

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

Enclosed is a Reregistration Eligibility Document (RED) for the pesticide active ingredient 10,10'-Oxybisphenoxarsine, hereafter referred to as OBPA. The RED is the Agency's evaluation of OBPA's data base, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for reregistration. Also enclosed is the EPA RED facts and the Pesticide Reregistration Handbook which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies outstanding product specific data requirements for end-use products and manufacturing-use products. These requirements are listed on the Requirements Status and Registrant's Response Form, which, along with the Data Call-In Response Form listing all of your company's products subject to the RED, is included as an Attachment. Instructions for completing both forms are contained in the RED package. All product specific data must be submitted and found acceptable by the Agency before a product can be reregistered.

Generic data requirements usually will have been fulfilled prior to making a reregistration eligibility decision. However, there may be some instances where additional generic data are required. If generic data requirements need to be fulfilled, all registrants must complete the appropriate Data Call-In Response Form and Requirements Status and Registrant's Response Form. These forms are in the appendices to the RED.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.



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The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 90 Days of Your Receipt of this Letter

1. For **each** product which is subject to this RED, you must complete, sign and submit the data call-in (DCI) response forms attached to the RED [Appendix G, Attachments B and C, has forms for product specific data]. Follow the instructions in Attachments B and C for completing those forms and submit the forms to the appropriate address specified in the Data Call-Ins. The DCI forms for product specific data are to be sent to the Registration Division (use the mailing distribution code RED-RD-PM22 for your product specific response).
2. No time extensions will be granted for submitting the 90-day responses. If the Agency does not receive a response for a product, it may issue a Notice of Intent to Suspend (NOIS) for that product.
3. Any requests for data waivers or time extensions to the 8-month deadline must be submitted as part of your 90-day response. Such requests will generally not be considered if submitted later than the 90-day response.

Within 8 Months of the Date of this Letter

1. For each product, you must submit a completed Application for Reregistration (EPA Form 8570-1), five copies of the label and labeling revised as specified by the RED and in accordance with current requirements, two completed copies of the Confidential Statement of Formula (CSF) (EPA Form 8570-4), a completed Certification with Respect to Citation of Data (EPA Form 8570-31), and data or references to data (see item 2 below).
2. You must submit or cite the required product specific data as part of your commitment for reregistration. For most products, you will probably be citing data which have already been submitted to the Agency. In these cases, you must submit a list of the studies and the corresponding EPA identifier numbers (i.e., ACCESSION or MRID numbers). Before citing these studies, you must make sure that they meet the Agency's current acceptance criteria (Appendix G, Attachment E). Be sure to follow data formatting requirements in P.R. Notice 86-5. Failure to adequately comply with the data requirements specified in this RED may result in the Notice of Intent to Suspend your product.

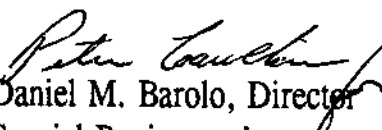
3. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the nominal concentration rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).
4. Send your Application for Registration to the **Registration Division Product Manager 22 (PM 22)** who is assigned to the product, **Cynthia Giles-Parker**. Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is **RED-RD-PM22**.

Questions on product specific data requirements and labeling (for both End-use and Manufacturing-use products) should be directed to the **Registration Division Product Manager 22 Team member** for OBPA, at (703) 305 - 5540.

Any questions in regard to this RED should be directed to **Venus Eagle, Chemical Review Manager, Reregistration Branch, Special Review and Reregistration Division** at (703) 308 - 8045.

The Agency is prepared to meet with any registrants who have questions about responding to the OBPA RED. If you wish to meet with the Agency, you must contact **Ms. Cynthia Giles-Parker** within two weeks of your receipt of the RED. The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,

  
Daniel M. Barolo, Director  
Special Review and  
Reregistration Division

Enclosures





# R.E.D. FACTS

## 10, 10'- OXYBISPHENOX- ARSINE (OBPA)

### Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces its decision and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for 10, 10'-Oxybisphenoxarsine (OBPA).

### Use Profile

OBPA is a bacteriostat, disinfectant (bactericide/germicide) and fungicide. It is registered to prevent the growth of microorganisms in plastics which are fabricated into shower curtains, floor coverings, wall coverings, coated fabrics, marine upholstery, automotive vinyl trim, vinyl molding, tarpaulins, awnings, gaskets, weather stripping, caulking, ditch liners and swimming pool liners. OBPA also is used as a preservative in adhesives, coatings and specialty products, in paper and plastic products, in textiles, fibers and cordage, in carpets, and in other pesticides.

OBPA is formulated as an emulsifiable concentrate, pelleted/tableted, soluble concentrate/liquid and ready-to-use liquid. The concentration varies from 1 to 5 percent, based on the total weight of formulation.

### Regulatory History

OBPA was initially registered as a pesticide in the United States in 1965. EPA issued a Registration Standard for OBPA in October 1981 (NTIS PB82-172271). The Registration Standard required additional product chemistry data, a hydrolysis study and an activated sludge metabolism study, which was later waived. In September 1991, EPA

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issued a Data Call-In (DCI) requiring product chemistry data and a repeat of the hydrolysis study (which was later rescinded).

EPA has now completed its review of the OBPA data base, including the data submitted in response to the 1991 DCI.

## **Human Health Assessment**

OBPA shows a high degree of acute toxicity when administered orally and to the skin and eyes. It has been placed in Toxicity Category I indicating the highest degree of acute toxicity for these effects.

In subacute feeding studies using rats, animals fed the highest dose levels had retarded growth, liver effects and an accumulation of arsenic in the liver and kidneys. In a subacute inhalation study, rats and guinea pigs sacrificed 48 hours after their last exposure to OBPA had mild to moderate heart effects and the rats had liver effects. Animals kept four months longer with no further exposure showed no effects of OBPA.

OBPA does not appear to cause developmental or reproductive toxicity, and shows no mutagenic activity. Metabolism studies show that arsenic accumulates in the liver and kidneys as a result of exposure to OBPA, however this arsenic is cleared from the body after two weeks.

### **Dietary Exposure**

OBPA is not registered for use on food, feed or processed commodities. Therefore, dietary exposure or risk is not expected.

### **Occupational and Residential Exposure**

Although occupational and residential exposure to OBPA occurs, such exposure is indirect and/or extremely low level. Direct occupational exposure during production of pesticide or plastic products containing OBPA is mitigated by the use of closed systems and appropriate protective gloves and eyewear. Indirect residential and other human exposure to OBPA in treated plastics is low because only a small percent of OBPA is added to these products, and only small amounts of OBPA are released, very slowly.

### **Human Risk Assessment**

OBPA does not pose human dietary risks since no food-related uses are registered and dietary exposure is not anticipated.

The potential for occupational exposure to OBPA is minimal provided that OBPA is used in a closed system and that appropriate Personal Protective Equipment (PPE) is worn. Residential exposure to OBPA is indirect and low level. No additional uses are proposed that would significantly increase human exposure to OBPA. Therefore, the

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potential human risks from exposure to OBPA pesticides are likely to be minimal.

## **Environmental Assessment**

### **Environmental Fate**

No further environmental fate data are needed because of the very limited environmental exposure expected from current uses of OBPA. The Registration Standard required an activated sludge study, which was later waived, and a hydrolysis study. The hydrolysis study was found deficient, but the Agency later determined that an additional hydrolysis study was not needed based on the fact that OBPA-treated materials will not result in significant levels of residues being released into the environment. An extractability study on pool liners and vinyl baby pants showed that leaching would not result in residues that exceed the 50 ppb maximum limit established for arsenic in drinking water.

### **Ecological Effects**

Studies usually required to determine effects on birds, fish and other nontarget organisms are waived because of OBPA's indoor, industrial use pattern. Avian and aquatic toxicity information is needed only to assess the need for precautionary label statements.

Since OBPA is highly corrosive, it would be very highly toxic to birds. Existing acute oral rat studies confirm that OBPA is highly toxic to terrestrial organisms.

Aquatic studies show that OBPA is very highly toxic to both freshwater and marine fish, and to freshwater aquatic and marine invertebrates, on an acute basis.

### **Ecological Effects Risk Assessment**

OBPA is an indoor, non-food, industrial use pesticide which is incorporated into plastics, textiles, adhesives, etc.. The Agency does not conduct risk assessments for nontarget organisms for indoor uses without effluent. Should residues of OBPA in effluent ever exceed 1.75 ppb, aquatic organisms would be acutely at risk.

## **Additional Data Required**

EPA is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling for reregistration of pesticide products containing OBPA.



## **Product Labeling Changes Required**

The labels of all registered pesticide products containing OBPA must comply with EPA's current pesticide labeling requirements. End-use and manufacturing use products also must bear the following label statement in the Environmental Hazards section:

"This pesticide is toxic to fish, aquatic invertebrates, birds, and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

In addition, labels must consistently reflect any potential eye and skin hazard (Danger, Warning or Caution Signal Words) and recommend appropriate protective equipment (protective eyewear [goggles or face shield], waterproof gloves, long sleeved shirts and long-legged pants, shoes and socks).

## **Regulatory Conclusion**

The use of currently registered pesticide products containing OBPA in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These OBPA products will be reregistered once the required product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products which contain other active ingredients in addition to OBPA will be eligible for reregistration only when all of their other active ingredients also are determined to be eligible.

## **For More Information**

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for OBPA during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the OBPA RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about OBPA or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC

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20460, telephone 703-308-8000. For information about reregistration of individual products containing OBPA, please contact Product Manager - Cynthia Giles-Parker, Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-5540.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.



# OBPA

## Summary of Requirements

### Within 90 Days of Receipt of this RED

1. Sign and submit data call-in response forms attached to the product specific DCI (Appendix G, Attachment B and C).

### Within 8 Months From the Date of this RED

1. Submit a completed Application for Reregistration (EPA Form 8570-1).
2. Submit five copies of the label and labeling revised as specified by the RED and in accordance with current requirements.
3. Submit two completed copies of the Confidential Statement of Formula (EPA Form 8570-4).
4. Submit a completed Certification With Respect to Data Compensation (EPA Form 8570-31), if applicable. EPA Form 8570-31 is required to establish ownership of product specific data only and allows only two options: development of data (owner submission method); and citing of specific data (selective method requiring a data matrix). The cite all method of support is not an acceptable option for responding to the product specific data requirements of the RED.
5. Submit the required data or references to data as specified by the RED/DCI for product specific data (Appendix G). Please note that products listed in Table I (Attachment D) did not fall into any batch. Therefore the acute toxicology data required in the product specific DCI (Appendix G) must be submitted for these products. (i.e., the grouping of similar products for purposes of submitting acute toxicology data does not apply to those products listed in Table I of Appendix G, Attachment D). All data submitted to fulfill requirements listed in **Appendix G** should be sent to:

Document Processing Desk (RED/RD/PM22)  
Office of Pesticide Programs (H7504C)  
Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460-0001



**REREGISTRATION ELIGIBILITY DOCUMENT**

**10,10'-OXYBISPHENOXARSINE (OBPA)**

**LIST A**

**CASE 0044**

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



## **OBPA REREGISTRATION ELIGIBILITY TEAM**

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Alan Halvorson

Biological Analysis Branch  
Economic Analysis Branch

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Chemical Coordination Branch  
Toxicology Branch II  
Occupational and Residential Exposure Branch

#### **Registration Division**

Theresa Stowe  
Joanne Hayes  
Bipin Gandhi

Fungicide-Herbicide Branch  
Registration Support Branch  
Registration Support Branch

#### **Special Review and Reregistration Division**

Venus Eagle  
Carol Stangle  
Gene Frane

Reregistration Branch  
Policy Planning and Operations Branch  
Policy and Special Projects Staff



