPA Office of Prevention, Pesticides and Toxic Substances |
| Pa | pascal, the pressure exerted by a force of one newton acting on an area of one square meter. |
| PAD | Population Adjusted Dose |
| PADI | Provisional Acceptable Daily Intake |
| PAG | Pesticide Assessment Guideline |
| PAM | Pesticide Analytical Method |
| 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 |
| PRN | Pesticide Registration Notice |
| 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 |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RQ | Risk Quotient |
| RS | Registration Standard |
| RUP | Restricted Use Pesticide |
| SAP | Science Advisory Panel |
| SCI-GROW | Tier I Ground Water Computer Model |
| SF | Safety Factor |
| SLC | Single Layer Clothing |
| SLN | Special Local Need (Registrations Under Section 24(c) of FIFRA) |
| TC | Toxic Concentration. The concentration at which a substance produces a toxic effect. |
| TD | Toxic Dose. The dose at which a substance produces a toxic effect. |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TLC | Thin Layer Chromatography |

GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|------|---|
| TMRC | Theoretical Maximum Residue Contribution |
| torr | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions. |
| TRR | Total Radioactive Residue |
| UF | Uncertainty Factor |
| µg/g | Micrograms Per Gram |
| µg/L | Micrograms Per Liter |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| UV | Ultraviolet ADI Acceptable Daily Intake. A now defunct term for reference dose (RfD). |

EXECUTIVE SUMMARY

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for bensulide. The decisions outlined in this document do not include the final tolerance reassessment decision for bensulide; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. A single tolerance will be revoked now, because there are no currently registered uses; one tolerance will be modified, and several other commodity definitions will be corrected. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for bensulide once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on bensulide. After considering the revised risks, as well as mitigation proposed by Gowan Company, the technical registrant of bensulide, and comments and mitigation suggestions from other interested parties including the Natural Resources Defense Council, several golf course organizations, and an agricultural extension agent, EPA developed its risk management decision for uses of bensulide that pose risks of concern. This decision is discussed fully in this document.

Bensulide is an organophosphate herbicide used on a variety of weeds, first registered in 1964 for pre-emergence control of crabgrass and annual bluegrass in turf. In 1968 bensulide was registered for weed control in food crops. Bensulide turf uses include golf courses and home lawns, and ornamentals. Use data from 1987 to 1996 indicate an average domestic use of approximately 550,000 lbs a.i. per year.

Overall Risk Summary

EPA's human health risk assessment for bensulide indicates some risk concerns. Food risk, both acute and chronic, is well below the Agency's level of concern. Similarly, drinking water risk estimates based on screening models, from both ground and surface water for acute and chronic exposures, is not of concern for all populations. There are, however, concerns for workers who mix, load, and apply bensulide to agricultural sites, golf courses, and home lawns. Additionally, there are concerns for homeowners who apply bensulide, and for children entering areas treated with bensulide if label requirements are not followed properly. Also, EPA has identified chronic risk to birds and mammals that exceed the Agency's level of concern.

To mitigate risks of concern posed by the uses of bensulide, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the worker, residential,

and ecological concerns. Results of the risk assessments, and required label amendments to mitigate those risks, are presented in this Interim RED.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to bensulide.

Occupational Risk- Agricultural Uses

Occupational exposure to bensulide is of concern to the Agency, and it has been determined that a number of mitigation measures are required. For the agricultural uses of bensulide, several mixer/loader/ applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than 100). EPA believes these risks can be mitigated to an acceptable level with the following label restrictions: addition of personal protective equipment or the use of closed systems, and restriction of chemigation to use only in certain states, where extensive data show that the number of acres treated is significantly lower than the Agency's standard assumptions. There are no re-entry risks of concern for workers entering bensulide-treated agricultural sites. Therefore, with the addition of the label restrictions and amendments detailed in this document, the Agency has determined that, until the outcome of the cumulative risk assessment for all of the organophosphates has been decided, all currently registered agricultural uses of bensulide may continue.

Occupational Risk- Turf Uses

Occupational exposure from the turf uses of bensulide is also of concern. Most risks to professional applicators of bensulide on turf stem from use of high exposure, handheld equipment. Although the addition of respirators can adequately protect against inhalation exposure, combined dermal and inhalation risks from most handheld equipment cannot be adequately mitigated – therefore, all but one of the handheld application methods that have risk concerns are being prohibited. The remaining hand-held method that has a risk concern is being retained for spot treatment only; this will mitigate risk to an acceptable level. The treatment of large turf areas other than golf courses is also being prohibited. This prohibition will help to mitigate not only the worker risk but also risk to children when bensulide is not applied properly, and the ecological risk discussed below.

For all remaining mixer and/or loader turf uses, respirators and gloves are required. For commercial or "for hire" applicators (a group that is likely to have multiple exposures) who apply bensulide to turf, respirators are required. For workers applying granulars with a push spreader, coveralls, gloves and a respirator are required.

Residential Risk

Risks to homeowner handlers using a handheld rotary application method (e.g., bellygrinder) to apply granular formulations of bensulide, and post-application risks to children when bensulide is not properly watered-in, are of concern to the Agency. The addition of label language to homeowner products prohibiting use of any handheld application method, as well as specific language directing homeowners to water in the herbicide as soon as possible, for efficacy and safety purposes, will mitigate these remaining risks.

Ecological Risk

Ecological risks are also of concern to the Agency. Turf use of bensulide poses greater risk concerns to aquatic, terrestrial and avian species than the agricultural uses. The high turf use rates, the persistence of the chemical, and the potential for surface water runoff all contribute to the ecological concerns from turf. Of particular concern is the potential for chronic avian risk, especially because avian species tend to be attracted to large turf areas (e.g., golf course fairways, parks) and may nest, feed or forage near or on these areas.

The mitigation measures that the Agency is requiring for the turf uses are expected to mitigate the potential for ecological risks. These measures include: prohibiting use on large non-golf course turf sites (e.g., parks and recreational areas), restriction of the golf course fairway use to a single grass type (i.e., bentgrass), and to certain states where bensulide serves a limited, but important purpose, and restriction of the number of fairway applications to one. To address at least in part the chronic avian risk, the Agency is further requiring that the fairway application be limited to the fall, to minimize exposure to birds during the breeding season, thereby mitigating the risk of reproductive impairment. While the Agency recognizes that this will not alleviate the risk entirely, it will provide some degree of protection.

For the turf uses of bensulide, the Agency has determined that, with the adoption of all of the label amendments and clarifications noted in this document, these uses may continue until the outcome of the cumulative assessment of all of the organophosphates has been decided.

The Agency is issuing this Interim Reregistration Eligibility Document (RED) for bensulide, as announced in a Notice of Availability published in the *Federal Register*. This Interim RED document includes guidance and time frames for complying with any required label changes for products containing bensulide. Note that there is no comment period for this document, and that the time frames for compliance with the required changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for bensulide have already been subject to numerous public comment periods, and a further comment period for bensulide was deemed unnecessary. The Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management

decision. With regard to complying with the requirements in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for bensulide can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further required risk mitigation measures for bensulide.

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 hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Bensulide belongs to a group of pesticides called organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency’s reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency’s revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the interim reregistration eligibility decision for bensulide. It is intended to be only the first phase in the reregistration process for bensulide. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The

TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- C Applying the FQPA 10-Fold Safety Factor
- C Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- C How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- C Refining Dietary (Food) Exposure Estimates
- C Refining Dietary (Drinking Water) Exposure Estimates
- C Assessing Residential Exposure
- C Aggregating Exposure from all Non-Occupational Sources
- C How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- C Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- C Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency published in the *Federal Register* on August 12, 1999 a draft Pesticide Registration Notice that presents EPA's proposed approach for managing risks from organophosphate pesticides to occupational users. This notice describes the Agency's baseline approach to managing risks to handlers and workers of organophosphate pesticides. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals will be required for most uses where current risk assessments indicate a risk and such protective measures are feasible. The draft guidance policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this Interim RED are consistent with that draft Pesticide Registration Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim reregistration eligibility and risk management decisions. Section V summarizes required label changes based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments

and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides/op, and in the Public Docket.

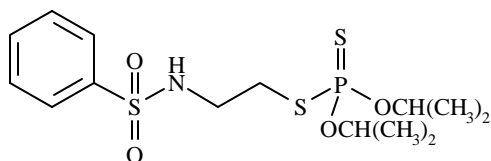
II. CHEMICAL OVERVIEW

A. Regulatory History

Bensulide was first registered in the United States in 1964 for pre-emergence control of crabgrass and annual blue grass on turf. In 1968 bensulide was registered for weed control in food crops.

B. Chemical Identification

BENSULIDE:



| | |
|------------------------|--|
| ! Common Name: | Bensulide |
| ! Bensulide: | [S-(O,O-diisopropyl phosphorodithioate) ester of N-(2-mercapto)benzenesulfonamide] |
| ! Chemical family: | Organophosphate |
| ! Case number: | 2035 |
| ! CAS registry number: | 741-58-2 |
| ! OPP chemical code: | 009801 |
| ! Empirical formula: | C ₁₄ H ₂₄ NO ₄ PS ₃ |
| ! Molecular weight: | 397.5 |

! Trade and other names: Prefar® 4-E; Prefar® 6-E; Bensumec® 4-LF; Pre-San® Granular 7G & 12.5G; Betasan® 4-E, 3G & 12.5G

! Basic manufacturer: Gowan Company (technical registrant)

Pure bensulide is a colorless solid with a melting point of 34.4°C. Technical bensulide is a viscous amber liquid at temperatures above 34°C and a solid below this temperature. Bensulide is soluble in water at 25 ppm at 20°C and is miscible with acetone, ethanol, 4-methylpentan-2-one, and xylene.

C. Use Profile

The following information is based on the currently registered uses of bensulide.

Type of Pesticide: Herbicide.

Summary of Use Sites:

Food: Bensulide is used for preemergent control of annual grasses and broadleaf weeds in agricultural crops (60-65% of all use). Current registered use sites are: carrots, fruiting vegetables, leafy vegetables (mostly head lettuce), dry bulb vegetables (onions), cucurbits (mostly melons), and cole crops (cauliflower, cabbage, broccoli, broccolini, broccoflower).

Other agricultural sites: Used on field grown herbaceous plants and field grown bulbs.

Residential: Products containing bensulide are intended for outdoor homeowner use on lawns and ornamentals, and application by professional lawn care operators to lawns, ornamentals, parks, and recreation areas.

Public Health: None.

Other Nonfood: Terrestrial non-food crops (i.e., turf, primarily golf course greens and tees).

Target Pests: Weeds include annual bluegrass; annual broadleaf; annual grasses; barnyardgrass; burning nettle; canarygrass; crabgrass; etc.

Formulation Types Registered: In addition to the technical, there are two end-use formulations: a granular formulation and an emulsifiable concentrate.

Method and Rates of Application:

Equipment - Groundboom, tractor drawn spreader, drip or sprinkler irrigation (chemigation), low pressure handwand, high pressure handwand, backpack sprayer, low pressure/high volume turfgun, push spreader, hand-held rotary spreader (bellygrinder).

Method and Rate - Soil incorporated, applied preemergent or preplant.

- Agricultural use rate is typically 5-6 lbs ai/acre, and the 6 lb rate is often used. In the southwest deserts, may be applied twice per year at up to 6 lbs/acre, for a maximum of 12 lbs ai/acre/year. The ornamental use for field grown plants and bulbs is applied at rates up to 9 lbs ai/acre, one time per year. Applied by groundboom or with sprinkler and chemigation systems.
- Turf use rates are typically 7.5 to 12.5 lbs ai/acre per application, applied twice per year, for a maximum of 25 lbs ai/year.

Timing - preemergence; preplant.

Use Classification: Bensulide is a general use product, registered for a variety of terrestrial food crops, terrestrial non-food crops, and outdoor residential uses.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of bensulide, based on available pesticide usage information for 1987 through 1996. A full listing of all uses of bensulide, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 550,000 lbs a.i. of bensulide are used annually, according to Agency and registrant estimates.

Table 1. Bensulide Estimated Usage for Representative Sites

| Crop | Lbs. Active Ingredient Applied (Wt. Avg.) ¹ | Percent Crop Treated (Likely Maximum) | Percent Crop Treated (Wt. Avg.) |
|--|--|---------------------------------------|---------------------------------|
| Cantaloupes | 36,000 | 24% | 22% |
| Carrots | 9,000 | 3% | 2% |
| Celery | 6,000 | 13% | 4% |
| Cole Crops (broccoli, cabbage, cauliflower) | 37,000 | 10% | 5% |
| Cucumbers (fresh and process) | 33,000 | 9% | 6% |
| Honeydew | 16,000 | 34% | 18% |
| Lettuce | 67,000 | 19% | 7% |
| Onions | 99,000 | 23% | 11% |
| Peppers (bell, hot, and sweet) | 32,000 | 12% | 4% |
| Pumpkins | 6,000 | 35% | 19% |
| Squash | 12,000 | 38% | 21% |
| Watermelons | 12,000 | 9% | 5% |
| Golf Courses | 68,000 | <2% | <2% |
| Lawn Care Operators (including residential and landscape) | 20,000 | <1% | <1 % |
| Lawn, Homeowners | <100,000 | <2% | <2% |
| Public/Government | 1,000 | unknown | unknown |
| Field grown herbaceous plants and bulbs | <1,800 | unknown | unknown |

¹Weighted Average is based on data for 1987-1996; the most recent years and more reliable data are weighted more heavily.

