

US EPA ARCHIVE DOCUMENT



# Reregistration Eligibility Decision (RED)

## Zinc Phosphide



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case zinc phosphide. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1997, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional generic data on zinc phosphide to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the date of your receipt of this letter. The second set of required responses is due 8 months from the date of your receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Mr. Frank Rubis at (703) 308-8184. Address

any questions on required generic data to the Special Review and Reregistration Division representative Ms. Susan Jennings at (703) 308-7130.

Sincerely yours,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

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

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

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

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

certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements.** Complete and sign EPA forms 8570-34 and 8570-35 for each product.

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

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

**By U.S. Mail:**

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

**By express:**

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

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



**REREGISTRATION ELIGIBILITY DECISION**

**ZINC PHOSPHIDE**

**LIST A**

**CASE 0026**





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## ZINC PHOSPHIDE REREGISTRATION ELIGIBILITY DECISION TEAM

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#### Biological and Economic Analysis Assessment

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## GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>0</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
µg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

## GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
$Q_1^*$	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard



## ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide zinc phosphide. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Zinc phosphide is a rodenticide that reacts with the acidic conditions in the gut to form phosphine gas, which interferes with cell respiration. Zinc phosphide is formulated as a bait/solid, dust, granular, pellet/tablet or wettable powder. The rodenticide may be used to control many species of rodents, including mice, ground squirrels, prairie dogs, voles, moles, rats, muskrats, nutria and gophers. Zinc phosphide may be used as an indoor or outdoor spot treatment for rodents as well as around burrows or underground in orchards, vineyards, various food crops, rangelands, and non-crop areas. Zinc phosphide is also applied as a broadcast treatment by ground or aerial applications.

The Agency has concluded that zinc phosphide, labeled and used as specified in this Reregistration Eligibility Decision document, will not cause unreasonable risks to humans or the environment and that all uses are eligible for reregistration. To support broadcast applications, the Agency is requiring additional aquatic toxicity data and further use information. The eligible uses include: indoor and outdoor residential and agricultural areas (including in and around homes, lawns, bulbs, in and around outside buildings/barns, rights-of-ways/fencerows/hedgerows), indoor and outdoor commercial or institutional premises and equipment, golf courses, and reforestation areas. The Agency has determined that certain application methods, in conjunction with certain use restrictions, do not result in residues of zinc phosphide on food crops. Therefore, these uses are not considered food uses for the purpose of tolerance or dietary risk assessment. These "non-food" crop uses are eligible for reregistration, provided they employ the application methods and other restrictions specified in this document. These crops include: alfalfa, barley, berries, oats, wheat, no-till corn, macadamia nut orchards, orchards/groves (post-harvest and dormant), sugar maple, and timothy (hay). In addition, the following crop uses that are considered food uses of zinc phosphide are eligible for reregistration: grapes, rangeland grasses and sugarcane. Artichokes and sugar beets have regional tolerances established for use in California; currently there are no labels that include the use on artichokes.

Although zinc phosphide is primarily used in agricultural and non-residential settings, rodenticides that are used in and around the home are responsible for a high number of accidental exposures each year. EPA is concerned about the continued risk of exposure to humans, especially children, from rodenticides used in residential settings as well as the cost and trauma associated with treating those who might have been accidentally exposed. Although there are not many incidents associated with zinc phosphide *per se*, the Agency believes that the common use pattern should be the primary determining factor shaping the regulatory decision regarding these rodenticides used in and around the home. Additionally, a margin of exposure (MOE) of 0.5 was calculated for zinc phosphide based on an acute neurotoxicity study and accidental ingestion of the bait formulation by a child. Generally, the Agency seeks to ensure that exposures have an MOE of 100 or greater. The Agency has also determined that a single swallow of zinc phosphide bait may be fatal to a young child.