## **GLOSSARY OF TERMS AND ABBREVIATIONS**

|                        |   |
|------------------------|---|
| <b>a.i.</b>            | <b>Active Ingredient</b>  |
| <b>CAS</b>             | <b>Chemical Abstracts Service</b>   |
| <b>CSF</b>             | <b>Confidential Statement of Formula</b>  |
| <b>EEC</b>             | <b>Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.</b>   |
| <b>EP</b>              | <b>End-Use Product</b>  |
| <b>EPA</b>             | <b>U.S. Environmental Protection Agency</b>   |
| <b>FIFRA</b>           | <b>Federal Insecticide, Fungicide, and Rodenticide Act</b>  |
| <b>FFDCA</b>           | <b>Federal Food, Drug, and Cosmetic Act</b>   |
| <b>HDT</b>             | <b>Highest Dose Tested</b>  |
| <b>LC<sub>50</sub></b> | <b>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 or feed, e.g., mg/l or ppm.</b>       |
| <b>LD<sub>50</sub></b> | <b>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). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.</b> |
| <b>LD<sub>10</sub></b> | <b>Lethal Dose-low. Lowest Dose at which lethality occurs</b>   |
| <b>LEL</b>             | <b>Lowest Effect Level</b>  |
| <b>MP</b>              | <b>Manufacturing-Use Product</b>  |
| <b>MPI</b>             | <b>Maximum Permissible Intake</b>   |
| <b>MRID</b>            | <b>Master Record Identification (number). EPA's system of recording and tracking studies submitted.</b>   |
| <b>N/A</b>             | <b>Not Applicable</b>   |

## **GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)**

|              |  |
|--------------|--|
| <b>NPDES</b> | <b>National Pollutant Discharge Elimination System</b>                             |
| <b>NOEL</b>  | <b>No Observed Effect Level</b>  |
| <b>OPP</b>   | <b>Office of Pesticide Programs</b>  |
| <b>PADI</b>  | <b>Provisional Acceptable Daily Intake</b>   |
| <b>ppm</b>   | <b>Parts Per Million</b>   |
| <b>RfD</b>   | <b>Reference Dose</b>  |
| <b>RS</b>    | <b>Registration Standard</b>   |
| <b>TD</b>    | <b>Toxic Dose. The dose at which a substance produces a toxic effect.</b>          |
| <b>TC</b>    | <b>Toxic Concentration. The dose at which a substance produces a toxic effect.</b> |
| <b>TMRC</b>  | <b>Theoretical Maximum Residue Contribution.</b>                                   |
| <b>TEP</b>   | <b>Typical End-Use Product</b>   |

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## VI. APPENDICES

Appendix A - Use Patterns Subject to Reregistration

Appendix B - Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

Appendix C - Citations Considered to be Part of the Data Base Supporting the Reregistration of OBPA

Appendix D - List of Available Related Documents

Appendix E - Pesticide Reregistration Handbook

Appendix F - Generic Data Call-In

Appendix G - Product Specific Data Call-In

|                |  |
|----------------|--|
| Attachment A - | Chemical Status Sheet  |
| Attachment B - | Product Specific DCI Response Forms (Form A) plus Instructions                   |
| Attachment C - | Requirements Status and Registrants' Response Forms (Form B) plus Instructions   |
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## EXECUTIVE SUMMARY

This Reregistration Eligibility Document (RED) will address the eligibility for reregistration of products containing 10, 10'-Oxybisphenoxarsine (OBPA).

OBPA is a bacteriostat, disinfectant (bactericide/germicide) and fungicide pesticide. Its use category is: indoor non-food. This arsenic-containing heterocyclic compound is incorporated into flexible vinyl sheeting and extrusions, silicone caulking compounds, thermoplastic adhesives, polyurethane, and latex emulsions (not including paints, ink bases and textiles) to prevent the growth of microorganisms. Although flexible vinyls and silicones in themselves are resistant to microbiological deterioration, the use of OBPA formulations in products made from these materials is necessary due to microbial susceptibility of plasticizers, lubricants, and fillers which are added to obtain desirable physical and chemical properties.

OBPA is formulated as an emulsifiable concentrate, pelleted/tableted, soluble concentrate/liquid and ready-to-use liquid. The concentration varies from 1 to 5%, based on total weight of formulation.

OBPA was initially registered as a pesticide in 1965. A Registration Standard was issued October 30, 1981 (NTIS PB82-172271). This Registration Standard summarized the available data supporting the reregistration of products containing OBPA which were used as indoor (non-food) antimicrobials. The Registration Standard also required additional product chemistry, a hydrolysis study and an activated sludge metabolism study, which was later waived. A Data Call-In (DCI), dated September 30, 1991, was issued requiring product chemistry and the repeat of the hydrolysis study. The Agency has now completed its review of the OBPA data base including the data submitted in response to the 1991 DCI.

The Agency has determined that the uses of OBPA as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency is not requiring any additional generic studies to be submitted at this time.

Before reregistering the products containing OBPA, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable, the Agency will reregister a product based on whether or not it meets the requirements in Section 3(c)(5) of FIFRA. Those products which contain other active ingredients in addition to OBPA will be eligible for reregistration only when all of the other active ingredients are determined to be eligible for reregistration.

## I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of OBPA. The document consists of six sections. Section I is the introduction. Section II describes OBPA, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for OBPA. Section V discusses the reregistration requirements for OBPA. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.<sup>1</sup>

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<sup>1</sup>EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

## II. CASE OVERVIEW

### A. Chemical Overview

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

- **Common Name:** OBPA
- **Chemical Name:** 10,10'-Oxybisphenoxarsine
- **Chemical Family:** Thenarsazine oxide
- **CAS Registry Number:** 58-36-6
- **OPP Chemical Code:** 012601
- **Empirical Formula:**  $C_{24}H_{16}As_2O_3$
- **Molecular Weight:** 502
- **Trade and Other Names:** Policida P-4
- **Basic Manufacturer:** Morton Thiokol, Inc.

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### B. Use Profile

Following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of OBPA is found in Appendix A.

#### For OBPA:

**Type of Pesticide:** Bacteriostat, Disinfectant (bactericide/germicide) and Fungicide.

**Use Sites:**

**INDOOR NON-FOOD:**  
Industrial Adhesives  
Resin/Latex/Polymer Emulsions  
Plastic Products  
Speciality Industrial Products  
Textiles/Textile Fibers/Cordage

**Target Pests:** Deterioration/spoilage bacteria, Mold.

**Formulation Types  
Registered**

**Type:**

End use, Manufacturing use

**Form:**

Emulsifiable concentrate, Liquid soluble concentrate, Solid soluble concentrate, Solid formulation not identified (manufacturing use)

**Methods and Rates of Application**

**Types of Treatment:** Industrial preservative

**Equipment:** Not applicable

**Timing:** During manufacture

**Rate of Application:**

**Industrial adhesives:**

From 150 up to 500 ppm of active ingredient by weight

**Resin/latex/polymer emulsions:**

From 150 up to 400 ppm of active ingredient by weight

**Plastic products:**

From 300 up to 500 ppm of active ingredient by weight

**Specialty industrial products:**

From 150 up to 400 ppm of active ingredient by weight



Textiles/textile fibers/cordage:  
From 400 up to 1000 ppm of active ingredient by weight

**Use Practices Limitations:** Product should not be used on items which come into contact with food stuffs nor items of clothing or infant wear. Do not apply directly to water.

### **C. Data Requirements**

Data required in the October 1981 Registration Standard for OBPA include studies on product chemistry, a hydrolysis study and an activated sludge metabolism study, which was later waived. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

### **D. Regulatory History**

OBPA was registered in the United States in 1965 for use as a disinfectant (bactericide/germicide), bacteriostat, and fungicide. A Registration Standard for OBPA was issued in October 1981 (NTIS PB82-172271) which evaluated studies submitted as a result of (1) an open literature search as of August 14, 1981 (2) the Agency's April 20, 1979 decision document to remove OBPA from the Rebuttable Presumption Against Registration (RPAR) list and (3) the data submitted by the registrants up through the time of publication of the 1981 Registration Standard. A Data Call-In (DCI) was issued in September 1991 for OBPA requiring additional product chemistry for Morton Thiokol, Inc. and a repeat hydrolysis study to replace the existing study which was found deficient. This Reregistration Eligibility Document reflects a reassessment of all data which were submitted in response to the Registration Standard and subsequent DCI.

## **III. SCIENCE ASSESSMENT**

### **A. Physical Chemistry Assessment**

OBPA is a white odorless powder which has a density of 0.489 g/ml. It is insoluble in water. The vapor pressure is extremely low of less than  $2.0 \times 10^{-7}$  at 25.7° C. This chemical is stable to sunlight and a temperature of 54° C. It is also stable to aluminum, copper, galvanized steel and stainless steel. OBPA is not an oxidizing and reducing agent and is non-flammable, non-explosive and non-corrosive.

## **B. Human Health Assessment**

### **1. Toxicology Assessment**

The toxicological database on OBPA is adequate and will support reregistration.

#### **a. Acute Toxicity**

Several acute toxicity studies of each type have been done with OBPA, some of which do not provide complete information. The more completely reported studies are summarized here. In general, the acute oral toxicity studies with technical OBPA found LD50's from about 15 to 40 mg/kg. A more complete report of a test in rats with technical OBPA had an LD50 of 36.9 mg/kg in males and of 31.6 in females (Anspach, 1977, GS044002). The toxic effects included congested adrenals, kidneys, and lungs, irritated digestive systems, and depleted fat stores. These results indicate toxicity category I.

The results found in acute dermal toxicity studies with technical OBPA varied widely. A study with rabbits using technical OBPA found an LD50 of 414 mg/kg (Anspach, 1977, GS044002). One that used technical OBPA on rats reported an LD50 of 121 mg/kg (Litton Bionetics, 1978, GS044039). OBPA is in Toxicity category I for dermal toxicity.

An acute inhalation toxicity study with guinea pigs estimated the LC50 at 1279 mg/L, results which place this compound in toxicity category IV for inhalation (Ballantyne, 1978, 05015857).

Two primary eye irritation studies in rabbits with technical OBPA found corneal opacity, conjunctivitis, and iritis (Anspach, 1977, 00013643; GS044002). In one study the effects lasted through 72 hours. The Agency considers this material to be in toxicity category I for eye irritation.

Results in different primary skin irritation studies were quite varied. One study with technical OBPA applied to intact and abraded skin of rabbits found slight to severe edema and peripheral or spotted erythema, results which fall in toxicity category II (Anspach, 1977, 00013643). Another study applied technical material to intact and abraded rabbit skin for 24 hours; the results indicated toxicity category III (Anspach, 1977, GS044002). The Agency considers that OBPA is in category II for dermal irritation.

**TABLE OF ACUTE TOXICITY DATA**

| TEST  | RESULT                      | TOXICITY CATEGORY |
|---|-----------------------------|-------------------|
| Acute Oral LD <sub>50</sub> (rat)                 | 15-40 mg/kg                 | I                 |
| Acute Dermal LD <sub>50</sub><br>(rat, rabbit)    | 121-414 mg/kg               | I                 |
| Acute Inhalation LC <sub>50</sub><br>(guinea pig) | 1279 mg/L                   | IV                |
| Eye Irritation<br>(rabbit)                        | Corneal Opacity             | I                 |
| Skin Irritation<br>(rabbit)                       | Varies<br>(edema, erythema) | II                |

**b. Subchronic Toxicity**

In a 35-day feeding study, 10 rats/sex/dose were given 0, 1, 10, 30, 100, or 300 ppm of OBPA in the diet (the percent active ingredient was not stated; Franz and Shrader 1959, 00024936; Oxen 1959, 00024940). Generally, animals at the two higher doses had retarded growth, higher liver weights, increased testes weights, proliferation of the portal bile duct, and accumulation of arsenic in liver and kidneys. The NOEL was 10 ppm (approximately 0.5 mg/kg/day).