III. SUMMARY OF BENSULIDE RISK ASSESSMENT

Following is a summary of EPA’s revised human health and ecological risk findings and conclusions for the organophosphate pesticide bensulide, as fully presented in the documents, “Bensulide Revised HED Chapter for the Reregistration Eligibility Decision Document,” dated June 15, 1999 (and addenda thereto), and “Revised EFED Chapter for Bensulide,” dated June 14, 1999 (and addenda thereto). The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

These risk assessments for bensulide were presented at a June 16, 1999 Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for bensulide only; the Agency must complete a cumulative assessment of the risks of all the organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for bensulide in August, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. The first five revisions noted below occurred as a result of comments received during Phase 3 and prior to the technical briefing for bensulide. During Phase 6 of the TRAC process; that is, after all public comment periods were over, the Agency incorporated the last point noted below into the risk assessment. The last revision was done as a result of an internal policy change. Major revisions to the human health risk assessment are listed below:

- Use of a 21-day dermal toxicity study to determine a dermal NOAEL for use in the occupational and residential risk assessment.
- Use of data from a transferable and total turf residue study in the assessment of post-application occupational and residential risks.
- Use of separate toxicological endpoints for dermal and inhalation exposures for the occupational and residential handler assessments.
- Addition of exposure scenarios to the occupational handler risk assessment based on registrant comments regarding bensulide use on golf courses.
- Consideration of exposure to children from non-dietary ingestion after contact with bensulide-treated turf.
- Use of GENEEC instead of PRZM-EXAMS to estimate environmental concentrations resulting from turf uses, for use in the drinking water assessment.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Confirmatory data are being required and are included in section V of this document.

Further details on the toxicity of bensulide can be found in the June 16, 1999 Human Health Risk Assessment and subsequent addenda. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1.

c. Population Adjusted Dose (PAD)

The PAD is a relatively new term that characterizes the dietary risk of a chemical, and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of bensulide, the FQPA safety factor is 1; therefore, the acute or chronic RfD = the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for bensulide were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91.

The Tier I acute dietary analysis used tolerance levels and assumed 100% of the registered commodities were treated. It is noted that bensulide residues have never been detected in field trials. The chronic dietary analysis used tolerance level residues and was refined with weighted average percent crop treated data. FDA monitoring data was not used to refine the assessment, given the low chronic dietary risk estimates based just on the tolerance-level residues and percent crop treated information.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Bensulide

| Assessment | Dose | Endpoint | Study | UF | FQPA Safety Factor | PAD |
|------------------------|-----------------------|--|---|-----|--------------------|-----------------|
| Acute Dietary | NOAEL = 15 mg/kg/day | Plasma ChE inhibition | Acute rat neurotoxicity (MRID 43195901) | 100 | 1X | 0.15 mg/kg/day |
| Chronic Dietary | NOAEL = 0.5 mg/kg/day | Plasma, brain ChE inhibition, decreased body weight gain | Chronic oral dog (MRIDs 44066401, 44052704) | 100 | 1X | 0.005 mg/kg/day |

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency’s risk concerns. The bensulide acute dietary risk from food is well below the Agency’s level of concern –that is, less than 100% of the acute PAD is utilized. For example, for the most exposed subgroups, children (1-6 years) and infants (<1 year), the % acute PAD values are less than 1% at the 95th percentile of exposure. The 95th percentile is reported here, because a Tier I deterministic assessment was conducted. A probabilistic assessment was not conducted at this time because the results of the Tier I assessment were so low.

Similarly, the chronic dietary risk from food alone is well below the Agency’s level of concern. For the most exposed subgroups, the % chronic PAD values are also less than 1%. In summary, both acute and chronic dietary exposure and risk associated with bensulide-treated foods are considered to be well below the Agency’s level of concern, even when tolerance-level residue values are used.

Refinements to the dietary analyses can be made using monitoring data for the chronic dietary analysis, and a probabilistic assessment for acute dietary analysis; however, given the low dietary risk estimates based on tolerance level residues and percent crop treated information, the Agency determined that further refinements are not warranted at this time. Refinements will be considered when the cumulative assessment for all of the organophosphates is conducted.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate of risk. In the case of bensulide, no monitoring data for either ground or surface water were available; therefore, modeling was used to estimate drinking water risks from these sources.

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than the other two.

Based on environmental fate data, bensulide is very persistent but not mobile in soil. There is uncertainty as to the fate of bensulide degradates in soil; however, based on the persistent qualities of the bensulide parent, the degradates are also expected to persist.

a. Surface Water

Based on its environmental fate characteristics, bensulide has the potential to be transported in water and on suspended sediment in runoff to surface waters. In its initial assessment, EPA used a Tier II PRZM-EXAMS screening model to estimate the upper-bound bensulide concentrations in drinking water derived from surface water for the agricultural as well as the turf uses. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. However, since this assessment was completed, the Agency has determined that the scenario used in PRZM-EXAMS does not have the appropriate parameters to accurately model turf runoff; therefore, the GENEEC model was used to model turf uses. PRZM-EXAMS continues to be used for agricultural uses.

The updated environmental concentrations for the turf uses using the GENEEC model are found in the 2/10/00 memo entitled, "Revised Estimated Environmental Concentrations in Ground and Surface Water for Bensulide used on Golf Course Fairways." The memo presents two scenarios for the turf use: one scenario modeled the high use rate and the maximum number of applications (i.e., 2) per year currently allowed on the label, the other modeled the high use rate and one application per year, to reflect proposed mitigation for ecological effects discussed in Section IV of this document.

b. Ground Water

Bensulide is not expected to leach to ground water because its high soil sorption affinity indicates that it will bind to soil organic matter. A Tier I screening model, SCI-GROW, was used to estimate

drinking water concentrations derived from ground water. There were two modeled scenarios: the first used maximum application rates, maximum number of applications allowed per year, irrigation, and very shallow ground water to simulate “high-end” exposures. The second differed in that it used only one application per year, to reflect proposed mitigation for ecological effects discussed in Section IV of this document.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a “drinking water level of comparison”(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency’s drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the HED Human Health Risk Assessment, dated June 16, 1999 and the memo entitled, “Addendum to HED Chapter for the Reregistration Eligibility Decision Document. New Estimated Water Concentrations from EFED,” dated 2/11/00.

For acute risk, the potential drinking water exposure derived from either ground or surface water is not of concern for all populations. That is, the environmental concentrations resulting from both the agricultural uses and turf uses (at either 1 application per year or two applications per year) are well below the DWLOCs. The table below presents the calculations for the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Acute Risk

| Population Subgroup | Acute PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Allowable Water Exposure (mg/kg/day) | Ground Water ¹ (ppb) (SCI-GROW) | Surface Water ² (ppb) (GENEEC) | Surface Water (ppb) ³ (PRZM-EXAMS) | DWLOC (ppb) |
|------------------------|-----------------------|---------------------------|--------------------------------------|--|---|---|-------------|
| U.S. Population | 0.15 | 0.000059 | 0.149941 | 0.5/1.0 | 106/189 | 165 | 5248 |
| Females 13-19 | 0.15 | 0.000060 | 0.14994 | 0.5/1.0 | 106/189 | 165 | 4498 |
| Children 1-6 | 0.15 | 0.000122 | 0.149878 | 0.5/1.0 | 106/189 | 165 | 1499 |

¹ The value of 0.5 ppb is with 1 turf application, the 1.0 ppb value is with 2 turf applications per year.

² The value of 106 ppb is with 1 turf application, 189 ppb is with 2 turf applications per year.

³ The value of 165 ppb is with broadcast vegetable application.

For chronic risk, potential exposure to drinking water derived from groundwater is not of concern for all populations. Groundwater estimates are well below the DWLOC regardless of whether one or two turf applications per year are applied. Also, potential exposure to drinking water derived from surface water resulting from the turf uses is not of concern, when either one or two applications per year are used. In either case, the environmental concentrations are below the DWLOC.

For chronic risk from the agricultural uses of bensulide, potential exposure to drinking water derived from surface water results in estimated environmental concentrations that are higher than the DWLOCs for two groups: females (13+, nursing) and non-nursing infants (< 1 year). For the general U.S. population, environmental concentrations are not of concern; that is, they are less than the DWLOC. For the group “females 13+, nursing,” the estimated environmental concentration is only slightly higher than the DWLOC, and the difference is considered to be insignificant. For the group “non-nursing infants,” the estimated environmental concentration is approximately three times higher than the DWLOC.

Even though the DWLOC is exceeded for some populations, the Agency has determined that this chronic drinking water risk estimate from the agricultural uses of bensulide is not of concern. In making this determination, the Agency considered the fact that PRZM-EXAMS is a Tier II model, and is considered to be a screening-level assessment. The results, even though they exceed in some cases, are considered to be health-protective because the estimated drinking water exposures are based on conservative modeling estimates and are expected to be higher than those actually found in drinking water. Also, bensulide is used on agricultural crops primarily in the Southwestern United States, where the climate is dry and rainfall is low. In these areas, surface water run-off is not expected to occur in significant amounts. The table below presents the calculations for the chronic drinking water assessment.

Table 4. Summary of DWLOC Calculations for Chronic Risk

| Population Subgroup | Chronic PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Allowable Water Exposure (mg/kg/day) | Ground Water (ppb) ¹ | Surface Water (ppb) ^{2,4} (GENEEC) | Surface Water (ppb) ³ (PRZM-EXAMS) | DWLOC (ppb) |
|---------------------------------------|-------------------------|---------------------------|--------------------------------------|---------------------------------|---|---|-------------|
| U.S. Population | 0.005 | 0.000015 | 0.004985 | 0.5/1.0 | 19/34 | 158 | 174 |
| Females (13+, nursing) | 0.005 | 0.000019 | 0.004981 | 0.5/1.0 | 19/34 | 158 | 150 |
| Non-nursing Infants (<1 yr) | 0.005 | 0.000039 | 0.004961 | 0.5/1.0 | 19/34 | 158 | 50 |

¹ The value of 0.5 ppb is with 1 turf application/year, the 1.0 ppb value is with 2 turf applications/year.

² The value of 19 ppb is with 1 turf application/year, 34 ppb is with 2 turf applications/year.

³ The value of 158 ppb is with broadcast vegetable application.

⁴ GENEEC values have been adjusted per SOP 99-5 to obtain a long-term average estimate. This SOP is cited and discussed in more detail in the February 11, 2000 addendum to the HED chapter available in the public docket.

3. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Occupational handlers of bensulide include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators, and lawncare and turf management professionals who treat either individual areas (e.g., a golf course superintendent who is responsible for his own course) or “for hire” handlers who treat multiple areas, and who may be exposed over multiple days. Residential handlers include homeowner applicators treating their own lawns. Bensulide exposure to adults and children can also occur from exposure to treated lawns or other turf areas. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency’s risk concern.

a. Toxicity

The toxicity of bensulide is integral to assessing the occupational and residential risk. All risk calculations are based on the most current toxicity information available for bensulide, including a 21-day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for bensulide are listed below.

Table 5. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Bensulide

| Assessment | Dose | Endpoint | Study | Absorption factor |
|----------------------------------|---------------------------|--|--|-------------------|
| Short-term dermal | NOAEL = 50 mg/kg/day | Plasma, brain ChE inhibition | 21-day dermal rat (MRIDs 44801101, 44809401) | N/A |
| Intermediate-term dermal | NOAEL = 50 mg/kg/day | Plasma, brain ChE inhibition | 21-day dermal rat (MRIDs 44801101, 44809401) | N/A |
| Short-term inhalation | Oral NOAEL= 5.5 mg/kg/day | maternal plasma ChE inhibition | developmental oral rat (MRID 00146585) | 100% |
| Intermediate - term inhalation | Oral NOAEL= 0.5 mg/kg/day | plasma ChE inhibition, decreased body weight gain. | chronic oral dog (MRIDs 44066401, 44052704) | 100% |
| Non-dietary ingestion (children) | NOAEL = 15 mg/kg/day | Plasma ChE | acute rat neurotoxicity (MRID 43195901) | N/A |

b. Exposure

Chemical-specific exposure data were not available for bensulide, so risks to pesticide handlers were assessed using data from the *Pesticide Handlers Exposure Database (PHED)*, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. to calculate risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from bensulide labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for bensulide, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on bensulide labels range from 3 to 6 pounds of active ingredient per acre in agricultural settings, and from 7.5 to 12.5 pounds of active

ingredient per acre on turf. The Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for specific types of application equipment. However, as the registrant supplied different values on acres treated per day for chemigation (40 acres of field typically applied per day by an applicator versus 350 acres potentially applied per day by an applicator) and golf courses (7 acres of greens and tees as opposed to 40 acres for an entire golf course), the Agency included these values in its assessment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls (EC)). The current labels for bensulide require handlers to wear long pants, a long-sleeved shirt, and chemical-resistant gloves. The levels of protection that formed the basis for calculations of exposure from bensulide activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Label: Long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves.
- Minimum PPE: Baseline + chemical resistant gloves and a respirator.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and a respirator.
- Engineering controls: Engineering controls such as a closed cab tractor or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods; there are no known devices that can be used to routinely lower the exposures for these methods.

For handlers, both short-term and intermediate-term assessments were conducted for bensulide, to reflect exposures of either 1-7 days, or one week to several month durations, respectively. For bensulide, which is applied as a preemergent or preplant herbicide no more than twice a year, short-term exposures are typically associated with private or individual growers or turf management professionals who treat their own fields or turf sites. Intermediate-term exposures would be more representative of commercial agricultural applicators, or “for hire” turf applicators, who would have multiple exposures through treatment of agricultural or turf areas over the course of seven days or more. MOEs for all short and intermediate-term scenarios may be found in the June 16, 1999 Human Health Assessment for Bensulide.

For the residential handler risk assessment, all application of bensulide by homeowners to turf is considered to be short-term, and assumes that no protective clothing is used. A recently submitted turf transferable residue (TTR) study was used in the residential assessment, to better define the amount of residues on bensulide-treated turf. All residential MOEs are discussed in the Human Health Assessment for bensulide.

Finally, exposure to workers through entry into agricultural fields treated with bensulide, and post-application exposure to homeowners entering or playing on lawns treated with bensulide were also considered.

c. Occupational & Residential Handler Risk Summary

In the revised assessment, risks for handlers were assessed using separate toxicological endpoints for both dermal and inhalation exposures. The resulting risks (MOE values) were then added in order to obtain an overall risk for each applicator that accounted for both dermal and inhalation exposures. Additionally, where it was logical, the risks associated with certain job functions were combined (e.g., a grower mixing/loading and then applying a spray solution to their own crops). Dermal and inhalation risks are mitigated using different types of protective equipment, so it may be acceptable to add a pair of gloves and not a respirator, and vice versa. All of the risk calculations for handlers completed in this assessment are included in Appendix A of the HED chapter, dated June 16, 1999.