To mitigate the potential risk to children from accidental ingestion of baits, the Agency is requiring several mitigation measures to be implemented in two phases. During Phase I the Agency will require zinc phosphide products, as well as those of several other rodenticides, to incorporate indicator dye (to help identify whether a child or pet has actually consumed the pesticide) and bittering agents into their formulations. These formulation changes are required of all zinc phosphide products, except for those used exclusively in an agricultural setting. In addition, registrants must

update their product labels to include the protective statements addressed in Section V of this document. During Phase II EPA will form a stakeholder group (including industry, states, various poison control centers, rodent control experts, the medical community and other interested parties) to develop additional means of significantly reducing exposures to children and pets. It is the Agency's intent that, within nine months or less from the issuance of the RED, the stakeholder group will conclude with recommendations on how to mitigate risk to children and pets. Possible outcomes of this group include: requiring all rodenticide baits used in residential settings to be placed in disposable, child-resistant bait stations or equivalently protective mechanisms; develop an exhaustive educational and outreach program for consumers and enhanced training for certified applicators; tamper-resistant bait stations; and additional labeling improvements. To monitor the progress of the measures prescribed during both phases, the Agency is also requiring registrants to submit annual American Association of Poison Control Center Data for years 1999 through 2009. Registrants are encouraged to share the cost of generating data and new technologies, whenever appropriate.

In establishing or reassessing tolerances, the Food Quality Protection Act (FQPA) requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mode of toxicity. The Act further directs the Agency to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residue.

Zinc phosphide, aluminum phosphide and magnesium phosphide all generate phosphine gas. The Agency believes the generation of phosphine should be considered as part of its aggregate assessment. Other chemicals may share a common mode of toxicity with phosphine gas. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. However, with respect to zinc phosphide tolerance reassessment, any future cumulative risk determination regarding other chemicals that have a common mode of toxicity with phosphine will not include the uses of zinc phosphide discussed in this document because the exposures to phosphine from zinc phosphide are so unlikely.

The Agency has determined that acute or chronic dietary exposure associated with the use of zinc phosphide is unlikely. Of those commodities designated as food uses for zinc phosphide, only three were found to have detectable residues after application (grasses, sugar beets, sugarcane). Since these three crops are not direct human food items, no acute or chronic dietary consumption of zinc phosphide is expected. Also, zinc phosphide will not concentrate during the processing of any commodity because the act of processing will not allow for unreacted zinc phosphide to remain in or on processed food items. No drinking water risk assessment was performed for zinc phosphide because no residues are expected in either ground or surface water. Exposure, other than accidental ingestion, is not expected. EPA does not believe "accidental ingestion" of baits should be considered in the FQPA determination for tolerance setting. Notwithstanding the absence of exposure, the Agency established an RfD for zinc phosphide. FQPA provides that EPA apply an additional tenfold margin of safety for infants and children to account for pre- and post-natal toxicity and the completeness of the toxicity and exposure database, unless EPA determines that a different margin of safety will be safe for infants and children.

The available data base for zinc phosphide does not indicate a potential for an increased sensitivity to infants or children, however, it does not include a developmental study in rabbits or a two-generation reproductive study in rats. The available data provided no indication of increased sensitivity of fetal rats to *in utero* exposure to zinc phosphide.

The prenatal exposure developmental toxicity study in rats demonstrated no developmental effects at the highest dose tested, which was maternally toxic. The Agency is not requiring additional developmental or reproduction studies at this time because exposure from food sources is expected to be minimal to non-existent, however, the Agency has established an RfD of 0.0001 mg/kg based on a subchronic oral study that showed no effects at 0.1 mg/kg. The Agency found, in its evaluation of dietary risk for zinc phosphide subsequent to the RfD determination, that no dietary or drinking water exposure is expected and no risk assessment is necessary. Should a risk assessment be required in the future, due to treated food crops, an additional uncertainty factor of 10 would be applied to the Reference Dose calculation. This uncertainty factor would account for the extrapolation from subchronic to chronic exposure, the lack of reproductive toxicity data, and the lack of chronic toxicity data in a non-rodent species. The RfD of 0.0001 mg/kg reflects this additional uncertainty factor. If food uses showing dietary exposure are proposed for registration, a risk assessment will have to be performed. If risks are unacceptable using the current RfD, which reflects an additional uncertainty factor of 10, further studies will be required.

To mitigate the potential exposure to handlers of particulate dusts from baits, tracking powders and wettable powders the Agency is requiring, among other changes, the use of dust/mist filter respirators and protective gloves.