A rat feeding study lasting 92 days gave doses of 0, 0.03, 0.1, 0.3, 1.0 or 3.0 mg/kg/day to 10 rats/sex/dose (unspecified percent active ingredient; McCollister et al. 1969, GS044042). The high dose group had retarded growth as well as lack of fat in the mesentery; there were microscopic liver lesions and inflammatory cellular infiltrates in the periportal area with bile duct hyperplasia. Arsenic accumulated in the liver and kidney at all doses and in the fat and hair in some of the higher doses. The NOEL was 1.0 mg/kg/day.

In an inhalation study, both rats and guinea pigs were exposed to 1-2 mg/M<sup>3</sup> of technical OBPA (percent not stated) during five days per week for 30 days (IPC 1957, 00013591; Ballantyne 1978, 05015857). Half of the animals were sacrificed 48 hours after the last exposure and the others were kept without further exposure for four months. The rats and guinea pigs killed at 48 hours had mild to moderate pulmonary congestion and hemorrhaging; only the rats had hepatic involvement. The animals killed four months later showed no effects of OBPA.

**c. Developmental Toxicity and Reproductive Toxicity**

An investigation of the effect of OBPA on fetal development and toxicity used dermal applications at 0.3, 3.0 or 30.0 mg/kg on pregnant rats (Beliles and Makris 1978, GS0440007). However, the animals also ingested the material put on their skin and the actual doses are uncertain. All high-dose rats and one mid-dose rat died during the test. There was no evidence of compound-related teratogenicity or inhibition of fetal development from the surviving animals. There was some evidence of fetal toxicity in the mid-dose group and the NOEL was estimated at 0.3 mg/kg.

**d. Mutagenicity**

A mouse lymphoma test was considered negative for mutagenicity with and without activation (Brusick and Weir 1976, 00013644). A mutagenicity study in *S. cerevisiae* and *S. typhimurium* with and without activation did not show mutagenicity (Brusick and Weir 1976, 00013647). An investigation of the metabolites of OBPA used the urine of rats treated with OBPA in the method of Durston and Ames. There was no indication of mutagenic activity with urine from treated or untreated rats (Beliles and Makris 1978, GS044007).

**e. Metabolism**

Metabolism studies in which OBPA was applied to the skin generally found arsenic accumulation in the liver and kidney with removal from the body through both feces and urine (Olson et al. 1959, 00026092; Dow 1964, 00024935; Ballantyne 1978, 05015857). There are indications that the arsenic is cleared from the body after two weeks.

**2. Exposure Assessment**

**a. Dietary Exposure**

OBPA is not used on food, feed or processed commodities; dietary exposure to OBPA is not expected.

**b. Occupational and Residential**

OBPA is an antimicrobial and antifungal pesticide used to treat polyvinylchloride (PVC), polyurethane, and ethylene-vinylacetate copolymer plastics. These plastics are fabricated into shower curtains,

floor coverings, wall coverings, ditch liners, coated fabrics (including mattresses), vinyl molding, marine upholstery, automotive vinyl trim, tarpaulins, awnings, gaskets (automotive, refrigerator, dishwasher), weather stripping, caulking, and swimming pool liners. Plastic products intended for indoor use contain up to 0.06% OBPA and plastic products intended for outdoor use contain up to 0.05% OBPA.

OBPA formulations range in concentrations from 1 to 5%. The OBPA formulations are either liquids or pelleted/tableted forms utilizing a resin carrier.

Occupational and residential exposure data were not required in the 1981 Registration Standard for OBPA based on the following reasons:

- 1) direct occupational exposure to OBPA is mitigated by the use of closed systems, when producing OBPA technical and OBPA formulations, or when producing plastic products containing OBPA;
- 2) indirect human exposure to OBPA in treated plastics is low due to the low percent of OBPA added to plastic coupled with the slow release of small amounts of OBPA from the plastic matrix; and
- 3) no additional uses are proposed that may result in significant increases in human exposure.

(Inhalation exposure from OBPA-treated products is negligible since it has a low vapor pressure.)

Based on the low potential for exposure to OBPA, exposure data are not required to support the reregistration of the current uses of OBPA, provided that (1) manufacturing is under closed systems, and (2) appropriate Personal Protective Equipment (PPE) is used.

### **3. Risk Assessment**

#### **a. Dietary**

There are no registered food or feed uses of OBPA, and therefore, dietary exposure or risk from OBPA is not expected.

**b. Occupational and Residential**

The potential for occupational exposure to OBPA is minimal provided that OBPA is used in a closed system and that appropriate protective eyewear and gloves are used. Therefore, the potential risk for acute or chronic toxicity from exposure to OBPA is also likely to be minimal.

In 1991, the Agency received a research proposal concerning the potential linkage between OBPA-treated mattresses to Sudden Infant Death Syndrome (SIDS). The proposal to investigate this environmental factor as a possible cause of SIDS was submitted by Dr. Julius Goldberg of the Loyola University Medical Center in Chicago, Illinois. As support for the proposal was the hypothesis that toxic gases may be produced by microfungi which attack PVC plastic materials. Some of these fungi can break down the arsenates in the PVC, and produce trimethyl arsine (Allsop and Hawksworth, 1992). However, in that study, the investigators could not draw any general conclusions regarding the significance of biofilms or other fungi that were isolated; this was due primarily to the limited number of mattress covers studied and the use of unmatched controls.

At the present time, there is no evidence to suggest that OBPA is linked to SIDS. A causal relationship between SIDS and environmental factors (or genetic factors) has not been established.

**C. Environmental Assessment**

**1. Environmental Fate**

The Agency finds that no further environmental fate data are needed because of the very limited exposure expected with current uses of this chemical. The Registration Standard required a hydrolysis study and an activated sludge study, which was later waived. The hydrolysis study was found deficient, but the Agency later determined that an additional hydrolysis study was not needed based on the fact that OBPA-treated material will not result in significant levels of residues being released into the environment. An extractability study on pool liners and vinyl baby pants showed that leaching would not result in exceedance of the 50 ppb maximum daily dietary intake for arsenic in drinking water.

**2. Ecological Effects**

No further ecological effects toxicity data are required to support current uses of this chemical.

a. **Ecological Effects Data**

**Topical Summaries**

**(1) Terrestrial Data - Effects on Birds**

Two studies were submitted and both were found to be scientifically sound.

| Author | Date | MRID No. |
|--------|------|----------|
| Fink   | 1976 | 00013648 |
| Fink   | 1976 | 00013649 |

**Avian Acute Toxicity Test -- Technical Active Ingredient**

The following tests are normally required to measure toxicity of technical grade active ingredient (TGAI):

- One avian single-dose oral study on either a waterfowl species (preferably mallard duck) or an upland species (preferably bobwhite quail).
- One subacute dietary study on either a waterfowl species (preferably mallard duck) or an upland species (preferably bobwhite quail).

No studies were conducted on the technical material, therefore normally a data gap would exist. However, the usual studies will be waived because: 1) the material is highly corrosive and therefore will be very highly toxic to birds; 2) existing acute oral rat data (45 mg/kg males and 15 mg/kg females) confirm the pesticide's high toxicity to terrestrial organisms; 3) the indoor use pattern does not require a risk assessment for birds, and avian toxicity information is needed only to assess the need for precautionary label statements.

**Avian Acute Toxicity Test -- Typical End-Use Product**

Studies are not required to support indoor non-food (industrial) use patterns. The single available acute oral toxicity study for a typical end-use product (TEP) is:

| Species                       | % Test Material | LD <sub>50</sub><br>mg/kg<br>product | Author | Date | MRID No. | Fulfills<br>Requirements |
|-------------------------------|-----------------|--------------------------------------|--------|------|----------|--------------------------|
| Avian oral<br>Mallard<br>duck | 5 %<br>TEP      | >10,000                              | Fink   | 1976 | 00013649 | No<br>requirement        |

The data indicate that OBPA (5%) is practically non-toxic to mallard duck (waterfowl species) on an acute oral basis.

#### Avian Subacute Dietary Test – Typical End-Use Product

The single available subacute dietary toxicity study is listed below:

| Species                          | % Test Material | LC <sub>50</sub><br>ppm product | Author | Date | MRID No. | Fulfills<br>Requirements |
|----------------------------------|-----------------|---------------------------------|--------|------|----------|--------------------------|
| Avian diet.<br>Bobwhite<br>quail | 5 %<br>TEP      | >10,000                         | Fink   | 1976 | 00013648 | No<br>requirement        |

These data indicate that OBPA (5%) is practically non-toxic to bobwhite quail (upland bird species) on a subacute dietary basis.

#### (2) Aquatic Data

Nine studies (in five reports) were submitted under this topic. All were found acceptable for use in a hazard assessment.

| Author      | Date | MRID No. |
|-------------|------|----------|
| Buccafusco  | 1977 | GS044009 |
| Heitmuller  | 1980 | 00030658 |
| Bentley     | 1976 | 00013641 |
| Lee & Regel | 1974 | GS044067 |
| WARF        | 1973 | 00013611 |

The minimum data required for establishing the acute toxicity of OBPA to freshwater fish is one fish acute toxicity study with the technical material. The preferred test species is either rainbow trout or bluegill sunfish.



### Fish Acute Toxicity Test – Technical Active Ingredient

The acceptable acute toxicity data are listed below:

| Species           | % A. I. | LC <sub>50</sub><br>pph, a.i. | Author     | Date | ID #     | Fulfills<br>Requirement |
|-------------------|---------|-------------------------------|------------|------|----------|-------------------------|
| Rainbow trout     | 95.6 %  | 3.5                           | Buccafusco | 1977 | GS044009 | Yes                     |
| Bluegill sunfish  | 95.6 %  | 8.0                           | Buccafusco | 1977 | GS044009 | Yes                     |
| Sheepshead minnow | 95.6 %  | 8.0                           | Holtmuller | 1980 | 00030658 | Yes                     |

The guideline requirement (72-1C) for a freshwater acute toxicity test has been fulfilled. There is sufficient information to characterize OBPA as very highly toxic to both freshwater and marine fish. The marine acute fish toxicity study is not required to support indoor non-food (industrial) use patterns.

### Fish Acute Toxicity Test – Typical End-Use Product

The data required for establishing the acute toxicity of OBPA typical end-use product to fish is one fish acute toxicity study with a typical formulated product. The preferred test fish species is either rainbow trout or bluegill sunfish. The acceptable fish studies are listed below:

| Species          | % A. I. | LC <sub>50</sub><br>ppm | Author      | Date | ID #     | Fulfills<br>Requirement |
|------------------|---------|-------------------------|-------------|------|----------|-------------------------|
| Rainbow trout    | 5.0 %   | 560                     | Bentley     | 1976 | 00013641 | Yes                     |
| Bluegill sunfish | 5.0 %   | 1800                    | Bentley     | 1976 | 00013641 | Yes                     |
| Rainbow trout    | 3.0 %   | 0.125                   | Lee & Regel | 1974 | GS044067 | Yes                     |
| Bluegill sunfish | 3.0 %   | 0.210                   | Lee & Regel | 1974 | GS044067 | Yes                     |
| Rainbow trout    | 2.0 %   | 0.2                     | WARF        | 1973 | 00013611 | Yes                     |
| Bluegill sunfish | 2.0 %   | 0.350                   | WARF        | 1973 | 00013611 | Yes                     |

These studies are not presently required for the indoor non-food (industrial) use pattern. These studies would fulfill the guideline

requirements for fish acute toxicity tests for OBPA with the typical end-use product. These studies showed that the 5% OBPA formulated product is practically non-toxic to freshwater fish in acute exposure. However, other studies using the products with lower contents of OBPA (2 & 3% a.i.) were found to be highly toxic to freshwater fish on an acute basis.