For agricultural uses of bensulide, three different exposure scenarios were assessed. For occupational uses on turf and ornamentals, 10 exposure scenarios were assessed. Residential use by homeowners accounted for the remaining 2 exposure scenarios. Within each of the scenarios, further analyses were conducted to determine the MOE at minimum and maximum application rates, and at maximum and typical acreage, where applicable. Each of these analyses is included in Appendix A, Tables 1-10 of the HED chapter. Tables 1 through 6 of Appendix A in the HED chapter illustrate how the calculations were performed to define the MOEs for handlers in this risk assessment. Tables 7 and 8 provide summaries of the MOE values calculated for each route of exposure, dermal and inhalation, respectively, in the risk assessment. Tables 9 and 10 provide the information that is key to interpreting the overall results of the risk assessment because they contain the overall risks calculated using several combinations of personal protection. The reader is referred to these tables for more information on this comprehensive assessment.

The following tables summarize the risk concerns after all assessments were revised using the most current data and assumptions for occupational handlers, based on combined dermal and inhalation exposures. The tables presented in this summary document outline the risks that remain of concern at baseline (i.e., those scenarios that have MOEs < 100), and provides the risk estimates for each of these scenarios at the existing label requirements, with PPE, and with engineering controls, to show the level to which these risks can be mitigated. Note that the scenarios that are not of concern at baseline (i.e., MOEs > 100) are not reported in this document, but may be found in the comprehensive worker risk tables in Appendix A of the HED chapter.

1) Agricultural Handler Risk

As stated above, the exposure scenarios with risks of concern at baseline are reported below, along with the risks for each of these scenarios at the current label, with PPE, and/or with engineering

controls. The risk summary presented in this document focuses only on the scenarios that remain of concern after all revisions to the assessment were made. Again, the scenarios that were not of concern once all refinements were made are not reported here, but can be found in the comprehensive worker risk tables in Appendix A of the HED chapter. The scenario numbers listed below correspond to scenario numbers detailed and discussed in Appendix A of the HED chapter. For the agricultural uses of bensulide, eight combinations of differing rates, acreages, and application methods for short-term and intermediate-term exposures were assessed; of these, 2 have remaining risk concerns for short-term and intermediate-term exposures, and one, applying sprays with a groundboom sprayer, has a risk concern for intermediate-term exposure only. All MOEs in the tables below are based on combined dermal and inhalation risks. The scenarios with remaining risk concerns at baseline are:

- (1a) mixing/loading (M/L) liquids for chemigation application (350 acres, 40 acres);
- (1b) M/L liquids for groundboom application (80 acres);
- (3) applying sprays with a groundboom sprayer (80 acres).

It should be noted that intermediate-term inhalation exposures are the main risk drivers for all scenarios. One scenario, mixing/loading liquids for chemigation on 350 acres, at the maximum rate of 6 lbs ai/acre, is of concern for dermal exposure. (See Appendix A/Table 7).

As previously explained, bensulide is used on agricultural sites as a pre-emergent/pre-plant herbicide. Some applicators, particularly growers who treat only their own fields, are more likely to have short-term exposures – that is, exposures of seven days or less. Other applicators, especially custom applicators who apply bensulide professionally to multiple fields, may be more likely to apply bensulide over the course of 1 week or several weeks. These professional applicators may have intermediate-term exposures that would result in risks of concern when using the personal protective clothing specified on the label, and when the Agency's standard assumption value of 350 acres treated/day is used.

Table 6. Agricultural Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)

| | | | Short-term MOE | | | |
|--|-------|------|-----------------------|----------------------------|----------------------------|----------------------|
| Scenario | Acres | Rate | Baseline ¹ | Current Label ² | Current label + respirator | Engineering Controls |
| (1a) M/L liquids for chemigation | 350 | 3 | 1 | 98 | 138 | 356 |
| | 350 | 6 | <1 | 49 | 69 | 178 |
| | 40 | 3 | 10 | 860 | 1210 | 3118 |
| | 40 | 6 | 5 | 430 | 605 | 1559 |
| (1b) M/L liquids for groundboom appl. | 80 | 3 | 5 | 430 | 605 | 1559 |
| | 80 | 6 | 2.5 | 215 | 302 | 780 |

¹ Long pants, long sleeve shirt, shoes, socks

² Long sleeve shirt, long pants, shoes, socks, chemical resistant gloves

| | | | Intermediate-term MOE | | | |
|--|-------|------|-----------------------|----------------------------|----------------------------|----------------------|
| Scenario | Acres | Rate | Baseline ¹ | Current Label ² | Current label + respirator | Engineering Controls |
| (1a) M/L liquids for chemigation | 350 | 3 | 1 | 23 | 95 | 197 |
| | 350 | 6 | <1 | 12 | 48 | 99 |
| | 40 | 3 | 10 | 204 | 833 | 1726 |
| | 40 | 6 | 5 | 102 | 417 | 863 |
| (1b) M/L liquids for groundboom appl. | 80 | 3 | 5 | 102 | 417 | 863 |
| | 80 | 6 | 2 | 51 | 208 | 432 |
| (3) A/ sprays with groundboom | 80 | 6 | 83 | 83 | 341 | 784 |

¹ Long pants, long sleeve shirt, shoes, socks

² Long sleeve shirt, long pants, shoes, socks, chemical resistant gloves

2) Golf Course & Other Professional Turf Use Risk

As with the agricultural scenarios reported above, the turf exposure scenarios with risks of concern at baseline, once all refinements were made, are reported below, along with the risk estimates with increasing levels of protection. The turf scenarios that do not have risks of concern (i.e., MOEs > 100) are not reported here, but can be found in the comprehensive tables in Appendix A of the HED chapter. The turf scenarios discussed in this section are for professional application to turf, including golf

course application, home-lawn application, and application to other turf sites, including recreational areas and parks. Homeowners applying bensulide to lawns are discussed later in this document. The scenario numbers listed below correspond to scenario numbers detailed and discussed in Appendix A of the HED chapter. For these turf uses of bensulide, the Agency assessed 27 combinations of rates, acreages, and application methods for short-term and intermediate-term exposures. Each combination was assessed at baseline, existing label requirements, with PPE and with engineering controls. For short-term exposures, 21 combinations had risks of concern at baseline once all refinements had been made; for intermediate-term exposures, 21 combinations also had risks of concern for combined dermal and inhalation exposure. Five more scenarios did not have sufficient data to assess the risks; the remaining turf scenario -applying sprays with a groundboom sprayer at the low application rate- had acceptable MOEs at baseline, and is therefore not reported in the table below. Different acreage values were chosen to reflect different use patterns: 40 acres reflects treatment of an entire 18-hole golf course; 7 acres represents application to greens and tees only. A 5 acre value is used to represent a high-end acreage value for home lawn application by a professional or “for hire” applicator, and 50 acres was used to estimate professional handler risk (i.e., mixing/loading liquids) from exposure on other turf sites, including parks and recreational areas.

The exposure scenarios included:

- (1b) M/L liquids for groundboom application (40 acres);
- (1c) M/L liquids for professional turf (50 acres)
- (2) loading granulars for tractor-drawn spreader application (40 acres);
- (5) Mixing/loading/applying (M/L/A) with a low pressure handwand (5 or 7 acres);
- (6) M/L/A with a high pressure handwand (1000 gallons);
- (7) M/L/A with a backpack sprayer (5 or 7 acres);
- (8) M/L/A with a low pressure/high volume turfgun (5 or 7 acres);
- (9) Loading and applying with a push-type granular spreader (5 acres);
- (10) Loading and applying with a hand-held rotary spreader (5 acres).

Most scenarios are of particular concern for intermediate-term inhalation exposure. High exposure, handheld application methods pose both dermal and inhalation concerns, even with short-term exposures. Exposure from these methods often cannot be mitigated with additional protective equipment like a respirator; also, as noted in the table below, mitigation through the addition of engineering controls is not feasible for these application methods.

Bensulide is used on turf grass as a pre-emergent/pre-plant herbicide, and may be applied up to two times/year for crabgrass and *poa annua* control. Some applicators, particularly those who treat individual areas like single golf courses, may have short-term exposures of seven days or less. Other applicators, like “for hire” applicators who apply bensulide professionally to multiple golf courses or large turf areas, may be more likely to apply bensulide over a 1 week or several week period, and thus

need additional levels of personal protection beyond those required by an individual with short-term exposures.

The risks of concern for golf course and other turf uses are summarized below:

Table 7. Golf Course & Other Turf Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)

| Scenario | Acres | Rate | Short-term MOEs | | | |
|--|-----------|------|-----------------------|----------------------------|----------------------------|----------------------|
| | | | Baseline ¹ | Current label ² | Current label + respirator | Engineering controls |
| (1b) M/L liquids for groundboom appl. | 40 | 7.5 | 4 | 344 | 484 | 124782 |
| | 40 | 12.5 | 2 | 206 | 291 | 748 |
| (1c) M/L liquids for professional turf appl. | 50 | 7.5 | 3 | 275 | 387 | 998 |
| | 50 | 12.5 | 2 | 165 | 232 | 599 |
| (5) M/L/A w/low pressure handwand | 5 | 7.5 | <1 | 133 | 204 | NF ³ |
| | 5 | 12.5 | <1 | 80 | 122 | NF |
| | 7 | 7.5 | <1 | 95 | 146 | NF |
| | 7 | 12.5 | <1 | 57 | 88 | NF |
| (6) M/L/A w/high pressure handwand | 1000 gal. | 0.16 | No data | 6 | 8 | NF |
| (7) M/L/A w/backpack sprayer | 5 | 7.5 | No data | 34 | 37 | NF |
| | 5 | 12.5 | No data | 20 | 22 | NF |
| | 7 | 7.5 | No data | 24 | 26 | NF |
| | 7 | 12.5 | No data | 14 | 16 | NF |
| (8) M/L/A with low pressure/high volume turfgun | 5 | 7.5 | 25 | 243 | 258 | NF |
| | 5 | 12.5 | 15 | 146 | 154 | NF |
| | 7 | 7.5 | 18 | 174 | 184 | NF |
| | 7 | 12.5 | 11 | 104 | 110 | NF |

| | | | Short-term MOEs | | | |
|---|-------|------|-----------------------|----------------------------|----------------------------|----------------------|
| Scenario | Acres | Rate | Baseline ¹ | Current label ² | Current label + respirator | Engineering controls |
| (9) Loading and applying w/push-type granular spreader | 5 | 7.5 | 32 | 70 | 73 | NF |
| | 5 | 12.5 | 19 | 42 | 44 | NF |
| (10) Loading and applying with hand held rotary spreader | 5 | 7.5 | 9 | 10 | 15 | NF |
| | 5 | 12.5 | 5 | 6 | 9 | NF |

¹ Long-sleeve shirt, long pants, shoes, socks

² Long-sleeve shirt, long pants, shoes, socks, chemical resistant gloves

³ N/F = Not Feasible

| | | | Intermediate-term MOEs | | | |
|--|----------|------|------------------------|----------------------------|----------------------------|----------------------|
| Scenario | Acres | Rate | Baseline ¹ | Current label ² | Current label + respirator | Engineering controls |
| (1b) M/L liquids for groundboom appl. | 40 | 7.5 | 4 | 82 | 333 | 690 |
| | 40 | 12.5 | 2 | 49 | 200 | 414 |
| (1c) M/L liquids for professional turf appl. | 50 | 7.5 | 3 | 65 | 266 | 552 |
| | 50 | 12.5 | 2 | 39 | 160 | 331 |
| (2) L/ granulars for tractor-drawn spreader appl. | 40 | 7.5 | 65 | 66 | 488 | 3270 |
| | 40 | 12.5 | 39 | 40 | 293 | 1962 |
| (3) A/sprays with groundboom sprayer | 40 | 12.5 | 80 | 80 | 327 | 753 |
| (4) A/ granulars with tractor-drawn spreader | 40 | 7.5 | 90 | 92 | 607 | 484 |
| | 40 | 12.5 | 54 | 55 | 365 | 290 |
| (5) M/L/A with low pressure handwand | 5 | 7.5 | <1 | 27 | 128 | NF ³ |
| | 5 | 12.5 | <1 | 16 | 77 | NF |
| | 7 | 7.5 | <1 | 19 | 91 | NF |
| | 7 | 12.5 | <1 | 12 | 55 | NF |
| (6) M/L/A with high pressure handwand | 1000 gal | 0.16 | No data | 2 | 6 | NF |

| Scenario | Acres | Rate | Intermediate-term MOEs | | | |
|--|-------|------|------------------------|----------------------------|----------------------------|----------------------|
| | | | Baseline ¹ | Current label ² | Current label + respirator | Engineering controls |
| (7) Backpack sprayer | 5 | 7.5 | No data | 17 | 33 | NF |
| | 5 | 12.5 | No data | 10 | 20 | NF |
| | 7 | 7.5 | No data | 12 | 24 | NF |
| | 7 | 12.5 | No data | 7 | 14 | NF |
| (8) Low pressure/high volume turfgun | 5 | 7.5 | 24 | 150 | 242 | NF |
| | 5 | 12.5 | 14 | 90 | 145 | NF |
| | 7 | 7.5 | 17 | 108 | 173 | NF |
| | 7 | 12.5 | 10 | 64 | 104 | NF |
| (9) Loading and applying with push-type granular spreader | 5 | 7.5 | 26 | 49 | 70* | NF |
| | 5 | 12.5 | 16 | 30 | 42* | NF |
| (10) Loading and applying with hand-held rotary spreader | 5 | 7.5 | 6 | 6 | 9 | NF |
| | 5 | 12.5 | 4 | 4 | 6 | NF |

¹ Long-sleeve shirt, long pants, shoes, socks

² Long-sleeve shirt, long pants, shoes, socks, chemical resistant gloves

³ N/F = Not Feasible

* For these scenarios, MOEs of 122 and 73, respectively, can be achieved with a double layer of clothing, chemical resistant gloves, and a respirator.

3) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture as well as exposures that can occur as a result of turf management activities. All of the post-application risk calculations for handlers completed in this assessment are included in Appendix B of the HED chapter.

For agricultural uses, the Agency does not consider post-application exposure problematic due to the cultivation practices that are anticipated with the pre-plant/pre-emergence use of bensulide on the labeled agricultural crops. Therefore, the Agency has determined that the current label requirement of 12 hours is adequate.