To mitigate the potential exposure of the rodenticide to non-target animals in an agricultural setting, the Agency is retaining the requirement that all zinc phosphide products labeled for field use (except those limited to underground baiting for pocket gophers and moles) must be restricted to use by pesticide certified applicators, or persons under their direct supervision.

Because the use of zinc phosphide will still present a hazard to non-target animals, the Agency is seeking ways to minimize exposure to these animals. The Agency is especially concerned about the broadcast use of zinc phosphide as it allows large tracts of land to be treated. However, the available data do not show that hand-baiting will necessarily result in reduced exposure to non-target animals. Rather than impose specific use restrictions at this time, the Agency will continue its evaluation of the risks associated with hand baiting versus broadcast applications and may impose additional data requirements or label amendments at a later date.

Although the use of zinc phosphide does present a risk to non-target wildlife, the Agency has determined that these adverse effects are not unreasonable due to the benefits of zinc phosphide. The use of the broadcast application allows the treatment of vast tracts of land where hand baiting is not feasible. In addition, the Agency believes that limiting the broadcast uses may indirectly encourage the use of other pesticides that are more hazardous to non-target animals than zinc phosphide.

Before reregistering the products containing zinc phosphide, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

## I. INTRODUCTION

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

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. Therefore, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of zinc phosphide, including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes zinc phosphide, 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 zinc phosphide. Section V discusses the reregistration requirements for zinc phosphide. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## II. CASE OVERVIEW

### A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

!	<b>Common Name:</b>	Zinc Phosphide
!	<b>Chemical Name:</b>	Zinc Phosphide
!	<b>Chemical Family:</b>	Inorganic compound
!	<b>CAS Registry Number:</b>	1314-84-7
!	<b>OPP Chemical Code:</b>	088601
!	<b>Empirical Formula:</b>	Zn <sub>3</sub> P <sub>2</sub>
!	<b>Trade and Other Names:</b>	n/a
!	<b>Basic Manufacturers:</b>	Bell Laboratories, Inc. and HACCO Inc.

### B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of zinc phosphide that were considered for reregistration is in Appendix A.

For zinc phosphide:

**Type of Pesticide:** Rodenticide

#### **Use Sites:**

*Nonfood:* Indoor and outdoor residential and agricultural areas (including in and around homes, on lawns, around bulbs, in and around outside buildings/barns, rights-of-ways/fencerows/hedgerows), indoor and outdoor commercial or institutional premises and equipment (including food handling establishments), golf courses, reforestation areas, alfalfa, barley, berries (dormant), oats, sugar maple, wheat, no-till corn, macadamia nut orchards, orchards/groves (post-harvest and dormant), timothy (hay). Zinc phosphide can also be used as a general, wide area, Public Health Use pesticide.

*Food:* grapes, rangeland grasses, and sugarcane. Artichokes and sugar beets have regional registrations in California; currently there are no labels that include use on artichokes.



**Target Pests:** black-tail jack rabbit, black-tail prairie dog, chipmunk, columbian ground squirrel, cotton rat, field mice, ground squirrels, Guanosine's prairie dog, house mouse, jack rabbits, marmot, meadow mouse, meadow vole, mice, microtus, muskrats, Norway rat, nutria, pine (woodland) vole, pine vole, pocket gophers, pocket gophers (plains), prairie dogs, red squirrel, Richardson ground squirrel, roof rat, southern pocket gopher, squirrels, white-tailed prairie dog, wood rats, yellow-faced pocket gopher.

**Formulation Types Registered:** bait/solid (1 - 2%), dust (10 - 63%), granular (2 - 63%), pellet/tablet (2%), wettable powder (80% as pre-mix for bait)

**Method and Rates of Application:**

Equipment - aircraft, bait box, duster, hand bulb duster, hand probe, hand at bait stations, hand probe, hand treatments, mechanical burrow builder, mechanical granule applicator, or mechanical broadcast.

Method and Rate - rates of application vary by pest with the highest of 0.2 lb/A on a wide variety of crops.

Timing - zinc phosphide is typically applied when infestation is noticed.

**Use Practice Limitations:** All labels include hazard statements for humans and domestic animals requiring that the product be kept away from humans, domestic animals, and pets. The use in some crop areas must be when the crop or orchard is dormant.