### (3) Effects to Non-target Aquatic Invertebrates

Two studies were found acceptable for use in a hazard assessment:

| Author     | Date | MRID No. |
|------------|------|----------|
| Browne     | 1980 | 00030657 |
| Heitmuller | 1979 | 00030656 |

The requirement to establish the acute toxicity of OBPA to aquatic invertebrates is a 48-h. Daphnia acute toxicity study using the technical material. The acceptable toxicity data are listed below:

| Species              | % Test Material | LC <sub>50</sub> ppb a.i. | Author     | Date | MRID NO. | Fulfills Requirements |
|----------------------|-----------------|---------------------------|------------|------|----------|-----------------------|
| <u>Daphnia magna</u> | 99.0 %          | 4.8                       | Browne     | 1980 | 00030657 | Yes                   |
| Grass shrimp         | 95.6 %          | 50.0                      | Heitmuller | 1979 | 00030656 | Yes                   |

The Daphnia test fulfills the guideline requirement for acute freshwater invertebrate toxicity testing. The data indicate that OBPA is very highly toxic to freshwater aquatic invertebrates. A marine acute invertebrate toxicity study is not required for this end-use. However, the grass shrimp study would fulfill the guideline requirement for a marine invertebrate study. That study shows that OBPA is very highly toxic to a marine invertebrate on an acute basis.

### (4) Non-Target Estuarine and Marine Organisms

No toxicity data are required for the end-uses registered.

### (5) Non-Target Insects

No toxicity data are required for the end-uses registered.

**(6) Non-Target Plants**

No toxicity data are required for the end-uses registered.

**b. Ecological Effects Risk Assessment**

OBPA is an indoor non-food use pesticide which is incorporated into plastics, adhesives, textiles etc. The Agency does not conduct risk assessments for nontarget organisms for indoor uses without effluent. Risk assessments for uses with effluent are based on residues in natural waters receiving the effluent. Should such residues of OBPA exceed 1.75 ppb, aquatic organisms are acutely at risk. This level is based on acute LC50 for the technical active ingredient as low as 3.5 ppb for an aquatic organism (rainbow trout).

**IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

**A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing OBPA as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing OBPA. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of OBPA, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of OBPA and to determine that OBPA can be used without resulting in unreasonable adverse effects to man or the environment. The Agency therefore finds that all products containing OBPA as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of OBPA are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing OBPA,

if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

#### **1. Eligibility Decision**

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

The Agency has determined that OBPA products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks or adverse effects to humans or the environment.

#### **2. Eligible and Ineligible Uses**

The Agency has determined that all uses of OBPA are eligible for reregistration.

### **B. Regulatory Position**

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

#### **1. Tolerance Reassessment**

There are no registered uses for OBPA in or on food or feed.

#### **2. Labeling Rationale**

The "Environmental Hazards" section should include the following:

##### **a. Manufacturing Use**

"This pesticide is toxic to fish, aquatic invertebrates, birds, and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA."

**b. End Use**

Indoor (Industrial use) - Same language as for the manufacturing use.

**V. ACTIONS REQUIRED BY REGISTRANTS**

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

**A. Manufacturing-Use Products**

**1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of OBPA for the above eligible uses has been reviewed and determined to be substantially complete. However, some of the product chemistry guidelines have not been completely fulfilled.

All of the product chemistry data for OBPA were originally required in the Registration Standard and are therefore not included in a generic Data Call-In for the RED.

There are no new generic data being called-in for OBPA.

**2. Labeling Requirements for Manufacturing-Use Products**

The "Environmental Hazards" section is to include the following:

"This pesticide is toxic to fish, aquatic invertebrates, birds, and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

In addition, labels must consistently reflect any potential eye and skin hazard (Danger, Warning or Caution Signal Words) and recommend appropriate personal protective equipment (protective eyewear {goggles or face shield}, long sleeved shirts and long-legged pants, waterproof gloves, shoes and socks).

**B. End-Use Products**

**1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

## **2. Labeling Requirements for End-Use Products**

Same language as for the manufacturing use.

End-use product labeling and personal protective equipment requirements will be determined upon submission or citation and review of acute toxicity studies conducted on the end-use product.

## **APPENDIX A**

### **Table of Use Patterns Subject to Reregistration**

# APPENDIX A - Case 0044, [OBPA] Chemical 012601 [10,10'-Oxybisphenoxarsine]

| Application Type  | Application Timing | Application Equipment | Surface Type | Form | Minimum Application Rate (ppm a.i.) | Maximum Application Rate (ppm a.i.) | Max. # Apps. @ Max. Rate | Min. Interval Between Apps. @ Max. Rate (Days) | Restricted Entry Interval | Geographic Limitations | Use Pattern Limitations  |
|---|--------------------|-----------------------|--------------|------|-------------------------------------|-------------------------------------|--------------------------|--|---------------------------|------------------------|--|
|   |                    |                       |              |      |                                     |                                     |                          |  |                           | Allowed                | Disallowed   |
| <b>USES ELIGIBLE FOR REREGISTRATION</b>                                   |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| <b>NON-FOOD/NON-FEED USES</b>   |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| <b>Site: ADHESIVES, INDUSTRIAL (Use Group: Indoor Non-Food)</b>           |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| Industrial preservative, During manufacture, Not on label, Not applicable |                    |                       |              | EC   | 150 W                               | 501 W                               | NS                       | NS   | NS                        | NA                     | NS   |
|   |                    |                       |              | SC/L |                                     |                                     |                          |  |                           |                        |  |
| <b>Site: EMULSIONS, RESIN/LATEX/POLYMER (Use Group: Indoor Non-Food)</b>  |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| Industrial preservative, During manufacture, Not on label, Not applicable |                    |                       |              | EC   | 150 W                               | 400 W                               | NS                       | NS   | NS                        | NA                     | NS   |
| <b>Site: PLASTIC PRODUCTS (Use Group: Indoor Non-Food)</b>                |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| Industrial preservative, During manufacture, Not on label, Not applicable |                    |                       |              | SC/L | 300 W                               | 500 W                               | NS                       | NS   | NS                        | NA                     | Do not apply in marine and/or estuarine, oil fields, or discharge effluent into lakes, streams, ponds or public water (NPDES license restriction). Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. |
|   |                    |                       |              | SC/S |                                     |                                     |                          |  |                           |                        |  |
| <b>Site: SPECIALTY INDUSTRIAL PRODUCTS (Use Group: Indoor Non-Food)</b>   |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| Industrial preservative, During manufacture, Not on label, Not applicable |                    |                       |              | EC   | 150 W                               | 400 W                               | NS                       | NS   | NS                        | NA                     | NS   |
| <b>Site: TEXTILES/TEXTILE FIBERS/CORDAGE (Use Group: Indoor Non-Food)</b> |                    |                       |              |      |                                     |                                     |                          |  |                           |                        |  |
| Industrial preservative, During manufacture, Not on label, Not applicable |                    |                       |              | EC   | 400 W                               | 1000 W                              | NS                       | NS   | NS                        | NA                     | NS   |

## Abbreviations used

Header: ppm a.i. = parts per million of active ingredient; Max. # Apps. = maximum number of applications  
Max. # Apps. @ Max. Rate = maximum number of applications at maximum rate  
Min. Interval Between Apps. @ Max. Rate (Days) = minimum interval between applications at maximum rate (in days)

Form: SC/S = soluble concentrate/solid; SC/L = soluble concentrate/liquid; EC = emulsifiable concentrate  
Rate: W = calculated by weight; V = calculated by volume; NC = not calculated  
In general: NA = not applicable; NS = not specified July 14, 1993



## **APPENDIX B**

### **Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision**

## **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for the pesticide Oxybisphenoxarsine (OBPA) covered by this Reregistration Eligibility Document. It contains generic data requirements that apply to OBPA in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. **Data Requirement** (Column 1). The data requirements are listed in the order in which they appear in 40 CFR, Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487 - 4650.
2. **Use Pattern** (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

|   |                              |
|---|------------------------------|
| A | Terrestrial food             |
| B | Terrestrial feed             |
| C | Terrestrial non-food         |
| D | Aquatic food                 |
| E | Aquatic non-food outdoor     |
| F | Aquatic non-food industrial  |
| G | Aquatic non-food residential |
| H | Greenhouse food              |
| I | Greenhouse non-food          |
| J | Forestry                     |
| K | Residential                  |
| L | Indoor food                  |
| M | Indoor non-food              |
| N | Indoor medical               |
| O | Indoor residential           |
3. **Bibliographic citation** (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

## APPENDIX B

# Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u>                | <u>Title of Study</u>       | <u>Use Patterns</u> | <u>Bibliographic Citation</u> |
|---------------------------------|-----------------------------|---------------------|-------------------------------|
| <b><u>PRODUCT CHEMISTRY</u></b> |                             |                     |                               |
| 61-1                            | Chemical Identity           | All                 | 42517401                      |
| 61-2(a)                         | Start. Mat. & Mnfg. Process | All                 | 42517401                      |
| 61-2(b)                         | Formation of Impurities     | All                 | 42517401                      |
| 62-1                            | Preliminary Analysis        | All                 | 42517402                      |
| 62-2                            | Certification of Limits     | All                 | 42517402                      |
| 62-3                            | Analytical Method           | All                 | 42517402                      |
| 63-2                            | Color                       | All                 | 42517403                      |
| 63-3                            | Physical State              | All                 | 42517403                      |
| 63-4                            | Odor                        | All                 | 42517403                      |
| 63-5                            | Melting Point               | All                 | 42517403                      |
| 63-6                            | Boiling Point               | All                 | 42517403                      |

## APPENDIX B

### Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u> | <u>Title of Study</u>   | <u>Use Patterns</u> | <u>Bibliographic Citation</u> |
|------------------|-------------------------|---------------------|-------------------------------|
| 63-7             | Density                 | All                 | 42517403                      |
| 63-8             | Solubility              | All                 | 42517403                      |
| 63-9             | Vapor Pressure          | All                 | 42517403                      |
| 63-11            | Octanol/Water Partition | All                 | 42517403                      |
| 63-12            | pH                      | All                 | 42517403                      |
| 63-13            | Stability               | All                 | 42517403                      |

## APPENDIX B

# Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u>                 | <u>Title of Study</u>                           | <u>Use Patterns</u> | <u>Bibliographic Citation</u> |
|----------------------------------|---|---------------------|-------------------------------|
| <b><u>ECOLOGICAL EFFECTS</u></b> |   |                     |                               |
| 71-1B                            | Acute Avian Oral - Quail/Duck - TEP             | M                   | 00013649                      |
| 71-2A                            | Acute Avian Dietary (LC <sub>50</sub> ) - Quail | M                   | 00013648                      |
| 72-1A                            | Fish Acute (LC <sub>50</sub> ) - Bluegill       | M                   | GS044009                      |
| 72-1B                            | Fish Acute - Bluegill - TEP                     | M                   | GS044067<br>00013641          |
| 72-1C                            | Fish Acute (LC <sub>50</sub> ) - Trout          | M                   | GS044009                      |
| 72-1D                            | Fish Acute - Trout - TEP                        | M                   | 00013641                      |
| 72-2A                            | Invertebrate Toxicity                           | M                   | 00030657                      |
| 72-3A                            | Estuarine/Marine Tox - Sheepshead<br>Minnow     | M                   | 00030658                      |
| 72-3C                            | Estuarine/Marine Tox. - Shrimp                  | M                   | 00030656                      |