In making this determination, the Agency has considered all available use information and current labeling. It does have some reservations, however, with regard to workers in transplanting operations. The United States Department of Agriculture (USDA) has indicated that, in most transplanting

operations, mechanical planters are used to place transplants in the soil and therefore workers are not exposed to bensulide. EPA agrees that workers are not likely to be exposed to soil directly through transplanting, but may contact bensulide through exposure to soil remaining on the transplant wheel. To better define this exposure, EPA is requesting information on this cultural practice in a Data Call-In that is being issued along with this Interim RED.

For turf uses, there is potential for post-application exposure to workers performing turf management activities (golf course greens keepers and landscaping personnel). Risk estimates were calculated using actual measured values derived from the turf transferable residue study, which accounts for watering-in of bensulide. Watering-in is required by labels for efficacy of the herbicide.

Following the watering-in of bensulide, MOEs are greater than 100 (i.e., not of concern) on the day of application, even when professionals are conducting high exposure activities (e.g., heavy weeding) following the highest application rate (MOE = 480). Even if the watering-in was not as extensive as the 0.5 inches achieved in the study (i.e., using the pre-watering in data), MOEs are still greater than 100 on the day of application, even when professionals are conducting high exposure activities following the highest application rate. Therefore, post-application risk from bensulide use on turf is not of concern.

4) Residential (Homeowner) Handler Risk

For homeowner handler exposure assessments, the Agency does not believe a tiered mitigation approach like that used for assessing occupational handler risk is appropriate. Homeowners often lack access to personal protective equipment (PPE) and also do not possess expertise in the proper use of PPE. As a result, homeowner handler assessments are completed using a single scenario based on the use of short-sleeved shirts and short pants (i.e., common homeowner attire during the pesticide application season). In addition, only short-term exposures were assessed, as the Agency does not believe homeowners who apply bensulide will be exposed to bensulide for more than 7 days. The exposure scenarios included:

- (9) M/L/A with push-type granular spreader (0.5 acres);
- (10) M/L/A with hand-held rotary spreader (0.5 acres).

The labels for homeowner products allow homeowners to use a push-type granular spreader or a hand-held rotary spreader (e.g., bellygrinder) to mix, load, and apply bensulide, and allow use rates of up to 12.5 lbs a.i. per application, which is recommended for heavy weed pressure. The labels also instruct homeowner handlers to “sprinkle the area with water for 10-15 minutes after application.....”

Risk estimates indicate that, when short-term dermal and inhalation exposures are combined, the Agency has no concerns for homeowners who load and apply bensulide with a push-type granular spreader. MOEs for this scenario are 305 and 183 for the low and high-use rate, respectively.

However, the Agency has concerns for homeowners who load and apply bensulide with a hand-held rotary spreader (e.g., bellygrinder). Combined short-term dermal and inhalation exposures result in MOEs of less than 10. Risks for homeowner handlers using a hand-held rotary spreader are in the table below.

Table 8. Homeowner Uses: Risk Concerns (combined dermal & inhalation MOEs)¹

| Scenario | Acres | Rate | Short-Term MOE |
|---------------------------------------|-------|------|----------------|
| (10) L/A with hand-held rotary method | 0.5 | 7.5 | 8 |
| | 0.5 | 12.5 | 5 |

¹ Shorts, short-sleeved shirt.

5) Residential Post-Application Risk

Bensulide can be used on home lawns, golf courses, and on other turf areas where exposure to adults and children may occur. Exposure may result from entering the area, performing yard work, playing or performing other recreational activities (e.g., golfing) on the treated areas. As a result, both toddler and adult risks were considered in the risk assessment.

Risks were calculated using actual measured values derived from a bensulide-specific turf transferable residue (TTR) study, which accounts for watering-in of bensulide in a controlled setting and use of 0.5 inches of water to thoroughly water in the granules. Post-application risks for adults in residential settings were calculated for individuals involved in light exposure activities such as golfing and also in heavy exposure activities such as heavy yard work.

Using the results of the TTR study, MOEs for adults were calculated to be greater than 100 on the day of application (MOE = 480) even when completing high exposure activities following the highest application rates. If the watering in was not as extensive as the 0.5 inches achieved in the study, MOEs are still greater than 100 on the day of application (MOE = 150) even when people are conducting high exposure activities following the highest application rate. Therefore, the Agency is not concerned about post-application exposure for residential adults, including golfers.

Post-application risks for toddlers in a residential setting were calculated for individuals involved in heavy exposure activities (e.g., hard play), and at the minimum and maximum application rates for bensulide using the bensulide TTR study. Also, risks from non-dietary ingestion (e.g., a child grabbing a handful of turf and mouthing it, or a child putting dirty hands in its mouth) of bensulide were calculated.

Following the watering-in of bensulide, the MOEs for dermal exposures were greater than 100 on the day of application at the highest application rate for toddlers in high exposure activities (e.g., hard play) over a long duration. If bensulide was used at the highest labeled application rate, and if the watering in was not as extensive (i.e., less than 0.5 inches), the MOE for dermal exposure is 74 and

therefore of concern to the Agency. The risks associated with non-dietary ingestion are not of concern to the Agency. Both prior to and following watering in of bensulide, MOEs for non-dietary ingestion are well above 100, based on guidance from the Agency's current standard operating procedures (SOPs) for residential exposure assessment. It should be noted here that the Agency's SOPs for residential exposure assessment will be updated sometime this year; once this occurs, it is expected that the risks will decrease even further using the new methodology.

4. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers who mouth grass). Aggregate exposure risk assessments for bensulide were conducted for acute (1-day), short-term (1-7 days), and chronic (lifetime) exposure. Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency. Results of the aggregate risk assessment are summarized here, and are discussed extensively in the June 16, 1999 HED chapter, as well as in the February 11, 2000 addendum to the HED chapter.

Acute aggregate exposure, by definition, consists only of food and drinking water exposure. Chronic aggregate exposure consists only of food and drinking water, because there is no chronic residential exposure to bensulide. Risk estimates indicate that acute aggregate exposure to bensulide is not of concern. Similarly, chronic aggregate exposure is not of concern (see drinking water discussion in Section III. B. 2. (c) of this document).

Short-term aggregate exposure to bensulide consists of food, residential exposure (dermal, inhalation, and non-dietary oral), and drinking water. Short-term aggregate exposure is not of concern when bensulide is watered-in thoroughly and consistently, provided that a homeowner uses a push-type drop spreader, rather than a hand-held rotary applicator.

A summary of the short-term aggregate exposures is shown in Table 9 below. The first column, "Total MOE for Non-Water Exposures," includes the combined risk estimates from food (the % PAD has been converted to an MOE so that food and residential exposures could be added together; methodology for this conversion is found in the HED chapter) and residential exposures for each population. As shown, the combined food and residential MOEs are not of concern; that is, MOEs are >100 for all populations. For drinking water, the environmental concentrations for either ground or surface water are significantly below the DWLOC, which is the maximum allowable concentration that will not exceed the Agency's level of concern. Therefore, even when drinking water is added to the food and residential exposures, the short-term aggregate exposure is not of concern.

Table 9. Drinking Water Levels of Comparison for Short-term Aggregate Exposure

| Population | Total MOE for Non-Water Exposures | Ground Water (ppb) ¹ (SCI-GROW) | Surface Water (ppb) ^{2, 4} (GENEEC) | Surface Water (ppb) ³ (PRZM-EXAMS) | DWLOC (ppb) |
|---|-----------------------------------|--|--|---|-------------|
| Homeowners Who Apply (General Pop. Handlers) | 183 | 0.5/1.0 | 19/34 | 158 | 2,388 |
| Yard work (General Pop., Heavy Activity) | 482 | 0.5/1.0 | 19/34 | 158 | 4,160 |
| Golfers (General Pop., Light Activity) | 8,257 | 0.5/1.0 | 19/34 | 158 | 5,186 |
| Toddlers | 236 | 05/1.0 | 19/34 | 158 | 863 |

¹ The value of 0.5 ppb is with 1 turf application/year, the 1.0 ppb value is with 2 turf applications/year.

² The value of 19 ppb is with 1 turf application/year, 34 ppb is with 2 turf applications/year

³ The value of 158 ppb is with broadcast vegetable application.

⁴ GENEEC values have been adjusted per SOP 99-5 to obtain a long-term average estimate. This SOP is cited and discussed in more detail in the February 11, 2000 addendum to the HED chapter available in the public docket.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated 6/14/99, available in the public docket. Since this document was completed, the Agency made changes in its approach to estimating environmental concentrations (ECs) for turf uses. This change, and the resulting risk quotients (RQs) are discussed fully in the 2/17/00 document entitled, "Addendum to the Bensulide RED: Revised Risk Assessment and Risk Characterization for Risk to Aquatic Organisms from Use on Turf."

Several revisions have been made since the preliminary risk assessment was completed, and include:

- Use of data from a turf residue study to assess exposure to terrestrial wildlife.
- Use of aquatic toxicity data to characterize risk to aquatic species.
- Use of GENEEC instead of PRZM-EXAMS to estimate environmental concentrations from the turf uses, for use in drinking water and ecological assessments.

1. Environmental Fate and Transport

Although the environmental fate data base for bensulide is not complete, information from acceptable laboratory studies indicates bensulide is persistent. Neither abiotic hydrolysis nor photolysis are major degradation processes in water or on soil surfaces. The main route of dissipation of bensulide appears to be aerobic soil metabolism with a reported half-life of 1 year, based on laboratory studies. Under aerobic conditions, it appears that mineralization of bensulide to carbon dioxide and immobilization as unextractable residues are the major mechanisms of dissipation in the soil. Under anaerobic soil conditions, bensulide did not degrade. Based on the lack of degradation under laboratory conditions, it is predicted that bensulide will be extremely persistent in anaerobic terrestrial ecosystems.

Information from acceptable laboratory studies indicates that bensulide is not mobile in the four soils tested (K_{oc} s ranged from 1,433 to 4,326 ml/g); however, the degradates bensulide oxon (N-[(2-(diisopropoxyphosphinoylthio)-1-ethyl]- benzenesulfonamide) and benzenesulphonamide ranged from mobile to highly mobile in the same four test soils. Bensulide has the potential to be transported both dissolved in water and on suspended sediment in runoff to surface waters where, based on laboratory data, it is expected to persist. Bensulide has the persistence characteristics of chemicals found capable of leaching to ground water; however, based on other environmental fate characteristics (i.e., high sorption capacity) and supporting groundwater modeling, bensulide is not expected to leach to ground water.

The environmental fate assessment developed from the results of the laboratory studies has not been confirmed by acceptable field dissipation information. In eight unacceptable field dissipation studies reportedly using bensulide at 6 and 12.5 lb ai/A, the half-life of bensulide was reported to range from 8-34 days in studies conducted in California, and from 91-210 days in studies conducted in Mississippi. However, in none of the studies was a consistent decline of parent compound observed. None of the studies are acceptable, because the application rate could not be confirmed and bare ground plots were not used for confirmation of application. The study plots had been planted to turf, and no mention was made of how the turf and thatch in the samples were separated from the soil or of any attempt to extract residues from the turf or thatch. The registrant is currently conducting a new field dissipation study that will be completed by mid-2000. Preliminary review of interim data from that study have confirmed the Agency's fate assessment of bensulide.

2. Risk to Birds and Mammals

The most significant risk from bensulide use is chronic avian risk due to eggshell thinning. Eggshell thinning caused by bensulide in laboratory studies is similar to the effects of the organochlorines DDT and DDE, but with approximately 10 times less potency; that is, 10 times greater concentration of bensulide is necessary to produce an effect equal in magnitude. Chronic risk from bensulide approaches that of DDT because bensulide is used at such high rates (two applications of up to 12.5 lbs ai/acre each on turf sites). This risk is of greater concern on large turf areas, where water fowl are attracted and

where they tend to feed and forage. These risks are increased by bensulide's persistence in soil (greater than 200 day soil half-life) and multiple applications.

Gowan Company, the registrant for bensulide, submitted data on residues on grass to aid the Agency in its assessment of dietary exposure to terrestrial wildlife. These data were collected in conjunction with a total turf residue study used in the human health assessment. (For more details on this study, refer to the EFED chapter, Addendum 2). The study shows the amount of the bensulide residues on grass that would be removed by irrigation, which is required within 36 hours after application. The Agency is able to conclude that irrigation will remove approximately one-third of the initial residues on short grass foliage, which means a reduction in exposure to birds and mammals. However, when the risk assessment was updated to reflect the new data, results still indicate that the turf uses pose a high risk of causing reproductive impairment in birds. The Agency has calculated risk quotients for birds; these are presented and discussed fully in the 6/14/99 EFED chapter.

Bensulide also poses chronic risk to mammals through residues on wildlife food items (if sprayed directly), risks that are increased by the stability and persistence of bensulide in the environment. The high persistence of bensulide also increases the opportunity for routes of avian and mammalian exposure other than in the diet. The Agency is particularly concerned with exposures from the large turf uses (primarily from golf course use). There is currently no acceptable field dissipation study for bensulide. However, Agency review of an interim report of an ongoing field dissipation study conducted by the registrant confirms bensulide's fate properties, particularly its persistence.

3. Risk to Aquatic Species

Most turf uses pose some risk to aquatic species. The Agency has recently updated its risk characterization for risk to aquatic organisms from turf use in a 2/17/00 memo entitled, "Addendum to the Bensulide RED: Revised Risk Assessment and Risk Characterization for Risk to Aquatic Organisms from Use on Turf." This update was conducted to reflect a change in the model used to estimate the environmental concentrations of bensulide, and results indicate a reduction in the overall level of risk predicted for aquatic organisms, although some high risks still exist. The memo also discusses the impact of the risk mitigation currently being proposed for use on golf course fairways; that is, the reduction in the total number of applications from 2 times/year to 1 time/year.

In general, the acute levels of concern for bensulide are exceeded for freshwater fish, including those for threatened or endangered species and for freshwater invertebrates. For estuarine and marine fish and nonendangered aquatic plants, turf poses a high acute risk at two applications per year; restricting the use to one application per year mitigates the high acute risk. Also, high acute risk to estuarine and marine invertebrates exists. Bensulide poses low chronic risk to freshwater fish, and high chronic risk to freshwater invertebrates.