**C. Estimated Usage of Pesticide**

This section summarizes the best estimates available for the pesticide uses of zinc phosphide. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Zinc phosphide is a rodenticide used almost exclusively by the agricultural industry. Very little zinc phosphide is used residentially. About half of the total volume is used in or around farm structures, and the other half is applied to various agricultural sites. There is limited information available on the market share and usage of rodenticides. The following table estimates zinc phosphide usage by site:

Zinc Phosphide Use by Site		
Site	Pounds Applied (% of total)	Acres Treated (% of site acres)
Sugar beets	10	< 1
Wheat, Barley and Oats	10	< 1

Rangeland	10	< 1
Landscape (turf, golf courses)	10	N/A
Farm Structures (barns, sheds, etc.)	40	N/A
Residential	5	N/A
Other (less than 5% per site of all others)	15	N/A

#### D. Data Requirements and Regulatory History

Zinc phosphide was first registered in the United States in 1947 by the United States Department of Agriculture (USDA) for use as a rodenticide. A Registration Standard was issued for zinc phosphide in June 1982. The Standard evaluated the available data with other relevant information on zinc phosphide and required the submission of additional data to maintain the existing registrations. A DCI was issued in 1987 and another in 1991 requiring further data for reregistration. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the two DCIs.

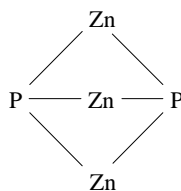
Following the issuance of the 1991 DCI, the Zinc Phosphide Consortium was formed. The consortium is made up of technical, formulator, as well as end-use product registrants. The USDA APHIS (Animal and Plant Health Inspection Service) is the consortium leader.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

##### IDENTIFICATION OF ACTIVE INGREDIENT

Zinc phosphide:



Empirical Formula:	$Zn_3P_2$
Molecular Weight:	258.09
CAS Registry No.:	1314-84-7
OPP Chemical No.:	088601

Technical zinc phosphide is a gray to black powder with a phosphine odor and melting point of 420 C. Zinc phosphide is insoluble in water and ethanol, and soluble in benzene and carbon disulfide. Zinc phosphide is stable in dry conditions, but reacts slowly with water (including atmospheric moisture) to form phosphine gas

(PH<sub>3</sub>). In the presence of acids or strong bases, phosphine gas is generated rapidly and may be spontaneously flammable or explosive. Technical zinc phosphide is classified as a flammable solid by the U.S. Department of Transportation.

### Manufacturing-use Products

There are three registered zinc phosphide manufacturing-use products (MPs). A list of the MPs subject to this reregistration eligibility decision is presented in the following table:

<b>MPs subject to this reregistration eligibility decision</b>		
<b>% AI</b>	<b>EPA Reg. No.</b>	<b>Registrant</b>
93%	61282-3	HACCO, Inc.
80%	61282-13	HACCO, Inc.
80%	12455-24	Bell Laboratories, Inc.

Additional generic and product-specific data are required for all three of the above products. In addition to submitting the required data, the registrants must certify that the suppliers of beginning materials and the manufacturing processes for the zinc phosphide products have not changed since the last comprehensive product chemistry review. Alternatively, the registrants may elect to submit complete updated product chemistry data packages for their products. The Agency considers these data to be confirmatory and does not expect them to alter the risk eligibility decision for zinc phosphide.

## **B. Human Health Assessment**

### **1. Toxicology Assessment**

The toxicological data base on zinc phosphide is adequate and will support reregistration eligibility. No further data are required at this time.

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

The acute toxicity testing for zinc phosphide is summarized in the following table and satisfy the requirements for acute toxicology data for zinc phosphide.



Acute Mammalian Toxicity				
Test	% AI	MRID	Results	Category
Oral LD <sub>50</sub> - rat	89%	00085366	21 (13-35) mg/kg	I
Dermal LD <sub>50</sub> - rabbit	94%	00006030	2000 - 5000 mg/kg	III
Inhalation LC <sub>50</sub>			waived	I*
Eye irritation - rabbit**	94%	00029247	Slight conjunctival redness, chemosis and discharge	IV
Dermal irritation - rabbit**	94%	00006029	non irritating	N/A
Skin sensitization**			waived	----
Acute Neurotoxicity	97%	43284301	NOEL = 5, LEL =10 mg/kg (myelin debris and vacuoles in peripheral nerves of 2 female rats)	N/A

\* In lieu of performing study, compound was designated as Toxicity Category I.