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# Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u>         | <u>Title of Study</u>              | <u>Use Patterns</u> | <u>Bibliographic Citation</u>                              |
|--------------------------|------------------------------------|---------------------|--|
| <b><u>TOXICOLOGY</u></b> |                                    |                     |  |
| 81-1                     | Acute Oral Toxicity - Rat          | ALL                 | 00024941, GS044002, 00024935, 00013591, 05015857, 00013643 |
| 81-2                     | Acute Dermal Toxicity - Rabbit/Rat | ALL                 | 00024935, 00013643, GS044002, GS044020, GS044039, GS044004 |
| 81-3                     | Acute Inhalation Toxicity - Rat    | ALL                 | 00024935, GS044035, 05015857, 00013591                     |
| 81-4                     | Primary Eye Irritation - Rabbit    | ALL                 | 00024938, 00024935, GS044002, 00013591, 05015857, 00013643 |
| 81-5                     | Primary Dermal Irritation - Rabbit | ALL                 | 00024937, 00024935, 00013591, 05015857, 00013643, GS044002 |
| 82-1A                    | 90-Day Feeding - Rodent            | ALL                 | 00024936, 00024940, GS044042                               |
| 82-4                     | 90-Day Inhalation - Rat            | ALL                 | 00013591, 05015857   |
| 83-3A                    | Teratogenicity                     | ALL                 | GS044007   |

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### Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u> | <u>Title of Study</u>             | <u>Use Patterns</u> | <u>Bibliographic Citation</u>          |
|------------------|-----------------------------------|---------------------|--|
| 84-2A            | Gene Mutation (Ames Test)         | ALL                 | 00013644                               |
| 84-2B            | Structural Chromosomal Aberration | ALL                 | 00013647                               |
| 84-4             | Other Genotoxic Effects           | ALL                 | GS044007                               |
| 85-1             | General Metabolism                | ALL                 | 00026092, 00024935, 00013591, 05015857 |

## APPENDIX B

### Generic Data Requirements for Reregistration of Oxybisphenoxarsine (OBPA) Data Citations Supporting Reregistration

| <u>Guideline</u> | <u>Title of Study</u>            | <u>Use Patterns</u> | <u>Bibliographic Citation</u>  |
|------------------|----------------------------------|---------------------|--|
|                  | <b><u>ENVIRONMENTAL FATE</u></b> |                     |  |
| 161-1            | Hydrolysis                       | M                   | 00125707   |
| -                | Activated Sludge Metabolism      | M                   | RESERVED   |
| -                | Extraction Studies               | M                   | GS044034, GS044062, GS044011, GS044056,<br>GS044023, GS044080, GS044048, GS044030,<br>GS044055, GS044012, GS044024 |



## **APPENDIX C**

### **BIBLIOGRAPHY**

**Citations Considered to be Part of the Data Base  
Supporting Reregistration**

## GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including 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 identifying number which 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 a identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document Date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. **Title.** In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. **Trailing Parentheses.** For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
- (1) **Submission Date.** The date of the earliest known submission appears immediately following the word "received".
  - (2) **Administrative Number.** The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) **Submitter.** The third element is the submitter. When authorship is de-faulted 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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- 42517403    Clark, A. (1992) Physical and Chemical Characteristics Testing for 10,10'-Oxybis-10-H-Phenoxarsine (OBPA): Guideline 63: Lab Project Number: 0922-042: 3130-F(01). Unpublished study prepared by Midwest Research Institute. 50 p.

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- GS044080 Aldous, K.M. (1977) Analysis of Silicone Caulking Compounds for Arsenic Content. (Unpublished study prepared by the N.Y State Department of Health)



## **APPENDIX D**

### **List of Available Related Documents**

## **APPENDIX D**

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

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. OBPA RED Fact Sheet (included in this RED)
4. PR Notice 91-2 (Included in this RED) Pertains to the Label Ingredient Statement

Federal publications on OBPA are available and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

- Guidance for the Reregistration of Pesticide Products Containing OBPA as the Active Ingredient (The 1981 Registration Standard): NTIS Stock No. PB82-172271.
- OBPA Data-Call-In (DCI) of 9-30-91.





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## PR NOTICE 91-2

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

**ATTENTION:** Persons Responsible for Federal Registration of  
Pesticide Products.

**SUBJECT:** Accuracy of Stated Percentages for Ingredients  
Statement

#### I. PURPOSE:

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

#### II. BACKGROUND

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

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

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

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

### III. REQUIREMENTS

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

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

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

#### IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

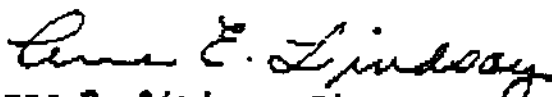
#### V. COMPLIANCE SCHEDULE

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

- (1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.
- (2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.
- (3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

#### VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024

  
Anna E. Lindsay, Director  
Registration Division (H-7505)



## **APPENDIX E**

### **Pesticide Reregistration Handbook**







# **Pesticide Reregistration Handbook**

## **How to Respond to the Reregistration Eligibility Document (RED)**





**PESTICIDE REREGISTRATION HANDBOOK**

**HOW TO RESPOND TO THE  
REREGISTRATION ELIGIBILITY DOCUMENT (RED)**

**OFFICE OF PESTICIDE PROGRAMS  
ENVIRONMENTAL PROTECTION AGENCY  
OCTOBER 1991**



*Printed on Recycled Paper*



# **PRODUCT REREGISTRATION HANDBOOK**

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## PESTICIDE REREGISTRATION HANDBOOK

### I. INTRODUCTION

#### A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

#### B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its uses and its regulatory history; describes EPA's decision concerning the eligibility of the uses of the chemical for reregistration; and explains the scientific and regulatory bases for this decision. EPA's reviews of the data by scientific discipline are available upon request.<sup>1</sup> Appendices to the RED contain: (1) a Data Call-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

#### C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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<sup>1</sup> EPA's science reviews and information on the registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.



If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

- whether all of the product specific data and labels/labeling are acceptable,
- whether all of the uses on the label/labeling are eligible,
- whether all of the active ingredients in the product are eligible, and
- if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be reregistered. Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as amendments in order to implement label changes required by the RED.

## **II. INSTRUCTIONS FOR RESPONDING**

### **A. How and When to Respond**

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1 summarizes how and when to respond to the RED. A step-by-step explanation follows.

**Step 1. Are Expedited Label Changes Required?** In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED. If expedited label changes are not required, go to Step 2.

- a. Application for Registration (EPA Form 8570-1). Complete

and sign the form. In Section II, insert the phrase "Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)." Applications for expedited label changes will be processed as applications for amended registration. Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.

Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

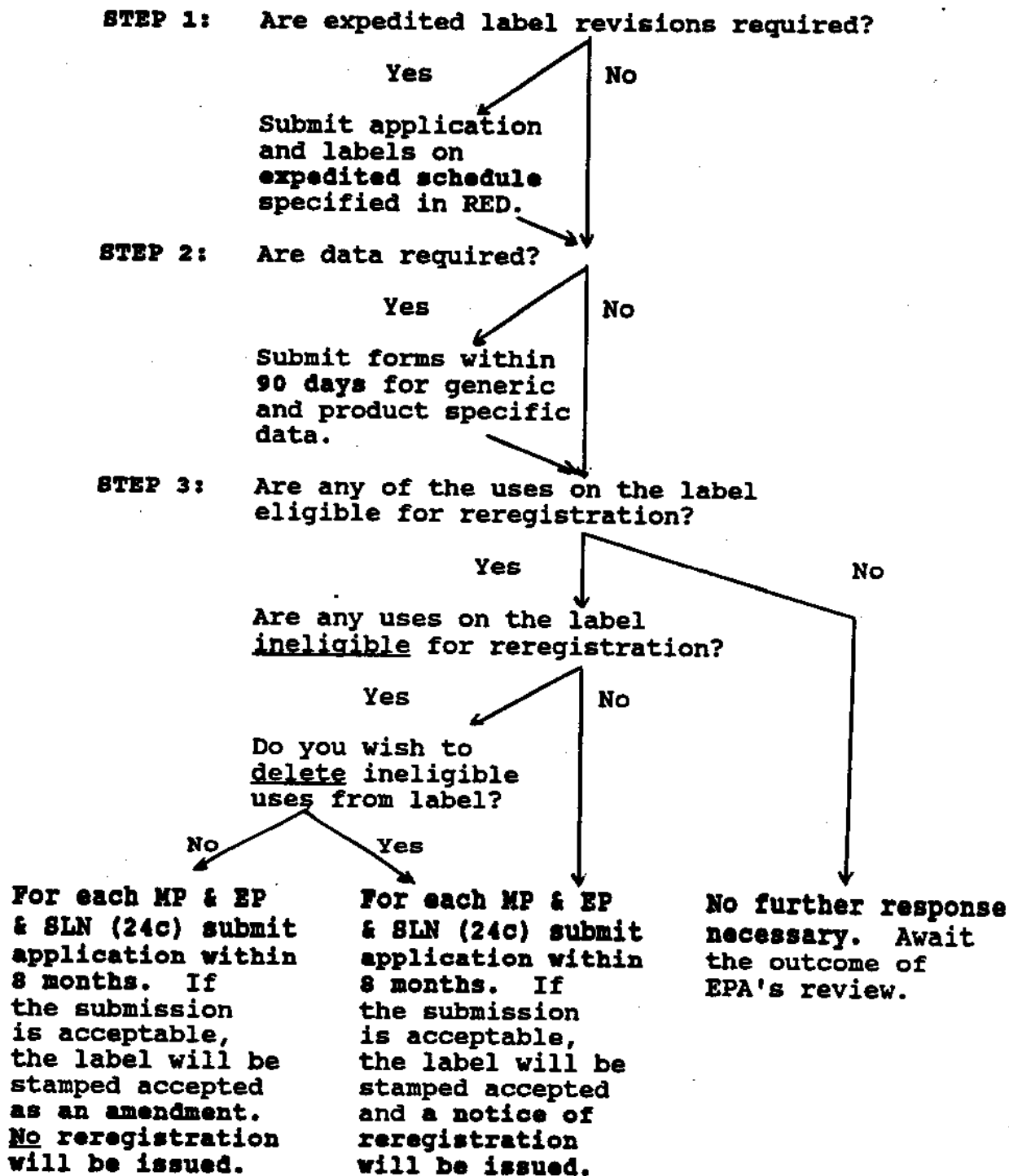
EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) and special local needs registrations (SLNs), must submit the items below for each product within 8 months of the date of issuance of the RED:

a. Application for Reregistration (use EPA Form 8570-1). Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase "Application for Reregistration." Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are ineligible uses on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.



**FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).**





c. **Product Specific Data.** You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.

d. **Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 85).** Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation. If CSFs are not provided for the alternate formulas, they will not be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. **Certification With Respect to Citation of Data (EPA Form 8570-31).** This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

#### **B. When No Response is Needed**

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.



### C. Where to Respond

By U.S. Mail:

Document Processing Desk (insert distribution code)  
Office of Pesticide Programs (H7504C)  
Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk (insert distribution code)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing generic data. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing product specific data or labeling. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

### III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

#### A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.



Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Call-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

## **B. Product Specific Data**

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

### **1. Product Chemistry**

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

#### **a. Data**

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together as being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

#### **b. Inert Ingredients**

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, a product containing a List 1 inert ingredient will not be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient. However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert may be reregistered if it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

## 2. Acute Toxicity

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each batch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

### **3. Product Performance**

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to EPA for review before tests are initiated.

#### **a. Efficacy Data Submission Waiver Policy**

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;
2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;
3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;
4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

c. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier. Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.



## **APPENDIX**

- A. Confidential Statement of Formula and Instructions**
- B. Instructions for Label Contents**
- C. Sample Label Formats--General Use & Restricted Use**
- D. Label Regulations (40 CFR 156.10)**





United States Environmental Protection Agency  
Office of Pesticide Programs (15-767)  
Washington, DC 20460

**Confidential Statement of Formula**

B.