Agricultural uses pose less risk because the use is generally in drier areas of the country where surface run-off is less likely, and use rates are lower (3 to 6 lbs ai/acre).

IV. INTERIM RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient is eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing bensulide active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient bensulide, as well as a bensulide-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient bensulide, EPA has sufficient information on the human health and ecological effects of bensulide to make an interim determination of reregistration eligibility and to make some interim decisions as part of the tolerance reassessment process under FQPA. Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to allow the continued use of bensulide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of interim reregistration eligibility of bensulide, and lists the submitted studies that the Agency found acceptable.

As a result of its assessment of the remaining risks of bensulide alone, EPA has determined that certain uses of bensulide, unless amended as set forth in this document, present risks inconsistent with FIFRA. Accordingly, EPA may commence a full risk/benefit analysis, the outcome of which may indicate that cancellation proceedings are warranted, unless registrants agree to label changes implementing the risk reduction measures discussed in this reregistration eligibility decision. At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For bensulide, if all changes outlined in this document are incorporated into the labels, then all risks will be mitigated and no outstanding risk concerns for this individual chemical will remain. But, because this is an Interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for bensulide after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing bensulide food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, bensulide tolerances will be reassessed in that light. At that time, the Agency will reassess bensulide along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration determination. By publishing this reregistration eligibility decision and requiring risk mitigation now for the individual chemical bensulide, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the RED, that any of the determinations described in this Interim RED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this Interim RED.

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. As stated previously, a mitigation proposal was received from Gowan Company; details of this proposal are discussed in the next section. Several other comments on mitigation were also received from 1.) an agricultural extension agent in the southwestern United States; 2.) Natural Resources Defense Council (NRDC); 3.) the Golf Course Superintendents Association of America (GCSAA); and 4.) members of the golf course industry. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

1.) *Comment.* A weed scientist/agricultural extension agent from the University of California, Imperial County, commented that he would like the current agricultural use pattern of bensulide to continue. He also supplied use and usage-type information for minor use crops grown in the Imperial Valley.

Response. This comment provided no specific mitigation suggestions. It did, however, provide valuable use and usage data, some of which had already been used to update the risk assessments.

2.) *Comment.* The National Resources Defense Council provided general comments on the organophosphates, and specific comments on bensulide. With regard to bensulide-specific comments on mitigation, NRDC recommends removing the residential uses, because of a special concern for toddlers.

Response. With regard to bensulide-specific mitigation, NRDC commented only on the residential risk to children. The Agency has reviewed NRDC's suggestion that the residential use of bensulide be removed, especially because of risk to toddlers. The Agency notes that the risk for both adults and toddlers are not of concern if label directions are followed; therefore, there is no risk basis for removing this use from the label. However, the Agency is requiring that the directions for use on the current language be clarified and expanded, to ensure that bensulide is used properly and safely.

3.) *Comment.* The Golf Course Superintendents Association of America commented that restricting the use of bensulide to greens and tees, as well as making the chemical Restricted Use, would not pose a burden on the golf industry. GCSAA did indicate, however, that reducing rates would severely reduce the efficacy of bensulide and therefore render it unsuitable for use on golf courses.

4.) *Comment.* Two golf course superintendents in Dublin, Ohio wrote that bensulide is needed for bentgrass greens, tees, and fairways.

Response to Comments 3 and 4. The Agency reviewed these comments, and determined that the use on greens and tees could remain unchanged from current practices. The use on fairways will be restricted to certain states and to one grass type, to satisfy the niche use of this chemical. The fairway use will be restricted, however, from two applications per year to one application per year in the fall, to partially alleviate the Agency's ecological concerns with regard to avian risk. Requiring that bensulide be a restricted use chemical was determined to be unnecessary at this time.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to bensulide is within its own "risk cup." In other words, if bensulide did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for bensulide meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and

children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to bensulide “fit” within the individual risk cup. Therefore, the bensulide tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

b. Tolerance Summary

In the individual assessment, tolerances for residues of bensulide in/on plant commodities [40 CFR §180.241] are presently expressed in terms of the combined residues of bensulide and its oxygen analog. Following evaluation of plant metabolism studies, the Agency has determined that the bensulide residues that warrant regulation in plant commodities are those that are currently regulated.

Adequate data are available to reassess the established tolerances for the following commodities: cucurbits, carrots, leafy vegetables, peppers and onions (dry bulb). EPA recommends that tolerances for cucurbits, and leafy vegetables be revised from 0.1 ppm to 0.15 ppm to account for the instability of bensulide *per se* in/on these commodities as evidenced in a nonconcurrent storage stability study. In addition, the established tolerance for carrots must be revised to a tolerance with regional registration. The established tolerance for cottonseed should be revoked because there are currently no registered uses of bensulide on cotton.

A tolerance must be proposed for the Brassica (cole) vegetables group; the Agency recommends the registrant propose a tolerance of 0.15 ppm. Also, some minor modifications to the tolerance expression must be made. A bensulide tolerance summary is presented below and in Table 5 of the HED chapter.

Table 10. Tolerance Summary for Bensulide.

| Commodity | Current Tolerance, ppm | Tolerance Reassessment*, ppm ¹ | Comment/ [Correct Commodity Definition] |
|--|------------------------|---|--|
| Tolerances Listed Under 40 CFR §180.241 | | | |
| Carrots | 0.10 | 0.10 | This tolerance must be modified to one with regional registration (TX). Also, labels must be amended to reflect a maximum seasonal use rate of 5 lb/A. |
| Cottonseed | 0.10 | Revoke | There are currently no registered uses of bensulide on cotton. |
| Cucurbits | 0.10 | 0.15 | [Cucurbit Vegetables Group] |

| Commodity | Current Tolerance, ppm | Tolerance Reassessment*, ppm ¹ | Comment/ [Correct Commodity Definition] |
|---|------------------------|---|---|
| Fruiting Vegetables³ | 0.10 | 0.10 | [Fruiting Vegetables (except cucurbits) Group] |
| Leafy vegetables | 0.10 | 0.15 | [Leafy Vegetables (except Brassica Vegetables) Group] |
| Onions (dry bulb) | 0.10 | 0.10 | |
| Tolerance to be Proposed | | | |
| Brassica (Cole) Leafy Vegetables Group | -- | 0.15 ² | [Brassica (Cole) Leafy Vegetables] |

¹ Existing tolerances have been reassessed in light of the submitted 3-year storage stability study for bensulide and bensulide oxon.

² The registrant should propose a tolerance of 0.15 ppm for Brassica (Cole) Leafy Vegetables.

³ Labels must be amended to restrict use to bell peppers only, unless three non-bell pepper field trials are conducted.

* The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon completion of the cumulative risk assessment of all organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data.

The Agency will commence proceedings to revoke the tolerance for cotton, and to modify the existing tolerance for carrots to a tolerance with a regional registration in Texas, as defined in § 180.1(n). Amendment of the commodity designations to reflect the correct commodity definitions will also be undertaken now. The establishment of a new tolerance for the group "brassica (cole) leafy vegetables" will be deferred, pending the outcome of the cumulative assessment.

2. 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 such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases 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 the Program include evaluations of potential effects in wildlife. For pesticide chemicals, 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 Agency's EDSP have been developed, bensulide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Required Label Modifications

The Agency is requiring that the bensulide registration be amended to mitigate risk to 1.) handlers from use on agricultural sites, 2.) professional handlers and homeowners handlers from use on turf sites, and 3.) nontarget organisms, primarily from use on turf. The Agency has determined that these measures, in addition to the existing label requirements, will reduce risks to workers, and homeowners to an acceptable level, and that unreasonable adverse effects are unlikely to result from such use. With regard to post-application risk to children, the Agency is requiring clarification and strengthening of the existing label language to ensure that no risk will occur from improper use. Regarding ecological risks, the registrant has not agreed to modification of its labels to fully mitigate these risks; this issue will be discussed in the appropriate section below. Provided the following risk mitigation measures are incorporated in their entirety into labels for bensulide-containing products, the Agency finds that all currently registered uses of bensulide are eligible for interim reregistration, pending a cumulative assessment of the organophosphates. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of required mitigation measures.

a. Agricultural and Turf Uses: Occupational and Ecological Risk Mitigation

For agricultural use, the following measures are required, in addition to the existing label requirements (long-sleeve shirt, long pants, shoes, socks, chemical resistant gloves):

- Require respirators for mixing/loading liquids for chemigation; mixing/loading liquids for groundboom applications.
- Require respirators or closed cabs for commercial applicators applying sprays with a groundboom sprayer.
- Limit chemigation use to California and Arizona.

For golf course and home lawn use, the following measures are required, in addition to the existing label requirements (long-sleeve shirt, long pants, shoes, socks, chemical resistant gloves):

- Require respirators for mixing/loading liquids; loading granulars for tractor drawn spreader; applying granulars with tractor drawn spreader.
- S** Require respirators for commercial or “for hire” applicators applying sprays with a groundboom sprayer and for commercial or “for hire” applicators applying liquids with a low pressure/high volume turf gun.

- Require respirators and coveralls for application with a push-type granular spreader.
- Prohibit use of a high pressure handwand, backpack sprayer and handheld rotary application methods.
- Restrict the use of a low pressure handwand to spot treatments only.
- Restrict the use on fairways to one application during the fall season.
- Restrict the use on fairways to only 18 states (OH, PA, NY, MI, CT, MA, IN, IL, NJ, WV, MN, WI, VT, NH, RI, DE, MD, and VA) and, in these states, to only *bentgrass* fairways.
- Prohibit use on ornamentals, parks and recreational areas on all labels.

b. Homeowner Use: Homeowner and Ecological Risk Mitigation

The following measures are required:

- Add a label statement prohibiting granular application with any handheld rotary methods (e.g., prohibit bellygrinder).
- Add a label statement in red print in front of homeowner product labels that states:

“THIS PRODUCT WILL NOT WORK IF NOT WATERED IN FOR 10-15 MINUTES. FOR SAFETY REASONS, WATER THIS PRODUCT IN AS SOON AS POSSIBLE FOLLOWING APPLICATION FOR 10-15 MINUTES AND DO NOT ALLOW CHILDREN OR PETS ON TREATED AREAS UNTIL DRY.”
- Prohibit use on ornamentals, parks and recreational areas.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of bensulide. Where labeling revisions are imposed, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. Dietary Mitigation

1) Acute Dietary (Food)

Acute dietary risk from food is well below the Agency’s level of concern – a Tier 1 DEEM™ analysis yielded percent acute PAD values that are less than 1% at the 95th percentile of exposure for the most exposed subgroups (children 1-6 years old, and infants <1 year old). Therefore, no mitigation measures are necessary at this time to address acute dietary risk from food.

2) Chronic Dietary (Food)

Chronic dietary risk from food is also below the Agency's level of concern – percent chronic PAD values are less than 1% for the most exposed population subgroups. Therefore, no mitigation measures are necessary at this time to address chronic dietary risk from food.

3) Drinking Water

As explained earlier in this document, most modeled estimates of potential drinking water exposure from both ground and surface water sources (i.e., EECs) do not exceed the acute or chronic DWLOC values, and therefore would not be of concern to the Agency. One scenario, chronic exposure from the agricultural uses of bensulide through surface water, exceeds the DWLOCs somewhat for non-nursing infants. However, this estimate is considered to be an overestimate in that it does not accurately represent what may be found in drinking water. No mitigation is necessary at this time.

b. Occupational Risk Mitigation

1) Agricultural Uses

To address risks from inhalation exposure for the agricultural handler scenarios discussed in Section III of this document and shown in Table 6 of that section, the following mitigation measures are required, in addition to the existing label requirements:

- respirators for mixing/loading liquids for chemigation;
- respirators for mixing/loading liquids for groundboom applications;
- either respirators or closed cabs for commercial applicators applying sprays with a groundboom sprayer.
- restrict the use of chemigation to California and Arizona

The respirators or closed cabs mitigate all inhalation MOEs to greater than 100, which eliminates this risk concern. Table 6 shows the MOEs that are achieved for each scenario when respirators or closed cabs are considered in the assessment.

Risks remain from dermal exposure when mixing/loading liquids for chemigation on 350 acres per day at the maximum rate of 6 lbs ai/acre (dermal MOE = 69 with a respirator). EPA recognizes that this may be an overestimate, however, both with the surrogate data used in the assessment and with the assumptions regarding acres treated. For example, the Agency's assessment analyzed the handling of 210 2.5 gallon jugs of Prefar 4-E (bensulide liquid formulation) to treat 350 acres per day. Handling multiple open jugs has far greater exposure potential than handling fewer bulk containers to treat the same area. The registrant, Gowan Company, has submitted extensive comments rebutting EPA's

standard assumptions for the chemigation use, and has indicated that the herbicide is transported and distributed in bulk containers, not in the standard 2.5 gallon jugs. While EPA does not agree that these bulk containers with a single coupling device constitute a closed system, as Gowan contends, the Agency does agree that using multiple open-pour jugs may not accurately estimate the actual handler exposure that can occur when using bulk containers. However, it does not have a study or any other data to better characterize this exposure scenario.

Gowan has also indicated that all chemigation with bensulide occurs in the states of Arizona and California. The registrant has successfully shown that the acreage treated with bensulide, for Arizona and California, is much less than the Agency standard assumption of 350 acres. Gowan submitted use data for 1996 to 1999 to the Crop Data Management System (CDMS), a voluntary use reporting system that records, among other things, extensive information on acreage treated and application rates. Approximately 4500 bensulide applications are summarized. Based on CDMS data, the median area of a chemigation application is 15 acres. The largest field treated was 190 acres, followed by one 170-acre field, two 157-acre fields, and 29 150-acre fields. Of the almost 4500 applications, only 73 of these involved areas of 100 acres or more. The maximum acreage permissible to achieve a dermal MOE of 100 or greater, when the highest rate of 6 lbs./acre is used, is 200 acres.

The Agency has determined that, in addition to requiring respirators to achieve MOEs of greater than 100, it is also requiring a label restriction that allows chemigation only in California and Arizona, where extensive records show that the maximum acres treated via chemigation fall below the 200-acre limit. The addition of these label restrictions to the current label requirements ensures that the dermal risks from chemigation use will be below the Agency's level of concern.