\*\* Data pertaining to eye irritation, dermal irritation and dermal sensitization are not required to support the TGAI. These data are presented for informational purposes.

#### b. Subchronic Toxicity

In a 90-day rat study zinc phosphide technical (97% AI) was administered by oral gavage to rats (10/sex/dose) at doses of 0, 0.1, 1.0, or 3.0 mg/kg/day for 91 days. Mortality (5 females and 1 male) and moribundity (1 male) were reported in the high-dose group. One mid-dose male was sacrificed moribund on Day 54. Clinical signs of excessive salivation and "cool to the touch" were observed at 1.0 mg/kg/day and above. Hydronephrosis and pyelonephritis were detected by microscopic histopathology in male kidneys at 3.0 mg/kg/day, and hydronephrosis was also observed at 1.0 mg/kg/day. Neither lesion was observed at 0.1 mg/kg/day. This study established a NOEL and LEL of 0.1 mg/kg/day and 1.0 mg/kg/day, respectively, based on increased mortality and on kidney hydronephrosis in male rats.

A 90-day neurotoxicity study was also submitted and will be discussed later in this document. All other subchronic toxicity studies were waived in the 1982 Registration Standard. (MRID 43436601)

#### c. Chronic Toxicity and Carcinogenicity

Although zinc phosphide is registered for use on food crops, no chronic toxicity or carcinogenicity studies are required because chronic exposure to zinc phosphide or its byproducts is expected to be negligible.

#### d. Developmental Toxicity

In a developmental toxicity study mated female rats (25/group) were administered zinc phosphide in single daily doses by gavage at levels of 0, 1, 2 or 4 mg/kg on days 6 through 15 of gestation. Nine maternal animals from the 4.0 mg/kg group were found dead between days 10 and 16 of gestation. The cause of death was not apparent from a gross examination. Mean body weight and food intake reductions in the 4.0 mg/kg group females were significantly lower for gestation days 6-10 but not altered by the end of the treatment period. The maternal NOEL was 2.0 mg/kg and the LEL was 4.0 mg/kg based on mortality. The developmental NOEL was at or above 4.0 mg/kg, which was the highest dose test. No further data are required at this time. (MRID 43083501)

Although the database did not include a developmental study on a non-rodent species, as residues are expected to be negligible the requirement is waived. If new uses result in detectable residues, then this requirement will be reinstated.

**e. Reproductive Toxicity**

Although the database did not include a two-generation reproductive toxicity study in rats, as residues are expected to be negligible the requirement is waived. If new uses result in detectable residues, then this requirement will be reinstated.

**f. Mutagenicity**

AMES SALMONELLA. Salmonella TA-strains of bacteria were exposed to zinc phosphide (97% AI) suspended in DMSO, at doses of up to 5000  $\mu\text{g}/\text{plate}$ , with and without metabolic activation (S9). No increased revertants were induced. Zinc phosphide was negative for gene mutation in the Ames test. (MRID 42987301)

MOUSE LYMPHOMA. Mouse lymphoma cells were exposed to zinc phosphide (97% AI) with and without mammalian metabolic activation (S9). Increased mutants at the thymidine kinase locus (TK) were induced in a dose-dependent manner at doses of 10 through 80  $\mu\text{g}/\text{ml}$  (+/- S9). Zinc phosphide was positive for gene mutation in this mouse lymphoma assay. (MRID 42987302)

CHROMOSOME ABERRATIONS. Mice were treated with zinc phosphide (97% AI) suspended in corn oil up to severely toxic levels (150 mg/kg). No increased aberrations (micronuclei) were induced. Zinc phosphide was negative for mutagenicity in this micronucleus test. (MRID 42987303)

These studies satisfy the requirements for mutagenicity testing.

**g. Metabolism**

Since residues are expected to be minimal or nonexistent, the requirement for a metabolism study with zinc phosphide has been waived. If new uses result in detectable residues, then this requirement will be reinstated.