☐ Basic Formulation  
☐ Alternate Formulation

See Instructions on Back

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)

11. Supplier Name & Address

12. EPA Reg. No.

13. Each Component in Formulation  
a. Amount  
b. % by Weight

14. Certified Limits  
% by Weight  
a. Upper Limit b. Lower Limit

15. Purpose in Formulation

EPA USE ONLY

16. Typed Name of Approving Official

17. Total Weight

100%

18. Signature of Approving Official

19. Title

20. Phone No. (Include Area Code)

21. Date





Instructions for Completing the Confidential Statement of Formula

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

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product-specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.



## **B. INSTRUCTIONS FOR LABEL CONTENTS**

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

Item 1. **PRODUCT NAME** - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

Item 3. **NET CONTENTS** - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. **EPA REGISTRATION NUMBER** - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. **EPA ESTABLISHMENT NUMBER** - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. **INGREDIENTS STATEMENT** - An ingredients statement is normally required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. **POUNDS PER GALLON STATEMENT** - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

Item 7. WARNINGS AND PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

| Size of Label on<br>Front Panel<br><u>in Square Inches</u> | Signal Word<br>Minimum Type Size<br><u>All Capitals</u> | "Keep Out of Reach<br>of Children"<br><u>Minimum Type Size</u> |
|--|---|--|
| 5 and under  | 6 point   | 6 point  |
| above 5 to 10  | 10 point  | 6 point  |
| above 10 to 15   | 12 point  | 8 point  |
| above 15 to 30   | 14 point  | 10 point   |
| over 30  | 18 point  | 12 point   |

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation). If your product has been classified for restricted use, then these requirements apply:



1. All uses restricted. The following statements must be placed in a black box at the top of the front panel of the label and labeling:
  - a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.
  - b. The reason for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.
  - c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification." The RED will specify what statement must be used.
2. Some but not all uses restricted. If the RED states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:
  - a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.
  - b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.
  - c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in



accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10(i)(2)]

#### **COLLATERAL LABELING .**

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. Collateral labeling must be made part of the response to the RED and submitted for review.

LABEL FORMAT FOR UNCLASSIFIED PRODUCTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS  
& DOMESTIC ANIMALS

CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL  
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use  
this product in a manner inconsistent  
with its labeling.

RE-ENTRY STATEMENT  
(If Applicable)

CROP: \_\_\_\_\_

DATE: \_\_\_\_\_

CROP: \_\_\_\_\_

PRODUCT  
NAME

ACTIVE INGREDIENT: \_\_\_\_\_ %  
INERT INGREDIENTS: \_\_\_\_\_ %  
TOTAL: \_\_\_\_\_ 100.00 %

THIS PRODUCT CONTAINS \_\_\_\_\_ LBS OF \_\_\_\_\_ PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: \_\_\_\_\_  
IF INHALED: \_\_\_\_\_  
IF ON SKIN: \_\_\_\_\_  
IF IN EYES: \_\_\_\_\_

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

INFO BY: \_\_\_\_\_

TOWN, STATE: \_\_\_\_\_

ESTABLISHMENT NO. \_\_\_\_\_

EPA REGISTRATION NO. \_\_\_\_\_

NET CONTENTS: \_\_\_\_\_

STORAGE AND  
DISPOSAL

STORAGE: \_\_\_\_\_  
DISPOSAL: \_\_\_\_\_

WARRANTY STATEMENT

CROP: \_\_\_\_\_

CROP: \_\_\_\_\_

CROP: \_\_\_\_\_

CROP: \_\_\_\_\_

**LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED USE**

**PRECAUTIONARY STATEMENTS**  
HAZARDS TO HUMANS  
& DOMESTIC ANIMALS  
**DANGER**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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**ENVIRONMENTAL HAZARDS**

\_\_\_\_\_

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\_\_\_\_\_

**PHYSICAL OR CHEMICAL HAZARDS**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**DIRECTIONS FOR USE**

This product is labeled for use as \_\_\_\_\_  
in accordance with the following instructions:

**RE-ENTRY STATEMENT**  
(If Applicable)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**STORAGE AND DISPOSAL**

**STORAGE** \_\_\_\_\_

\_\_\_\_\_

**DISPOSAL** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

CROP: \_\_\_\_\_

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**RESTRICTED USE PESTICIDE**  
Due to (insert reason\*)  
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

(\*for example, "Due to high acute toxicity.")

**PRODUCT NAME**


ACTIVE INGREDIENT: \_\_\_\_\_ %

INERT INGREDIENTS: \_\_\_\_\_ %

TOTAL: \_\_\_\_\_ 100.00%

THIS PRODUCT CONTAINS \_\_\_\_\_ LBS OF \_\_\_\_\_ PER GALLON

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER—POISON**



**STATEMENT OF PRACTICAL TREATMENT**

If SWALLOWED: \_\_\_\_\_

If INHALED: \_\_\_\_\_

If ON SKIN: \_\_\_\_\_

If IN EYES: \_\_\_\_\_

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY: \_\_\_\_\_

TOWN, STATE: \_\_\_\_\_

ESTABLISHMENT NO.: \_\_\_\_\_

EPA REGISTRATION NO.: \_\_\_\_\_

**NET CONTENTS** \_\_\_\_\_

CROP: \_\_\_\_\_

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WARRANTY STATEMENT

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\_\_\_\_\_

submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to

these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

#### § 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

## PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136-136y.

### § 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regu-

lations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and

other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- (iv) A false or misleading comparison with other pesticides or devices;
- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
- (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and
- (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
  - (A) "Contains all natural ingredients";
  - (B) "Among the least toxic chemicals known"
  - (C) "Pollution approved"
- (6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.
- (ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

- (b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.
- (2) No name, brand, or trademark may appear on the label which:
  - (i) Is false or misleading, or
  - (ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.
- (c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for \* \* \*," "Distributed by \* \* \*," or "Sold by \* \* \*" to show that the name is not that of the producer.
- (d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.
- (2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.
- (3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.
- (4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."
- (5) In addition to the required units specified, net content may be expressed in metric units.
- (6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average con-

tent of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.," of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement—(1) General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of

the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning

the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

| Hazard indicators                 | Toxicity categories                                      |   |  |  |
|-----------------------------------|--|---|--|--|
|                                   | I  | II  | III  | IV                                     |
| Oral LD <sub>50</sub> .....       | Up to and including 50 mg/kg.                            | From 50 thru 500 mg/kg..  | From 500 thru 5000 mg/kg.                                | Greater than 5000 mg/kg.               |
| Inhalation LC <sub>50</sub> ..... | Up to and including .2 mg/liter.                         | From .2 thru 2 mg/liter....   | From 2. thru 20 mg/liter...                              | Greater than 20 mg/liter.              |
| Dermal LD <sub>50</sub> .....     | Up to and including 200 mg/kg.                           | From 200 thru 2000.....   | From 2,000 thru 20,000....                               | Greater than 20,000.                   |
| Eye effects.....                  | Corrosive; corneal opacity not reversible within 7 days. | Corneal opacity reversible within 7 days; irritation persisting for 7 days. | No corneal opacity; irritation reversible within 7 days. | No irritation.                         |
| Skin effects.....                 | Corrosive.....   | Severe irritation at 72 hours.  | Moderate irritation at 72 hours.                         | Mild or slight irritation at 72 hours. |

(1) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such



that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size require-

ments for the front panel warning statements on various sizes of labels:

| Size of label front panel in square inches | Points                             |                                 |
|--|------------------------------------|---------------------------------|
|  | Required signal word, all capitals | "Keep out of reach of children" |
| 5 and under                                | 6                                  | 6                               |
| Above 5 to 10                              | 10                                 | 6                               |
| Above 10 to 15                             | 12                                 | 8                               |
| Above 15 to 30                             | 14                                 | 10                              |
| Over 30                                    | 18                                 | 12                              |

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

| Toxicity category | Precautionary statements by toxicity category   |  |
|-------------------|---|--|
|                   | Oral, inhalation, or dermal toxicity  | Skin and eye local effects   |
| I                 | Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]. | Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.] |
| II                | May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].            | Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]   |
| III               | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].                  | Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.   |
| IV                | [No precautionary statements required.]   | [No precautionary statements required.]  |

(ii) **Environmental hazards.** Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD<sub>50</sub> of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC<sub>50</sub> of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD<sub>50</sub> of 100 mg/kg or less, or a subacute dietary

LC<sub>50</sub> of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) **Physical or chemical hazards.** Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

| Flash point  | Required text  |
|--|--|
| (A) PRESSURIZED CONTAINERS   |  |
| Flash point at or below 20° F; if there is a flashback at any valve opening.   | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame. | Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.                |
| All other pressurized containers   | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.                           |
| (B) NONPRESSURIZED CONTAINERS  |  |
| At or below 20° F  | Extremely flammable. Keep away from fire, sparks, and heated surfaces.   |
| Above 20° F and not over 80° F   | Flammable. Keep away from heat and open flame.   |
| Above 80° F and not over 150° F  | Do not use or store near heat or open flame.   |

(i) **Directions for Use—(1) General requirements—(1) Adequacy and clarity of directions.** Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) **Placement of directions for use.** Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag.

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations,

and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be

considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988]



## **APPENDIX F**

### **Generic Data Call-In**

**No generic data are being called-in for:**

**Oxybisphenoxarsine (OBPA)**

## **APPENDIX G**

### **Product Specific Data Call-In**







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

DATA CALL-IN NOTICE

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment C, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment F).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You Are Receiving This Notice
- Section II - Data Required By This Notice
- Section III - Compliance With Requirements Of This Notice
- Section IV - Consequences Of Failure To Comply With This Notice
- Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

- A - Data Call-In Chemical Status Sheet
- B - Product-Specific Data Call-In Response Form
- C - Requirements Status and Registrant's Response Form
- D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- E - EPA Acceptance Criteria
- F - List of Registrants Receiving This Notice
- G - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in

Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

## II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

## II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

### III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

### III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment B and Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment A.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified timeframe (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the

Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to

share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) "[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."



b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment A. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

**Option 6. Citing Existing Studies** -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question.

Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

#### SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

##### IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or
  - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless

you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

#### **IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE**

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### **IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS**

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to

the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

#### **SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS**

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

#### **SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment B for generic data and Attachment C for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment A. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,



Daniel M. Barolo, Director  
Special Review and  
Reregistration Division

#### Attachments

- A - Data Call-In Chemical Status Sheet
- B - Product-Specific Data Call-In Response Form
- C - Requirements Status and Registrant's Response Form  
for the Product Specific Data Call-In
- D - EPA Grouping of End-Use Products for Meeting Acute  
Toxicology Data Requirements for Reregistration
- E - EPA Acceptance Criteria
- F - List of Registrants Receiving This Notice
- G - Cost Share and Data Compensation Forms, and Product  
Specific Data Report Form



## **ATTACHMENT A**

### **Product Specific DCI Chemical Status Sheet**





## **ATTACHMENT A**

### **OBPA**

#### **PRODUCT SPECIFIC DATA CALL-IN CHEMICAL STATUS SHEET**

##### **INTRODUCTION**

You have been sent this Product Specific Data Call-In Notice because you have products containing OBPA.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of OBPA products. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration (Attachment D), (5) EPA Acceptance Criteria (Attachment E), (6) List of Registrants Receiving this Notice (Attachment F), and (7) the Cost Share and Data Compensation Forms (Attachment G) in replying to this OBPA Product Specific Data Call-In. Instructions and guidance accompany each form.

##### **DATA REQUIRED BY THIS NOTICE**

The additional data requirements needed to complete the product specific database for OBPA are contained in the Requirements Status and Registrant's Response (Attachment C). The Agency has concluded that additional data on OBPA are needed for specific products. While product specific data requirements were imposed in the 1981 Registration Standard, a complete listing is provided in Attachment C. If you, as a registrant of an OBPA product, responded to the 1981 Registration Standard and submitted the data relating to your specific product, simply choose response number 6 and cite the MRID number that was assigned to your study. Otherwise, these data are required to be submitted to the Agency within the time-frame listed. These data are needed to complete the reregistration of all eligible OBPA products.