2) Golf Course and Professional Turf Uses

To address inhalation risk from the golf course and professional turf use scenarios discussed in Section III of this document and shown in Table 7 of that section, respirators are required for the following turf uses, in addition to the existing label requirements:

- mixing/loading liquids;
- loading granulars for tractor drawn spreader application;
- applying granulars with a tractor drawn spreader;
- commercial or “for hire” applicators applying sprays with a groundboom sprayer; and
- applying liquids with a low pressure/high volume turf gun by commercial or “for hire” applicators.

The addition of respirators to the existing label requirements will mitigate all inhalation MOEs to greater than 100, which would eliminate this risk concern.

To address dermal and inhalation risks, the following risk mitigation measures are required, in addition to the existing label requirements:

- add respirators and coveralls for application with a push-type granular spreader;
- prohibit use of handheld application methods, such as the high pressure handwand, backpack sprayer and handheld rotary application methods (e.g., bellygrinder); and
- allow use of the low pressure handwand for spot treatments only;
- delete use on ornamentals, parks and recreational areas.

Prohibiting the handheld application methods eliminate those risks entirely. Restricting use of the low pressure handwand to spot treatments only would eliminate the Agency’s concern with this application method. Table 7 shows the MOEs that are achieved for each scenario when the above measures are considered in the assessment.

Dermal and inhalation risks remain, however, for the intermediate-term exposure from the push-type granular spreader use at the high use rate, even with the addition of a respirator, gloves and coveralls. The MOE is 74 for intermediate-term exposure, based on application to 5 acres per day at the high use rate of 12.5 lbs./acre. With the same protective clothing requirements and the same 5 acre treatment area, the MOE for intermediate-term exposure at the low use rate of 7.5 lbs./acre is 122, and is not of concern. The Agency has reviewed its assumptions used in this assessment, and has determined that treatment of 5 acres in one day using a push-type granular spreader is excessive. Applications to golf courses is the only remaining large turf use that can be treated with bensulide. Information received from the golf course industry indicates that, if a granular product in a push-type spreader is used to treat parts of the course (e.g., greens and tees), this would be completed over 2-3 days. More likely is that a tractor-drawn spreader would be used for these areas. Therefore, a short-term exposure is a more accurate representation for this particular pattern of use; short-term MOEs are greater than 100, even at the maximum use rate. Also, using a push-type spreader to treat 5 acres per day for more than 7 days is unlikely, even for hired applicators. Most “for hire” applicators treating large areas of turf for this amount of time would likely choose an alternative application method or alternate this application method with others. Therefore, the intermediate-term risk estimate is probably highly conservative, and respirators and coveralls would sufficiently mitigate this exposure scenario to an acceptable level.

c. Homeowner Risk Mitigation

1) Handler Risk

To address dermal and inhalation risk to homeowners loading/applying granulars with a handheld rotary method (e.g. bellygrinder), labels will prohibit this use. This measure will eliminate the risk of concern. Use of a push-type spreader to apply granules resulted in MOEs that did not exceed the Agency’s level of concern; therefore this use may continue.

2) Post-Application Risk

If the current label is not followed and bensulide is not watered-in extensively after application at the maximum application rate (12.5 lbs ai/acre), then children involved in high exposure activities are at risk (post-application MOE = 74). To address this post-application risk to children who enter lawns treated with bensulide, product label language will be clarified to require extensive watering-in and complete drying of the lawn before allowing persons or pets to enter the treated area. It will also direct users to follow directions for safety reasons. As stated, bensulide is relatively expensive compared to other alternatives, so it is more likely that a homeowner who buys it will follow the instructions and water the product into the grass, to ensure its efficacy. Based on the Agency's risk assessment, if the label is followed and bensulide is watered-in, post-application exposure is not of concern for adults (including golfers) and children.

In addition to strengthening the label language on homeowner products, the Agency is prohibiting the use of bensulide on all other non-golf course turf areas, such as parks and recreational areas. These are areas where it may be difficult to follow the label instructions to thoroughly and immediately water-in the product, and to restrict entry of children and pets until the area is dry. Prohibition of bensulide on these areas will eliminate exposure entirely.

2. Environmental Risk Mitigation

Generally, the environmental risk from bensulide use is to nontarget organisms resulting from use on large turf areas, especially golf courses. This risk is due to the high use rates (7.5 to 12.5 lbs ai/acre), the persistence of the chemical (the soil half-life is more than 200 days, based on laboratory studies) and multiple applications (up to two times a year). Exposure to the environment may be significant, and because bensulide is especially toxic to birds, small mammals, and some aquatic species, risk is of concern.

To address the risk to nontarget avian, mammalian, and aquatic species, a number of mitigation measures are being implemented. Prohibition of use on ornamentals, parks and recreational areas will reduce exposure to avian and mammalian species, and eliminate the potential for surface water run-off that could affect aquatic organisms. While the use on golf course greens and tees will continue unchanged, the use on fairways will be restricted to use on bentgrass in certain states, and to only one application/year in the fall. Greens and tees are not expected to contribute to avian risk, since the grass height is so low that these areas would not be conducive to foraging, and run-off from these areas is expected to be minimal. Use on fairways constitutes a much larger area, and may result in surface water run-off that could impact aquatic organisms. Also, birds and mammals may be attracted to these areas, and feed and forage there. As discussed in the ecological risk section of this document, the endpoint of concern for birds is eggshell thinning. Therefore, the Agency is particularly concerned about bensulide use during the avian breeding season.

Thus far, Gowan has agreed to limit the use on fairways to a single application of 12.5 pounds ai/acre per year, and limit the use to bentgrass fairways only in 18 states. However, the Agency is requiring that this use be restricted further, to allow a single application in the fall only, so that bensulide is not applied during avian breeding periods, which are generally during the spring. Based on Agency discussions with golf course superintendents and the registrant, bensulide has a very limited, but important, use on fairways. It appears to have a niche market in some areas where other alternatives may damage the fairway grass and where cost is secondary to overall performance. However, a number of alternatives exist, and most, if not all, are less expensive alternatives to bensulide.

The Agency initially determined that the fairway use of bensulide should be prohibited, but after considering comments received during Phase 5 noting the importance of the niche use of the chemical, it is allowing the single fall application to bentgrass fairways in 18 states. As an alternative to this fairway restriction, the registrant may prohibit fairway use in its entirety.

E. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing bensulide. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

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

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has completed and distributed over 300 county bulletins.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift

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

"Do not allow this product to drift"

V. WHAT REGISTRANTS MUST DO

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of bensulide for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

| | |
|--------------------|--|
| Guideline 830.6313 | (Guideline #63-13) Stability of the TGAI on exposure to metals and metal ions |
| Guideline 830.7050 | UV/visible absorption for the PAI |
| Guideline 830.1800 | (Guideline #62-3) Analytical Method |
| Guideline 850.4400 | (Guideline #123-2) Aquatic Plant Growth and Reproduction Study with Duckweed and a Freshwater Diatom |
| Guideline 850.4225 | (Guideline #123-1(a)) Seedling Emergence, Tier II |
| Guideline 850.4250 | (Guideline #123-1(b)) Vegetative Vigor, Tier II |
| N/A | (Guideline #72-4(b)) Life Cycle Invertebrate |
| Guideline 810.1000 | (Guideline #90-1) Use/Usage Data |
| Guideline 860.1500 | Crop Field Trials for fruiting vegetables (except cucurbits) on non-bell peppers |

Regarding the use and usage data cited above, as discussed in Section III, "Post Application Occupational Risk," the Agency is requesting that the technical registrant submit further information on practices associated with agricultural transplanting operations. Specifically, the Agency is interested in exposure to bensulide-treated soil that remains on the transplant wheel.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. Registrant responses are under review.

2. Labeling Requirements for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies.

All registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels must be submitted within 90 days of signature of this document. The Registration Division contact for bensulide is Mr. Jim Tompkins. His phone number is (703) 305-5697.

B. End-Use Products

1. Additional Generic Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, accompanies this Interim RED.

2. Labeling Requirements for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV. Specific language to implement these changes is specified in the Table 11 at the end of this section. Registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels must be submitted within 90 days of signature of this document. The Registration Division contact for bensulide is Mr. Jim Tompkins. His phone number is (703) 305-5697.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this Interim RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell bensulide products bearing old labels/labeling for 12 months from the date of issuance of this Interim RED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this Interim RED. Registrants and persons other than the registrant remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

D. Required Labeling Changes Summary Table

| Table 11: Summary of Required Labeling Changes for Bensulide | | |
|---|---|--------------------|
| Description | Required Labeling | Placement on Label |
| Manufacturing Use Products | | |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group | “Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].” | Directions for Use |
| | <p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> | Directions for Use |
| Environmental Hazards Statements Required by the RED and Agency Label Policies | "This chemical is toxic to fish and aquatic invertebrates, and poses a risk to reproduction of birds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA.” (Insert any additional chemical specific manufacturing use environmental hazards here) | Directions for Use |

| Description | Required Labeling | Placement on Label |
|--|--|--|
| End Use Products Intended for Occupational Use (WPS) | | |
| <p>PPE Requirements Established by the RED¹ for liquid products</p> | <p>“Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts correct material as per supplements 3 of PR Notice 93-7). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> * long-sleeved shirt and long pants, * chemical-resistant gloves, * shoes plus socks <p>In addition, a NIOSH-approved dust-mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N², R, P, or HE filter must be worn by 1) mixers, loaders, 2) persons participating in chemigation, and 3) commercial or for-hire applicators (due to risk from repeated exposures).”</p> | <p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p> |
| <p>User Safety Requirements</p> | <p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p> |

| Description | Required Labeling | Placement on Label |
|-----------------------------|--|--|
| Engineering Controls | <p>“Engineering Controls”</p> <p>“When handlers use closed systems or enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p> |
| User Safety Recommendations | <p>“User Safety Recommendations”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p> | <p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p> |

| Description | Required Labeling | Placement on Label |
|--|---|--|
| Environmental Hazards | <p>“Environmental Hazards”</p> <p>"This chemical is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Do not apply when weather conditions favor drift from the treated area.”</p> <p>“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”</p> <p>“Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.”</p> <p>“This product may impair reproduction in birds if used during the breeding season.”</p> | Precautionary Statements immediately following the User Safety Recommendations |
| Restricted-Entry Interval | “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.” | Directions for Use, Agricultural Use Requirements Box |
| Early Re-entry Personal Protective Equipment established by the RED. | <p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <p>*coveralls, *chemical-resistant gloves (such as, or made of, any waterproof material), *shoes plus socks”</p> | |

| Description | Required Labeling | Placement on Label |
|--|--|---|
| General Application Restrictions | “Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.” | Place in the Direction for Use directly above the Agricultural Use Box. |
| Chemigation Restrictions | “This product may only be applied by chemigation in Arizona and California” | Directions for Use |
| Aerial Application and Spray Drift Restrictions | “This product may not be applied by aircraft.” “Do not allow this product to drift.” | Directions for Use in General Precautions and Restrictions |
| End Use Products Intended for Occupational Use (Non-WPS) | | |
| PPE Requirements Established by the RED ¹ for Liquid Products | <p>“Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product (registrant inserts chemical resistant material as per instructions in Supplement Three of PR Notice 93-7). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers and loaders must wear:</p> <ul style="list-style-type: none"> * long-sleeved shirt and long pants, * chemical-resistant gloves, * shoes plus socks * a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N², R, P, or HE filter. <p>Applicators and other handlers must wear:</p> <ul style="list-style-type: none"> * long-sleeved shirt and long pants. | Precautionary Statements under Hazards To Humans and Domestic Animals |

| Description | Required Labeling | Placement on Label |
|--|---|--|
| <p>PPE Requirements Established by the RED¹ for Granular Products</p> | <p>“Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product (registrant inserts chemical resistant material as per instructions in Supplement Three of PR Notice 93-7). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart.”</p> <p>“ Applicators using a push type spreader and all loaders must wear:</p> <ul style="list-style-type: none"> * coveralls over long-sleeved shirt and long pants, * chemical resistant gloves, * chemical resistant footwear plus socks” * a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N², R, P, or HE filter. <p>All other applicators and handlers must wear:</p> <ul style="list-style-type: none"> * long-sleeved shirt and long pants, * chemical-resistant gloves * shoes plus socks <p>In addition to the above, for-hire applicators (non-golf-course employees) must wear a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N², R, P, or HE filter (due to risk from repeated exposures) when applying this product to golf courses.”</p> | <p>Precautionary Statements under Hazards To Humans and Domestic Animals</p> |

| Description | Required Labeling | Placement on Label |
|--|--|--|
| User Safety Requirements | “Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.” | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following the PPE requirements) |
| Engineering Controls for liquid products | “Engineering Controls” “When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.” | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |
| Engineering Controls for granular products | “Engineering Controls” “When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.” | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |
| User Safety Recommendations | See User Safety Recommendations for WPS above. | Placed in a box in the Precautionary Statements under Hazards to Humans and Domestic Animals immediately following Engineering Controls. |

| Description | Required Labeling | Placement on Label |
|-------------------------------|---|--|
| Environmental Hazards | <p>“Environmental Hazards”</p> <p>"This chemical is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Do not apply when weather conditions favor drift from the treated area.”</p> <p>“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”</p> <p>“Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.”</p> <p>“This product may impair reproduction in birds if used during the breeding season.”</p> | Precautionary Statements following the User Safety Recommendations under the Heading “Environmental Hazards” |
| Watering-In/Entry Restriction | <p>“IMPORTANT: THIS PRODUCT WILL NOT WORK UNLESS IT IS WATERED IN FOR 10-15 MINUTES. FOR SAFETY REASONS, WATER THIS PRODUCT IN AS SOON AS POSSIBLE FOLLOWING APPLICATION FOR 10-15 MINUTES AND DO NOT ALLOW CHILDREN OR PETS ON TREATED AREAS UNTIL DRY FOLLOWING THE WATERING.”</p> <p>“WATERING-IN MUST BE PERFORMED BY THE COMMERCIAL APPLICATOR OR THE COMMERCIAL APPLICATOR MUST PROVIDE THE ABOVE WATERING-IN INSTRUCTIONS TO THE RESIDENT IN WRITING USING BOLD-FACE TYPE AND/OR RED PRINT OR OTHER METHODS TO ENSURE THE WARNING IS PROMINENTLY DISPLAYED ON THE MATERIAL PROVIDED TO THE RESIDENT.”</p> | Directions for Use Under General Precautions and Restrictions |