## **h. Neurotoxicity**

### Acute

In an acute range-finding study, rats zinc phosphide was administered by gavage to rats at dose levels of 1, 2, 3, 4, 8 and 10 mg/kg/day. There were no changes in toxicity, body weight or food consumption initially and 7 days after, nor were there any neurotoxicity effects. Although this study is not guideline, it does establish an LOEL of greater than 10 mg/kg. (MRID 4328301)

### Subchronic

In a 13-week subchronic neurotoxicity study, rats (11/sex/group) were dosed by gavage with zinc phosphide (97% AI) daily via oral gavage at levels of 0, 0.1, 0.5, or 2 mg/kg. A positive control group was included using trimethyltin chloride in water administered by gavage at 4.5 mg/kg (11/sex), one dose weekly for three weeks starting at week 8 of the dosing period. Although no dose range finding study was referenced in the report to establish the high dose set at 2 mg/kg/day, the Agency agrees with the high-dose setting based on a 90-day study that had been previously submitted.

Each rat was observed twice daily for mortality and overt signs of toxicity. Routine functional observational batteries and motor activity assessments were carried out one week before dosing and during experimental weeks 4, 8 and 13. Following the in-life neurotoxicity evaluation, six rats per sex from each test group (except for the positive control group males) were randomly selected for necropsy and neuropathology evaluation. Eight of the positive control females euthanized in extremis and the one surviving male were necropsied and prepared for neuropathology analysis.

One male and one female from the low-dose groups and one male from the high dose group died of causes unrelated to the zinc phosphide administration. There were no adverse effects that could be ascribed to zinc phosphide. All of the animals in the positive control group were normal until dosing with trimethyltin chloride during week 8. They exhibited signs of overt toxicity beginning in week 9, becoming irritable, emaciated and unkempt in appearance. Three of the positive control males were found dead in their cages and the other 8 males were sacrificed in extremis by week 11. All of the positive control females survived longer but had to be euthanized in extremis by week 12.

Neuropathological examinations on some of the peripheral nerve sections in all treatment groups were incomplete because of inadequate tissue fixation. None of the neuropathological examinations that were performed on the zinc phosphide treated animal tissues showed any lesions that could be related to the treatment. The cerebral cortex of the positive control animals showed hemorrhage of the choroid plexus, necrosis of the hippocampus and dilation of the lateral ventricles. The findings in the other sections of the trimethyltin chloride treated animals were either within normal limits, not diagnostic secondary to inadequate fixation or revealed artifacts of preparation (vacuoles and myelin debris). This study is not acceptable due to inadequate neuropathological analyses, however, it is sufficient to show systemic, behavioral and neuropathological NOELs of 2 mg/kg/day, the highest dose tested.

A second 13-week subchronic neurotoxicity study in rats (MRID #43903802) was a partial repeat of the first study that was necessary due to inadequate fixation of nervous tissues during the neuropathology component in the initial study. In this study, rats (11/sex/group) were dosed daily with zinc phosphide (95% AI) via oral gavage (2 ml/kg) at levels of 0, 0.1, 0.5, or 2 mg/kg. A positive control group (initial study only) using trimethyltin chloride in water administered by gavage at 4.5 mg/kg (11/sex), one dose weekly for three weeks starting at week 8 of the dosing period.

Each rat was observed twice daily for mortality and overt signs of toxicity. Routine observations, functional observational batteries and motor activity assessments were carried out one week before dosing and during weeks 4, 8 and 13 of the study. Eight days after the final set of neurobehavioral evaluations, 6 animals per sex per group were randomly selected for neuropathology evaluation. No postmortem examination was reported for the remaining animals.

Four animals died of causes unrelated to the zinc phosphide administration. Clinical signs, body weights and food consumption in the treated animals were comparable to control animals. Cause of the animals death was not reported, however, except for one mid-dose female all tissues were reported to be normal.