##### **INQUIRIES AND RESPONSES TO THIS NOTICE**

Any questions in regards to this RED, should be directed to Venus Eagle, Chemical Review Manager, Reregistration Branch, Special Review and Reregistration Division, at (703) 308 - 8045.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Cynthia Giles-Parker (703) 305 - 5540.

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

Cynthia Giles-Parker, Product Manager 22  
Fungicide-Herbicide Branch  
Registration Division (H7505C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

**RE: OBPA**

## **ATTACHMENT B**

### **Product Specific Data Call-In Response Forms (Form A) plus Instructions**



## **INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA**

- Item 1-4.**      **Already completed by EPA.**
- Item 5.**        **If you wish to voluntarily cancel your product, answer "yes". If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).**
- Item 6.**        **Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.**
- Item 7a.**        **For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."**
- Item 7b.**        **For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." if you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver. See item 6 with regard to identical products and data exemptions.**
- Items 8-11.** **Self-explanatory.**
- Note:** You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.



**United States Environmental Protection Agency**  
**Washington, D. C. 20460**  
**DATA CALL-IN RESPONSE**

Form Approved

OMB No. 2070-0107  
2070-0057

Approval Expires 03-31-96

**INSTRUCTIONS:** Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
 Use additional sheet(s) if necessary.

|   |  |  |  |  |  |
|---|--|--|--|--|--|
| 1. Company name and Address<br>SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000   |  | 2. Case # and Name<br>0044 OBPA  |  | 3. Date and Type of DCI<br>PRODUCT SPECIFIC  |  |
| 4. EPA Product Registration<br><br>NNNNNN-NNNNN   | 5. I wish to cancel this product registration voluntarily. | 6. Generic Data<br>6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.<br><br>N.A. |  | 7. Product Specific Data<br>7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."<br><br>N.A. |  |
|   |  | 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."<br><br>N.A.               |  | 7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."<br><br>                                |  |
| 8. Certification<br>I certify that the statements made on this form and all attachments are true, accurate, and complete.<br>I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.<br>Signature and Title of Company's Authorized Representative _____ |  |  |  | 9. Date  |  |
| 10. Name of Company Contact _____   |  |  |  | 11. Phone Number _____   |  |





## **ATTACHMENT C**

**Product Specific Data Call-In Requirements Status and  
Registrant's Response Forms (Form B) plus Instructions**

**INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA**

- Item 1-3      Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.
- Item 4.        The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.
- Item 5.        The study title associated with the guideline reference number is identified.
- Item 6.        The use patterns (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.
- Item 7.        The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8.        The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.
- Item 9.        Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.
1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.
  2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.
6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.
7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to

supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

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

**United States Environmental Protection Agency**  
**Washington, D. C. 20460**  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved

OMB No. 2070-0107  
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
 Use additional sheet(s) if necessary.

|  |   |  |   |   |                                  |                         |                  |                        |  |
|--|---|--|---|---|----------------------------------|-------------------------|------------------|------------------------|--|
| 1. Company name and Address<br><b>SAMPLE COMPANY</b><br><b>NO STREET ADDRESS</b><br><b>NO CITY, XX 00000</b> |   | 2. Case # and Name<br><b>0044 OBPA</b><br><b>EPA Reg. No. NNNNNN-NNNNN</b> |   | 3. Date and Type of DCI<br><b>PRODUCT SPECIFIC</b><br><b>ID# NNNNNN-RD-NNNN</b> |                                  |                         |                  |                        |  |
| 4. Guideline Requirement Number  | 5. Study Title  | Progress Reports   |   |   | 6. Use Pattern                   | 7. Test Substance       | 8. Time Frame    | 9. Registrant Response |  |
|  |   | 1  | 2 | 3   |                                  |                         |                  |                        |  |
| 61-1   | <u>Prod Chem - Regular Chemical</u><br><br>Product identity & composition(1)<br>Descrip of starting materials,(1,2)<br>production & formulation<br>proc<br>Discussion of formation of (1,3)<br>impurities<br>Preliminary analysis (1,4)<br>Certification of limits (1,5)<br>Analytical method (1)<br>Color<br>Physical state<br>Odor<br>Melting point (6)<br>Boiling point (7)<br>Density |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP and TGAI | 8 MOS.<br>8 MOS. |                        |  |
| 61-2 (a)   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP and TGAI | 8 MOS.<br>8 MOS. |                        |  |
| 61-2 (b)   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP and TGAI | 8 MOS.<br>8 MOS. |                        |  |
| 62-1   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP          | 8 MOS.<br>8 MOS. |                        |  |
| 62-2   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP          | 8 MOS.<br>8 MOS. |                        |  |
| 62-3   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP          | 8 MOS.<br>8 MOS. |                        |  |
| 63-2   |   |  |   |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO | MP/EP<br>MP/EP          | 8 MOS.<br>8 MOS. |                        |  |
| 63-3   |   |  |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO  | MP/EP and TGAI<br>MP/EP and TGAI | 8 MOS.<br>8 MOS.        |                  |                        |  |
| 63-4   |   |  |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO  | TGAI<br>TGAI                     | 8 MOS.<br>8 MOS.        |                  |                        |  |
| 63-5   |   |  |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO  | MP/EP and TGAI<br>MP/EP and TGAI | 8 MOS.<br>8 MOS.        |                  |                        |  |
| 63-6   |   |  |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO  | TGAI<br>TGAI                     | 8 MOS.<br>8 MOS.        |                  |                        |  |
| 63-7   |   |  |   | ABCDEFHIJKLMNO<br>ABCDEFHIJKLMNO  | MP/EP and TGAI<br>MP/EP and TGAI | 8 MOS.<br>8 MOS.        |                  |                        |  |

## 10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete.  
 I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and title of Company's Authorized Representative \_\_\_\_\_

12. Name of Company Contact \_\_\_\_\_

13. Phone Number \_\_\_\_\_

**United States Environmental Protection Agency**  
**Washington, D. C. 20460**  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved

OMB No. 2070-0107  
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
 Use additional sheet(s) if necessary.

| 1. Company name and Address<br>SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 |   | 2. Case # and Name<br>0044 OBPA<br>EPA Reg. No. NNNNNN-NNNN |   | 3. Date and Type of DCI<br>PRODUCT SPECIFIC<br>ID# NNNNNN-RD-NNNN |                  |                   |               |                        |
|---|---|---|---|---|------------------|-------------------|---------------|------------------------|
| 4. Guideline Requirement Number   | 5. Study Title                            | Progress Reports  |   |   | 6. Use Pattern   | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|   |   | 1   | 2 | 3   |                  |                   |               |                        |
| 63-8  | Solubility                                |   |   |   | ABCDEFGH IJKLMNO | TGAI/PAI          | 8 MOS.        |                        |
| 63-9  | Vapor pressure                            |   |   |   | ABCDEFGH IJKLMNO | TGAI/PAI          | 8 MOS.        |                        |
| 63-10   | Dissociation constant                     |   |   |   | ABCDEFGH IJKLMNO | TGAI/PAI          | 8 MOS.        |                        |
| 63-11   | Octanol/water partition coefficient       |   |   |   | ABCDEFGH IJKLMNO | PAI               | 8 MOS.        |                        |
| 63-12   | pH  |   |   |   | ABCDEFGH IJKLMNO | MP/EP and TGAI    | 8 MOS.        |                        |
| 63-13   | Stability                                 |   |   |   | ABCDEFGH IJKLMNO | MP/EP and TGAI    | 8 MOS.        |                        |
| 63-14   | Oxidizing or reducing action              |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-15   | Flammability                              |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-16   | Explosibility                             |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-17   | Storage stability                         |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-18   | Viscosity                                 |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-19   | Miscibility                               |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-20   | Corrosion characteristics                 |   |   |   | ABCDEFGH IJKLMNO | MP/EP             | 8 MOS.        |                        |
| 63-21   | Dielectric breakdown voltage              |   |   |   | ABCDEFGH IJKLMNO | EP                | 8 MOS.        |                        |
| <u>Acute Toxic - Regular Chemical</u>   |   |   |   |   |                  |                   |               |                        |
| 81-1  | Acute oral toxicity-rat (1,36,37)         |   |   |   | ABCDEFGH IJKLMNO | MP/EP and TGAI    | 8 MOS.        |                        |
| 81-2  | Acute dermal toxicity-rabbit/rat (1,2,37) |   |   |   | ABCDEFGH IJKLMNO | MP/EP and TGAI    | 8 MOS.        |                        |
| 81-3  | Acute inhalation toxicity-rat (3)         |   |   |   | ABCDEFGH IJKLMNO | MP/EP and TGAI    | 8 MOS.        |                        |

Initial to indicate certification as to information on this page  
 (full text of certification is on page one).

Date

**United States Environmental Protection Agency**  
Washington, D. C. 20460

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved

OMB No. 2070-0107  
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

|   |                                   |   |   |   |                   |                        |                        |
|---|-----------------------------------|---|---|---|-------------------|------------------------|------------------------|
| 1. Company name and Address<br><b>SAMPLE COMPANY</b><br><b>NO STREET ADDRESS</b><br><b>NO CITY, XX 00000</b>  |                                   | 2. Case # and Name<br><b>0044 OBPA</b><br><b>EPA Reg. No. NNNNNN-NNNN</b> |   | 3. Date and Type of DCI<br><b>PRODUCT SPECIFIC</b><br><b>ID# NNNNNN-RD-NNNN</b> |                   | 9. Registrant Response |                        |
| 4. Guideline Requirement Number   | 5. Study Title                    | 6. Use Pattern  |   |   | 7. Test Substance | 8. Time Frame          | 9. Registrant Response |
|   |                                   | Progress Reports  |   |   |                   |                        |                        |
|   |                                   | 1   | 2 | 3   |                   |                        |                        |
| 81-4  | Primary eye irritation-rabbit (2) |   |   |   | MP/EP             | 8 mos.                 |                        |
| 81-5  | Primary dermal irritation (1,2)   |   |   |   | MP/EP             | 8 mos.                 |                        |
| 81-6  | Dermal sensitization (4)          |   |   |   | MP/EP             | 8 mos.                 |                        |
| Initial to indicate certification as to information on this page (full text of certification is on page one). |                                   |   |   |   | Date              |                        |                        |





United States Environmental Protection Agency  
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0044 OBPA

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repack of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGA = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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

Footnotes: (The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.)

Prod Chem - Regular Chemical

- 1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: \*158.155 for product identity and composition (61-1); \*158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); \*158.167 for discussion of formation of impurities (61-3); \*158.170 for preliminary analysis (62-1); \*158.175 for certification of limits (62-2); and \*158.180 for enforcement analytical methods (62-3).
- 2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
- 3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
- 4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
- 5 Certified limits are not required for inert ingredients in products proposed for experimental use.
- 6 Required if technical chemical is solid at room temperature.
- 7 Required if technical chemical is liquid at room temperature.
- 8 Required if technical chemical is organic and non-polar.
- 9 Required if test substances are dispersible with water.
- 10 Required if product contains an oxidizing or reducing agent.
- 11 Required if product contains combustible liquids.
- 12 Required if product is potentially explosive.
- 13 Required if product is a liquid.
- 14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- 15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

- 1 Not required if test material is a gas or highly volatile.
- 2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

United States Environmental Protection Agency  
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0044 OBPA

Footnotes (cont.):

- 3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
- 4 Required unless repeated dermal exposure does not occur under conditions of use.
- 36 Special testing (acute, subchronic, and/or chronic) is required for organophosphates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
- 37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

## **ATTACHMENT D**

### **EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration**

## **ATTACHMENT D**

### **EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING 10.10'-Oxybisphenoxarsine (OBPA) FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREISTRATION**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient OBPA, the Agency considered batching end-use products. This process involves grouping similar products 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.).