| Description | Required Labeling | Placement on Label |
|--|---|---|
| Application Restrictions | <p>“Do not apply this product in a way that will contact workers or other persons”</p> <p>“For use only on golf courses (greens, tees and bentgrass fairways only) and on residential lawns.”</p> <p>“Do not use on parks, recreational areas, or other public sites.”</p> <p>“Applications on bentgrass fairways is limited to following states: OH, PA, NY, MI, CT, MA, IN, IL, NJ, WV, MN, WI, VT, NH, RI, DE, MD, VA”). “Applications on bentgrass fairways may only be made in the Fall and are limited to one application per year.”</p> <p>“Applications to greens and tees are limited to two per year”</p> <p>Note: The following sites must be removed from the label:</p> <ul style="list-style-type: none"> * fairways (unless as specified above) * parks * recreational areas * ornamentals * groundcovers | Directions For Use under General Precautions and Restrictions |
| Application Equipment Restrictions (granular products) | <p>“This product may only be applied by tractor-drawn spreader or by push type spreader.”</p> <p>Note: All other equipment (except as specified above) must be removed from the label.</p> | Direction for Use under General Precautions and Restrictions |
| Application Equipment Restrictions (liquid products) | <p>“This product may only be broadcast applied by groundboom or by low pressure/high volume turfgun. This product may be applied by low pressure handwand for spot treatments only.”</p> <p>Note: All other application equipment (except as specified above) must be removed from the label.</p> | Direction for Use under General Precautions and Restrictions |

| Description | Required Labeling | Placement on Label |
|---|---|--|
| End Use Products Intended Primarily for Use by Homeowners | | |
| Application Restrictions | “Do not apply this product in a way that will contact people or pets” | Directions for Use under General Precautions and Restrictions |
| Application/Entry Restriction | “IMPORTANT: THIS PRODUCT WILL NOT WORK UNLESS IT IS WATERED IN FOR 10-15 MINUTES. FOR SAFETY REASONS, WATER THIS PRODUCT IN AS SOON AS POSSIBLE FOLLOWING APPLICATION FOR 10-15 MINUTES AND DO NOT ALLOW CHILDREN OR PETS ON TREATED AREAS UNTIL DRY FOLLOWING THE WATERING.” | Directions for Use under General Precautions and Restrictions Statement must be in the color red and in all caps. |
| Application Equipment Restrictions | “This product may only be applied by a push-type spreader. Hand-held rotary broadcast spreaders are prohibited.” | Directions for Use under General Precautions and Restrictions |

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

² If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped.

Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label. Instructions in the Labeling Required section not in quotes represents actions that the registrant must take to amend their labels or product registrations.

VI. RELATED DOCUMENTS AND HOW TO ACCESS THEM

This Interim Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, 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 September 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 July 7, 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: "<http://www.epa.gov/pesticides/op>."

VII. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR INTERIM REREGISTRATION

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|---|---------------------|---|-----------------|------------------------|--|--|
| Food/Feed Uses | | | | | | |
| Brassica (Cole) Leafy Vegetables Group ³ | | | | | | |
| Preplant incorporated or preemergence | 4 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. |
| Soil broadcast/band treatment (groundboom) | 6 lb/gal EC | | | | | |
| Chemigation | | | | | | |
| Carrots | | | | | | |
| Preplant incorporated or preemergence | 4 lb/gal EC | 5.0 lb/A | 1/crop cycle | 5.0 lb/A | 12 hours | Use limited to TX. Feeding treated carrots to livestock is prohibited. Labels must be amended to reflect a maximum seasonal use rate of 5 lb/A. |
| Soil broadcast/band treatment (groundboom) | 6 lb/gal EC | | | | | |

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|---|---------------------|---|-----------------|------------------------|--|--|
| Cucurbit Vegetables Group ⁴ | | | | | | |
| Preplant incorporated or preemergence | 4 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Application may be made alone or as tank mix with ALANAP® (naptalam) for weed control in cantaloupes, cucumbers, muskmelons, and watermelons,. Tank mix use prohibited in CA. Chemigation may only occur in California and Arizona. |
| Soil broadcast/band treatment (groundboom) | 6 lb/gal EC | | | | | |
| Chemigation | | | | | | |
| Fruiting Vegetables Group ⁵ | | | | | | |
| Preplant incorporated or preemergence | 4 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. Labels must be amended to restrict use to bell peppers only unless three required non-bell pepper field trials are conducted. |
| Soil broadcast/band treatment (groundboom) | 6 lb/gal EC | | | | | |
| Chemigation | | | | | | |

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|--|--------------------------------|---|-----------------|------------------------|--|--|
| Garlic | | | | | | |
| Preplant incorporated or preemergence Soil broadcast/band treatment (groundboom) Chemigation | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. |
| Seed bed preparation (fall) Soil band and bed-up (groundboom) | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Use limited to ID and OR. |
| Leafy Vegetables (except Brassica Vegetables) Group ⁶ | | | | | | |
| Preplant incorporated or preemergence Soil broadcast/band treatment (groundboom) Chemigation | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. |

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|--|--------------------------------|---|-----------------|------------------------|--|--|
| Onions, Bulb | | | | | | |
| Preplant incorporated or preemergence Soil broadcast/band treatment (groundboom) Chemigation | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. |
| Preplant (fall) Soil band and bed-up (groundboom) | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Use limited to ID and OR. Application through any type of irrigation system is prohibited. |
| | 4 lb/gal EC 6 lb/gal EC | 3.0 lb/A | 1/crop cycle | 3.0 lb/A | 12 hours | Use limited to OR and WA. Application through any type of irrigation system is prohibited. |

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|--|--------------------------------|---|---------------|------------------------|--|---|
| Onions, Bulb (Continued) | | | | | | |
| Postplant incorporated, at layby Soil band treatment (groundboom) Chemigation | 4 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Use limited to AZ for onions grown for seed. Not for feed use or human consumption. Feeding to animals is prohibited. |
| Shallots | | | | | | |
| Preplant incorporated or preemergence Soil broadcast/band treatment (groundboom) Chemigation | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Chemigation may only occur in California and Arizona. |
| Seed bed preparation (fall) Soil band and bed-up (groundboom) | 4 lb/gal EC 6 lb/gal EC | 6.0 lb/A | 1/crop cycle | 6.0 lb/A | 12 hours | Use limited to ID and OR. Application through any type of irrigation system is prohibited. |

| Site Application Type | Formulation % AI | Max. Single Application Rate (lb ai/A) | Max.# Apps | Max. Seasonal Total | Agricultural Reentry Interval ¹ | Restrictions/Comments ² |
|---|---------------------|---|---------------|------------------------|--|--|
| Field Grown Herbaceous Plants | | | | | | |
| Preplant or preemergence to flatplanted or bedded crops. Groundboom Chemigation | 4 lb/gal EC | 9.0 lb/A | 1/yr | 1 | 12 hours | Chemigation may only occur in California and Arizona. May not be used in residential areas. |
| Field Grown Bulbs | | | | | | |
| Preplant or preemergence to flatplanted or bedded crops. Groundboom Chemigation | 4 lb/gal EC | 9.0 lb/A | 1/yr | 1 | 12 hours | Chemigation may only occur in California and Arizona. May not be used in residential areas. |

1. The restricted entry interval (REI) for the 4 and 6 lb/gal EC formulations is 12 hours, except if the product is soil-injected or soil-incorporated. Then workers are allowed to enter the treated area if there will be no contact with anything that has been treated.
2. The following rotational crop restrictions are established for the 4 and 6 lb/gal EC formulations: carrots, cotton, and crops on the label (or crops from labeled crop groupings) may be replanted following application, without restrictions. A 120 day plantback interval has been established for all other crops, and the soil must be tilled to minimum of 4 inches prior to replanting.
3. Includes broccoli, broccolini, broccoflower, Chinese broccoli, broccoli raab (rapini), brussels sprouts, cabbage, Chinese cabbage (bok choy, napa), Chinese mustard cabbage (gai choy) cauliflower, cavalo broccolo, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, and rape greens.

4. Includes chayote, Chinese waxgourd (Chinese preserving melon), citron melon, cucumbers, gherkin, edible gourd (hechima, Chinese okra), muskmelons (including muskmelon, true cantaloupe, cantaloupe, casaba, Crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melons), pumpkins, summer squash (crookneck squash, straightneck squash, zucchini, scallop squash, vegetable marrow, spaghetti squash, hyotan, cucuzza, balsam apple, balsam pear, bitter melon, Chinese cucumber), winter squash (including butternut squash, calabaza, hubbard squash, acorn squash), and watermelons.
5. Includes eggplant, ground cherry, pepinos, peppers (bell peppers, chili peppers, cooking peppers, pimentos, sweet peppers), and tomatillo. However, all labels must be amended to restrict use to bell peppers only unless three required non-bell pepper field trials are conducted.
6. Includes arugula (roquette), cardoon, celery, Chinese celery, celtuce, chervil, chrysanthemum (edible leafed garland), corn salad, cress (garden, upland), dandelion, dock (sorrel), endive (escarole), Florida fennel, lettuce (head or leaf), orach, parsley, radicchio (red chicory), and Swiss chard.
7. Alyssum, aster, bachelor's button, calendula, candy-tuft, coral bell, daisy, marigold, pansy, primrose, stock, sweet pea, wallflower.
8. Daffodil, dahlia, freesia, gladiolus, narcissus, ranunculus, tulip.

| Site Application Type | Formulation %AI | Max. Single Application Rate (lb ai/A) | Max.# Apps/Yr | Max. Yearly Total | Reentry Interval | Restrictions/Comments |
|---|--|---|------------------|----------------------|---------------------|--|
| Turf Uses | | | | | | |
| Golf Course–Greens and Tees | | | | | | |
| Groundboom Tractor drawn spreader | 3.6-12.5 lbs AI/ 100 lbs. Granular | 12.5 | 2 | 25 lb/A | N/A | Low pressure hand wand may be used for spot treatment only. All other hand-held application methods are prohibited. |
| Drop spreader Low pressure hand wand | 4-12.5 lb/gal EC | 12.5 | 2 | 25 lb/A | N/A | |

| Site | Formulation | Max. Single Application Rate (lb ai/A) | Max.# Apps/Yr | Max. Yearly Total | Reentry Interval | Restrictions/Comments |
|---|--|--|---------------|-------------------|------------------|---|
| Application Type | %AI | | | | | |
| Golf Course–Fairways | | | | | | |
| Groundboom Tractor drawn spreader | 3.6-12.5 lbs AI/ 100 lbs. Granular | 12.5 | 1 | 12.5 lb/A | N/A | <p>May only be applied one time in the Fall. May only be applied to bentgrass fairways in the following states: OH, PA, NY, MI, CT, MA, IN, IL, NJ, WV, MN, WI, VT, NH, RI, DE, MD, VA.</p> <p>Low pressure hand wand may be used for spot treatment only. All other hand-held methods are prohibited.</p> <p>May not be used on parks, recreational areas, or ornamentals and ground covers.</p> |
| Drop spreader Low pressure hand wand | 4-12.5 lb/gal EC | 12.5 | 1 | 12.5 lb/A | N/A | |

| Site | Formulation | Max. Single Application Rate (lb ai/A) | Max.# Apps/Yr | Max. Yearly Total | Reentry Interval | Restrictions/Comments |
|------------------|--|--|---------------|-------------------|------------------|---|
| Application Type | %AI | | | | | |
| Home Lawns | | | | | | |
| Drop spreader | 3.6-12.5 lbs AI/ 100 lbs. Granular | 12.5 | 2 | 25 lb | N/A | May not be used on parks, recreational areas, or ornamentals and ground covers. Do not use a bellygrinder or any other hand-held method when applying. |

**Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES
USED TO MAKE THE INTERIM REREGISTRATION DECISION**

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #2035 (bensulide) covered by this Interim RED. It contains generic data requirements that apply to bensulide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

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

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
 - A. Terrestrial food
 - B. Terrestrial feed
 - C. Terrestrial non-food
 - D. Aquatic food
 - E. Aquatic non-food outdoor
 - F. Aquatic non-food industrial
 - G. Aquatic non-food residential
 - H. Greenhouse food
 - I. Greenhouse non-food
 - J. Forestry
 - K. Residential
 - L. Indoor food
 - M. Indoor non-food
 - N. Indoor medical
 - O. Indoor residential

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

APPENDIX B

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|--------------------------|----------------------|----------------------------------|-------------|--|
| PRODUCT CHEMISTRY | | | | |
| 830.1550 | 61-1 | Product Identity and Composition | All | 41532001, 00163310, 00088284, 42685001 |
| 830.1600 | 61-2A | Start. Mat. & Mnfg. Process | All | 00163310, 00088284 |
| 830.1670 | 61-2B | Formation of Impurities | All | 00163310, 00088284 |
| 830.1700 | 62-1 | Preliminary Analysis | All | 40033501, 00163299 |
| 830.1750 | 62-2 | Certification of limits | All | 40033501, 00163299 |
| 830.1800 | 62-3 | Analytical Method | All | DATA GAP |
| 830.6302 | 63-2 | Color | All | 41532001, 00157314 |
| 830.6303 | 63-3 | Physical State | All | 41532001, 00157314 |
| 830.6304 | 63-4 | Odor | All | 41532001, 00157314 |
| 830.7050 | | UV/Visible Absorption | All | DATA GAP |
| 830.7200 | 63-5 | Melting Point | All | 41532001, 00157314 |
| 830.7220 | 63-6 | Boiling Point | All | 41532001, 00157314 |
| 830.7300 | 63-7 | Density | All | 41532001, 42685001 |
| 830.7840 830.7860 | 63-8 | Solubility | All | 41532001, 00157314 |
| 830.7950 | 63-9 | Vapor Pressure | All | 41532001, 00157314 |

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|---------------------------|----------------------|-------------------------------------|-------------|--|
| 830.7370 | 63-10 | Dissociation Constant | All | 41532001, 00157314 |
| 830.7550 | 63-11 | Octanol/Water Partition Coefficient | All | 41532001, 00157314 |
| 830.7000 | 63-12 | pH | All | 41532001, 00157314 |
| 830.6313 | 63-13 | Stability | All | DATA GAP |
| 830.7100 | 63-18 | Viscosity | All | 41532001 |
| 830.6319 | 63-19 | Miscibility | All | 41532001 |
| 830.6320 | 63-20 | Corrosion characteristics | All | 00157314 |
| ECOLOGICAL EFFECTS | | | | |
| 850.2100 | 71-1 | Avian Acute Oral Toxicity | A,C,K | 00158455 |
| 850.2200 | 71-2A | Avian Dietary Toxicity - Quail | A,C,K | 43616001, 00158456 |
| 850.2200 | 71-2B | Avian Dietary Toxicity - Duck | A,C,K | 00158457 |
| 850.2400 | 71-3 | Wild Mammal Toxicity | A,C,K | 92005011 |
| 850.2300 | 71-4A | Avian Reproduction - Quail | A,C,K | 43616001, 43121901, 44486901 |
| 850.2300 | 71-4B | Avian Reproduction - Duck | A,C,K | 43121902, 43616001, 43616002, 44486901 |
| 850.1075 | 72-1A | Fish Toxicity Bluegill | A,C,K | 41931001, 00157316 |
| 850.1075 | 72-1C | Fish Toxicity Rainbow Trout | A,C,K | 00157315, 40098001 |
| 850.1010 | 72-2A | Invertebrate Toxicity | A,C,K | WAIVED |
| | 72-3A | Estuarine/Marine Toxicity - Fish | A,C,K | WAIVED, 42750201, 40228401 |

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|----------------------|----------------------|--|-------------|--|
| | 72-3B | Estuarine/Marine Toxicity - Mollusk | A,C,K | 42750202, 40228401 |
| | 72-3C | Estuarine/Marine Toxicity - Shrimp | A,C,K | 42750203, 40228401 |
| | 72-4A | Fish- Early Life Stage | A,C,K | 44720408 |
| | 72-4B | Estuarine/Marine Invertebrate Life Cycle | A,C,K | DATA GAP, 44720407 |
| 850.1500 | 72-5 | Life Cycle Fish | A,C,K | Data may be required depending on results of fish-early life stage study |
| | 123-1 | Non-target Terrestrial Plant Phytotoxicity | A,C,K | DATA GAP |
| 850.4400 | 123-2 | Aquatic Plant Growth | A,C,K | DATA GAP, 44720402, 44720404, 44720405, 44720406 |
| | 123-3 | Aquatic Plant Toxicity | A,C,K | 44720403 |
| 850.3020 | 141-1 | Honey Bee Acute Contact | A,C,K | 00036935 |
| TOXICOLOGY | | | | |
| 870.1100 | 81-1 | Acute Oral Toxicity-Rat | A,C,K | 00097921, 92005011 |
| 870.1200 | 81-2 | Acute Dermal Toxicity-Rabbit/Rat | A,C,K | 41597501, 00097921 |
| 870.1300 | 81-3 | Acute Inhalation Toxicity-Rat | A,C,K | 41646201 |
| 870.2400 | 81-4 | Primary Eye Irritation-Rabbit | A,C,K | 41597502 |
| 870.2500 | 81-5 | Primary Skin Irritation | A,C,K | 00097921, 92005012 |
| 870.2600 | 81-6 | Dermal Sensitization | A,C,K | 00160075 |

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|----------------------|----------------------|--|-------------|--|
| 870.6100 | 81-7 | Acute Delayed Neurotoxicity - Hen | A,C,K | 43334302, 43306301, 00131485 |
| 870.6200 | 81-8 | Acute Neurotoxicity Screen | A,C,K | 43195901 |
| 870.3100 | 82-1A | 90-Day Feeding - Rodent | A,C,K | 43919601 |
| 870.3150 | 82-1B | 90-Day Feeding - Non-rodent | A,C,K | 44052703 |
| 870.3200 | 82-2 | 21-Day Dermal - Rabbit/Rat | A,C,K | 44801101, 44809401, 42162002 |
| 870.4100 | 83-1A | Chronic Feeding Toxicity - Rodent | A,C,K | 43919602, 44161101, 00132002 |
| 870.4100 | 83-1B | Chronic Feeding Toxicity - Non-Rodent | A,C,K | 44052701, 44052702, 44052703, 44066401, 44052704 |
| 870.4200 | 83-2A | Oncogenicity - Rat | A,C,K | 43919602, 44161101, 00132002 |
| 870.4200 | 83-2B | Oncogenicity - Mouse | A,C,K | 44161105 |
| 870.3700 | 83-3A | Developmental Toxicity - Rat | A,C,K | 00146585 |
| 870.3700 | 83-3B | Developmental Toxicity - Rabbit | A,C,K | 42864201, 00152845 |
| 870.3800 | 83-4 | 2-Generation Reproduction - Rat | A,C,K | 43948701, 00131486 |
| 870.4300 | 83-5 | Combined Chronic Toxicity/ Carcinogenicity | A,C,K | 43919602, 44161101 |
| 870.5140 | 84-2A | Gene Mutation (Ames Test) | A,C,K | 00153493, 41902601 |
| 870.5375 | 84-2B | Structural Chromosomal Aberration | A,C,K | 41902601, 41902602, 42479201 |
| | 84-4 | Other Genotoxic Effects | A,C,K | 43273901 |

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|---------------------------|----------------------|------------------------------------|-------------|--|
| 870.7485 | 85-1 | General Metabolism | A,C,K | 42225401, 42007901, 42007902, 42007903, 42007904 |
| ENVIRONMENTAL FATE | | | | |
| | 160-5 | Chemical Identity | A,C,K | 00163310, 00088284 |
| 835.2120 | 161-1 | Hydrolysis | A,C,K | 00160074 |
| 835.2240 | 161-2 | Photodegradation - Water | A,C,K | 40513401 |
| 835.2410 | 161-3 | Photodegradation - Soil | A,C,K | 42162001 |
| 835.2370 | 161-4 | Photodegradation - Air | A,C,K | 41532001 |
| 835.4100 | 162-1 | Aerobic Soil Metabolism | A,C,K | 40460301 |
| 835.4200 | 162-2 | Anaerobic Soil Metabolism | A,C,K | 40460302 |
| 835.1240 | 163-1 | Leaching/Adsorption/Desorption | A,C,K | 42826701, 43180701, 43180702, 00162706 |
| 835.6100 | 164-1 | Terrestrial Field Dissipation | A,C,K | 44908801 |
| 835.1850 | 165-1 | Confined Rotational Crop | A,C,K | 43459201, 42578002 |
| | 165-4 | Bioaccumulation in Fish | A,C,K | 41931001 |
| RESIDUE CHEMISTRY | | | | |
| | 171-2 | Chemical Identity | A | 00163310, 00088284 |
| 860.1300 | 171-4A | Nature of Residue - Plants | A | 44223801, 42578001, 42507901, 42350401, 42281301 |
| 860.1340 | 171-4C | Residue Analytical Method - Plants | A | 92005036 |

Data Supporting Guideline Requirements for the Interim Reregistration of Bensulide

| New Guideline Number | Old Guideline Number | REQUIREMENT | USE PATTERN | CITATION(S) |
|----------------------|----------------------|---|-------------|---|
| 860.1380 | 171-4E | Storage Stability | A | 43975701, 41597503 |
| 860.1500 | 171-4K | Crop Field Trials (Bulb Vegetables) | A | 43665702, 43638201, 43334301 |
| 860.1500 | 171-4K | Crop Field Trials (Carrot) | A | 43755902, 43494401 |
| 860.1500 | 171-4K | Crop Field Trials (Cucumber) | A | 43782601 |
| 860.1500 | 171-4K | Crop Field Trials (Cucurbit Vegetables) | A | 43775201, 92005037, 92005038, 92005039 |
| 860.1500 | 171-4K | Crop Field Trials (Fruiting Vegetables) | A | DATA GAP FOR NON-BELL PEPPERS; 43711302, 92005041, 92005040, 00028822, 92005033, 92005034 |
| 860.1500 | 171-4K | Crop Field Trials (Leafy Vegetables) | A | 43764201, 43755901, 43746201, 43699901, 43682001, 43682002, 43676402 |
| 860.1500 | 171-4K | Crop Field Trials (Peppers) | A | 43755901, 43744701, 43711301, 43665701, 43672801 |
| OTHER | | | | |
| 810.1000 | 90-1 | Use/Usage Data | A,B,H,I,L,M | DATA GAP |

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, 1921 Jefferson Davis Highway, 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/op

These documents include:

HED Documents:

1. Human Health Risk Assessment, Bensulide
2. Acute and Chronic Dietary Exposure Analyses for the Revised HED Reregistration Eligibility Decision Document (RED)
3. Revised Occupational and Residential Reregistration Eligibility Document for Bensulide
4. Product Chemistry
5. Revised Estimated Environmental Concentrations in Ground and Surface Water for Bensulide used on Golf Course Fairways

EFED Documents:

- a. Environmental Risk Assessment, Bensulide
- b. Review of Additional Data for Bensulide (Chemical # 009801) and Addendum of the Ecological Risk Assessment for Reregistration.
- c. Updates to the Risk Assessment of the Bensulide RED, Based on Recently Submitted Data on Persistence of Residues on Grass.

**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

See attached table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Product Specific REQUIREMENTS STATUS AND REGISTRANT'S
RESPONSE page 1 of 2

Product Specific Footnotes and Key Definitions for Guideline Requirements

Page 1 of 2

Appendix G. EPA'S BATCHING OF BENSULIDE 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 bensulide 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.

Forty five products were found which contain bensulide as the active ingredient. These products have been placed into seven batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation. The following bridging strategies may be employed:

- Batch 2 may cite Batch 1 with the exception of eye and skin irritation data
- Batch 5 may rely on Batch 4 data
- Batches 6 and 7 may use the policy for granular pesticide products. However, due to the differences in inerts in Batch 6, products within Batch 6 may not share eye irritation 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.

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 1 | 10163-202 | Bensulide...46.0% | liquid |
| | 2217-777 | Bensulide...46.0% | liquid |
| | 34704-211 | Bensulide...46.0% | liquid |
| | 769-895 | Bensulide...46.0% | liquid |
| | 961-336 | Bensulide...46.0% | liquid |

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 2 | 10163-196 | Bensulide...46.0% | liquid |
| | 10163-200 | Bensulide...46.0% | liquid |
| | 10163-205 | Bensulide...46.0% | liquid |
| | 2217-696 | Bensulide...46.0% | liquid |
| | 56076-3 | Bensulide...46.0% | liquid |

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 3 | 10163-197 | Bensulide...34.8% | liquid |
| | 33955-554 | Bensulide...34.8% | liquid |
| | 5887-135 | Bensulide...34.8% | liquid |
| | 8660-128 | Bensulide...34.8% | liquid |

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 4 | 10163-198 | Bensulide...12.5% | liquid |
| | 34704-209 | Bensulide...12.5% | liquid |
| | 769-894 | Bensulide...12.5% | liquid |
| | 538-11 | Bensulide...11.0% | liquid |

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 5 | 538-26 | Bensulide...8.5% | solid |
| | 10163-204 | Bensulide...7.0% | solid |
| | 34704-208 | Bensulide...7.0% | solid |
| | 769-896 | Bensulide...7.0% | solid |
| | 8660-127 | Bensulide...7.0% | solid |
| | 961-338 | Bensulide...7.0% | solid |

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|-----------|--------------|---------------------|------------------|
| 6* | 538-129 | Bensulide...5.2% | solid |
| | 538-155 | Bensulide...4.78% | solid |
| | 538-53 | Bensulide...4.6% | solid |
| | 9198-73 | Bensulide...4.6% | solid |
| | 34704-216 | Bensulide...3.6% | solid |
| | 9198-72 | Bensulide...3.6% | solid |
| | 961-337 | Bensulide...3.6% | solid |
| | 538-156 | Bensulide...3.58% | solid |
| | 3234-36 | Bensulide...3.28% | solid |

*Batch 6 products may not share eye irritation data.

| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| 7 | 10163-199 | Bensulide...3.6% | solid |
| | 32802-15 | Bensulide...3.6% | solid |
| | 34704-210 | Bensulide...3.6% | solid |
| | 769-897 | Bensulide...3.6% | solid |
| | 869-212 | Bensulide...3.6% | solid |

| No Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
|----------|--------------|---------------------|------------------|
| | 10163-201 | Bensulide...92.0% | liquid |
| | 10163-222 | Bensulide...63.5% | liquid |
| | 2217-778 | Bensulide...7.0% | solid |
| | 538-164 | Bensulide...5.25% | solid |
| | 538-77 | Bensulide...5.1% | solid |
| | 8660-126 | Bensulide...3.6% | solid |
| | 10163-203 | Bensulide...3.6% | solid |

Appendix H. LIST OF REGISTRANTS SENT THIS DATA CALL-IN

Insert List–Page 1 of 1

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/.](http://www.epa.gov/opprd001/forms/)

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

| | | |
|---------|--|--|
| 8570-1 | Application for Pesticide Registration/Amendment | http://www.epa.gov/opprd001/forms/8570-1.pdf. |
| 8570-4 | Confidential Statement of Formula | http://www.epa.gov/opprd001/forms/8570-4.pdf. |
| 8570-5 | Notice of Supplemental Registration of Distribution of a Registered Pesticide Product | http://www.epa.gov/opprd001/forms/8570-5.pdf. |
| 8570-17 | Application for an Experimental Use Permit | http://www.epa.gov/opprd001/forms/8570-17.pdf. |
| 8570-25 | Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need | http://www.epa.gov/opprd001/forms/8570-25.pdf. |
| 8570-27 | Formulator's Exemption Statement | http://www.epa.gov/opprd001/forms/8570-27.pdf. |

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

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. 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' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) 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. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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

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

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

Date of receipt
EPA identifying number
Product Manager assignment

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

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

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

- a. Health and Environmental Effects Science Chapters.
- b. Detailed Label Usage Information System (LUIS) Report.