However, batching of end-use products containing OBPA was not possible after considering the available information described above. Table I lists all the end-use products containing OBPA. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

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), 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 cited, the registrant must clearly identify the material tested by its EPA registration number.

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 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). Since the end-use products containing OBPA could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Not Batched Containing OBPA

| EPA REG. NO. | % of OBPA | Formulation Type |
|--------------|-----------|------------------|
| 34688-37     | 1.0       | liquid           |
| 34688-38     | 2.0       | liquid           |
| 34688-46     | 5.0       | liquid           |
| 34688-49     | 5.0       | liquid           |
| 2829-82      | 1.0       | liquid           |
| 2829-96      | 2.0       | liquid           |
| 2829-102     | 1.0       | liquid           |
| 2829-104     | 1.0       | liquid           |
| 2829-105     | 2.0       | liquid           |
| 2829-109     | 2.0       | liquid           |
| 2829-110     | 2.0       | liquid           |
| 2829-115     | 5.0       | pellets          |
| 2829-120     | 96.0      | powder           |
| 2829-125     | 5.0       | liquid           |
| 2829-90      | 2.0       | liquid           |



## **ATTACHMENT E**

### **EPA Acceptance Criteria**





## SUBDIVISION D

| <u>Guideline</u> | <u>Study Title</u>                                |
|------------------|---|
| Series 61        | Product Identity and Composition                  |
| Series 62        | Analysis and Certification of Product Ingredients |
| Series 63        | Physical and Chemical Characteristics             |



## 61 Product Identity and Composition

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ☐ Name of technical material tested (include product name and trade name, if appropriate)
2. ☐ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3. ☐ Name and upper certified limit for each impurity or each group of impurities present at  $\geq 0.1\%$  by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at  $<0.1\%$
4. ☐ Purpose of each active ingredient and each intentionally-added inert
5. ☐ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6. ☐ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
7. ☐ Description of each beginning material in the manufacturing process
  - ☐ EPA Registration Number if registered; for other beginning materials, the following:
    - ☐ Name and address of manufacturer or supplier
    - ☐ Brand name, trade name or commercial designation
    - ☐ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity
8. ☐ Description of manufacturing process
  - ☐ Statement of whether batch or continuous process
  - ☐ Relative amounts of beginning materials and order in which they are added
  - ☐ Description of equipment
  - ☐ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained
  - ☐ Statement of whether process involves intended chemical reactions

8. (continued)

- \_\_\_\_\_ Flow chart with chemical equations for each intended chemical reaction
- \_\_\_\_\_ Duration of each step of process
- \_\_\_\_\_ Description of purification procedures
- \_\_\_\_\_ Description of measures taken to assure quality of final product

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

## 61 Product Identity and Composition

### GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 1, 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement of Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration, and certified limits.
3. Name and upper limit for all impurities present at  $\geq 0.1\%$  and those toxicologically significant impurities present at  $<0.1\%$ .
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental or internal code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

## 62 Analysis and Certification of Product Ingredients

### ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

## 62 Analysis and Certification of Product Ingredients

### GUIDANCE FOR SUMMARIZING STUDIES

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

1. Number of representative samples analyzed for all active ingredients and all impurities at  $\geq 0.1\%$ .
2. Degree of accountability or closure in analyses in item #1.
3. Chemical names of toxic impurities which were analyzed for levels  $<0.1\%$ .
4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.
5. Statement of precision and accuracy of method(s) in item #4.
6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.
7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.
8. Proposed upper certified limit for each impurity present at  $\geq 0.1\%$  and certain toxicologically significant impurities at  $<0.1\%$  with brief explanation of how limits were determined.
9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).
10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).





## 63 Physical and Chemical Characteristics

### ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

#### 63-2 Color

- ☐ Verbal description of coloration (or lack of it)
- ☐ Any intentional coloration also reported in terms of Munsell color system

#### 63-3 Physical State

- ☐ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
- ☐ Based on visual inspection at about 20-25° C

#### 63-4 Odor

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

#### 63-5 Melting Point

- ☐ Reported in C°
- ☐ Any observed decomposition reported

#### 63-6 Boiling Point

- ☐ Reported in C°
- ☐ Pressure under which B.P. measured reported
- ☐ Any observed decomposition reported

#### 63-7 Density, Bulk Density, Specific Gravity

- ☐ Measured at about 20-25° C
- ☐ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft<sup>3</sup> or lbs/gallon.]

63-8 Solubility

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

63-9 Vapor Pressure

- \_\_\_ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
- \_\_\_ Experimental procedure described
- \_\_\_ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

- \_\_\_ Experimental method described
- \_\_\_ Temperature of measurement specified (preferably about 20 - 25° C)

63-11 Octanol/water Partition Coefficient

- \_\_\_ Measured at about 20-25° C
- \_\_\_ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
- \_\_\_ Data supporting reported value provided

63-12 pH

- \_\_\_ Measured at about 20 - 25° C
- \_\_\_ Measured following dilution or dispersion in distilled water

63-13 Stability

- \_\_\_ Sensitivity to metal ions and metal determined
- \_\_\_ Stability at normal and elevated temperatures
- \_\_\_ Sensitivity to sunlight determined

## 63 Physical and Chemical Characteristics

### GUIDANCE FOR SUMMARIZING STUDIES

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

1. Description of color.
2. Description of physical state.
3. Description of odor.
4. Indication of melting point (in C°).
5. Indication of boiling point (in C°).
6. Indication of density, bulk density, and specific gravity.
7. Indication of solubility.
8. Indication of vapor pressure.
9. Indication of dissociation constant.
10. Indication of octanol/water partition coefficient.
11. Indication of PH.
12. Description of stability.



## SUBDIVISION F

| <u>Guideline</u> | <u>Study Title</u>                                     |
|------------------|--|
| 81-1             | Acute Oral Toxicity in the Rat                         |
| 81-2             | Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig |
| 81-3             | Acute Inhalation Toxicity in the Rat                   |
| 81-4             | Primary Eye Irritation in the Rabbit                   |
| 81-5             | Primary Dermal Irritation Study                        |
| 81-6             | Dermal Sensitization in the Guinea Pig                 |
| 81-7             | Acute Neurotoxicity in the Hen                         |



## 81-1 Acute Oral Toxicity in the Rat

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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





## 81-1 Acute Oral Toxicity in the Rat

### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, end-use product, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing and for at least 14 days.
7. Summarization of body weights
8. Summarization of gross necropsy
9. Significance of changes from the Acceptance Criteria



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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. The number of animals/sex/dose
3. Weight range of animals
4. Verification of single, dermal exposure
5. Duration of dermal exposure
6. Statement of vehicle control
7. Doses tested and results
8. Preparation of application site
9. Area of application site (percent body surface)
10. Occlusion of test material on application site
11. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
12. Summarization of body weights
13. Summarization of gross necropsy
14. Significance of changes from Acceptance Criteria

## 81-3 Acute Inhalation Toxicity in the Rat

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

### 81-3 Acute Inhalation Toxicity in the Rat

#### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. Statement of the inhalability of test substance
3. The number of animals/sex/dose
4. Duration of inhalation exposure
5. Number of chamber air changes/hour and the percent oxygen content of chamber air
6. Ranges for chamber air temperature and relative humidity
7. Air flow rate
8. Analytical concentrations of test material in breathing zone
9. Results of aerosol particle-size determination
10. Doses tested (or limit dose of 5mg/L or highest attainable)
11. Individual observations on day of dosing and for at least 14 days.
12. Summarization of body weights
13. Summarization of gross necropsy
14. Significance of changes from Acceptance Criteria

## 81-4 Primary Eye Irritation in the Rabbit

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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



## 81-4 Primary Eye Irritation in the Rabbit

### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive, cause severe dermal irritation or has a pH of  $<2$  or  $>11.5$
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual daily observations afterwards, until eyes are normal or for 21 days
10. Significance of changes from Acceptance Criteria

## 81-5 Primary Dermal Irritation Study

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

## 81-5 Primary Dermal Irritation Study

### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD 50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for day of dosing and individual daily observations thereafter
12. Significance of changes from Acceptance Criteria.

## 81-6 Dermal Sensitization in the Guinea Pig

### ACCEPTANCE CRITERIA

dose your study meet the following acceptance criteria?

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

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

## 81-6 Dermal Sensitization in the Guinea Pig

### GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive or has pH <2 or >11.5.
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

## 81-7 Acute Neurotoxicity in the Hen

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ☐ Study performed on an organophosphate cholinesterase inhibiting compound.
2. ☐ Technical form of the active ingredient tested.
3. \* ☐ Positive control utilized.
4. ☐ Species utilized, domestic laying hen 8-14 months of age.
5. ☐ Dosing oral by gavage or capsule (dermal or inhalation may be used).
6. ☐ An acute oral LD is determined.
7. ☐ Dose tested equal to an acute oral LD or a limit test of 5000 mg/kg.
8. \* ☐ Dosed animals may be protected with atropine and/or 2-PAM.
9. ☐ Sufficient test animals so that at least 6 survive.
10. ☐ Negative (vehicle) control group of at least 6 hens
11. \* ☐ Positive control of at least 4 hens. (if used)
12. ☐ Test dose repeated if no signs of delayed neurotoxicity observed by 21 days after dosing.
13. ☐ Observation period 21 days after each dose.
14. ☐ Individual daily observations.
15. ☐ Individual body weights.
16. ☐ Individual necropsy not required.
17. ☐ Histopathology performed on all animals. Tissue to be fixed in sin preferably using whole animal perfusion techniques. At least three sections of each of the following tissues:
  - ☐ brain, including medulla oblongata
  - ☐ spinal cord; upper cervical, mid-thoracic and lumbro-sacral regions
  - ☐ tibial nerve; proximal regions and branches
  - ☐ sciatic nerve

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



**ATTACHMENT F**

**List of Registrants sent this DCI**





## United States Environmental Protection Agency

Washington, D. C. 20460

## LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0044 OBPA

| Co. Nr. | Company Name | Additional Name | Address | City & State | Zip |
|---------|--------------|-----------------|---------|--------------|-----|
|---------|--------------|-----------------|---------|--------------|-----|

|                  |  |                           |  |                          |                |
|------------------|--|---------------------------|--|--------------------------|----------------|
| 002829<br>034688 | MORTON INTERNATIONAL, INC.<br>AKZO CHEMICALS, INC. | SPECIALTY CHEMICALS GROUP | 333 WEST WACKER DRIVE<br>300 SOUTH RIVERSIDE PLAZA | CHICAGO IL<br>CHICAGO IL | 60606<br>60606 |
|------------------|--|---------------------------|--|--------------------------|----------------|



**ATTACHMENT G**

**Product Specific Data Call-In Cost Share and  
Data Compensation Forms**





United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

Form Approved

OMB No. 2070-0107  
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

|              |                |
|--------------|----------------|
| Company Name | Company Number |
| Product Name | EPA Reg. No.   |

I Certify that:

- For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
- That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)  
  
☐ The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
- That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

|                                       |      |
|---------------------------------------|------|
| Signature                             | Date |
| Name and Title (Please Type or Print) |      |

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

|                                       |      |
|---------------------------------------|------|
| Signature                             | Date |
| Name and Title (Please Type or Print) |      |



United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0107

2070-0057

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Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

|              |                |
|--------------|----------------|
| Company Name | Company Number |
| Product Name | EPA Reg. No.   |

I Certify that:

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

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

|                 |               |
|-----------------|---------------|
| Name of Firm(s) | Date of Offer |
|-----------------|---------------|

**Certification:**

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

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