Neurobehavioral observations were comparable to control animals, except for assessments of alterations of posture, rearing, touch, click and pinch observations which were statistically altered in the mid- or high-dose animals. Neuropathological examination of the control and high-dose animals suggested no adverse changes in morphology. Although neither 13-week subchronic neurotoxicity study is satisfactory, together the two studies provide sufficient information to fulfill the guideline requirements for a subchronic neurotoxicity study. Due to the inconclusive findings in these studies, the overall NOEL for subchronic neurotoxicity was established at 0.1 mg/kg/day, the lowest dose tested. (MRIDs 43903801 and 43903802)

## **2. Toxicological Endpoints for Risk Assessment**

### **a. Acute Dietary**

No acute endpoints were identified; therefore, an acute dietary risk assessment is not required. An acute endpoint was identified for accidental poisoning. The NOEL is 5 mg/kg based on the occurrence of myelin debris and bubbles in peripheral nerves of two females in the high dose group of the acute neurotoxicity study and supporting information from the subchronic neurotoxicity test.

### **b. Short and Intermediate Term Occupational Endpoints**

No short- or intermediate-term dermal or inhalation endpoints were identified for zinc phosphide; therefore this risk assessment is not required.

### **c. Chronic Occupational/Residential (Non-Cancer) Endpoints**

No chronic occupational endpoints were identified; therefore, this risk assessment is not required.

#### d. Reference Dose

A chronic dietary reference dose (RfD) was established for zinc phosphide at 0.0001 mg/kg/day, based on the NOEL of 0.1 mg/kg/day in the subchronic oral toxicity study in rats. The LEL in this study is 1.0 mg/kg/day, based on increased mortality and kidney hydronephrosis. The RfD includes an uncertainty factor of 100 to account for the interspecies extrapolation and intraspecies variability. The RfD also includes an additional uncertainty factor of 10 to account for the extrapolation from subchronic to chronic exposure, the lack of reproductive toxicity data, and the lack of chronic toxicity data in a non-rodent species. This second uncertainty factor will also accommodate the inability to assess the potential for increased sensitivity of infants and children due to the lack of sufficient animal data on *in utero* and early postnatal exposure to zinc phosphide.

The Agency has determined that a chronic dietary risk assessment is not required because dietary residues are expected to be minimal. Zinc phosphide has not been reviewed by the FAO/WHO Joint Committee Meeting on Pesticide Residue (JMPR) and no acceptable daily intake (ADI) has been established by that Committee.

#### e. Carcinogenic Classification

The requirement for carcinogenicity studies has been waived for zinc phosphide because chronic exposure is expected to be negligible.

### 3. Dietary Exposure, Risk Assessment and Characterization

#### a. Dietary Exposure from Food Sources

##### GLN 860.1200: Directions for Use

The reregistration of zinc phosphide in the United States is being supported by the Zinc Phosphide Consortium (ZPC). For the purposes of reregistration, the ZPC has provided the Agency with a summary of food and non-food uses it seeks to support, and current labels and proposed label changes. The ZPC has indicated that they will support the following crop uses: artichokes, grapes, grasses (rangeland), sugar beets, and sugarcane. The ZPC also supports many crop uses that have been designated as non-food. These designations are based on labeling requirements and application methods. For the purposes of reregistration, the Agency has evaluated the available residue chemistry database to support the use patterns classified as food uses. For the reregistration of end-use products, labeling must bear the corresponding restrictions, rates and methods as specified for the food and non-food designations.

*Determination of food versus non-food uses:* According to OPPTS GLN 860.1000, the application of a rodenticide as a bait around the borders of cropland or in a tamper-resistant bait box within cropland is considered a non-food use while application of the bait directly to the crop is considered a food use. Specific examples of food vs. non-food use determinations have been summarized by the Agency in connection with registrations for the rodenticides sodium fluoroacetate and strychnine.

EPA considers the following to be food uses: (I) any aerial applications where food or feed crops or livestock are present; (ii) broadcast and above-ground spot baiting on pastures or rangeland; (iii) broadcast applications to food or feed crops; (iv) applications in livestock areas; and (v) broadcast applications to ditch banks.

EPA considers the following to be non-food uses: (I) underground applications; (ii) applications to buffer zones (perimeters of a field) where grazing can be restricted; (iii) orchard uses where the bait is placed on the ground (with appropriate grazing restrictions); (iv) applications to bare ground around animal burrow entrances, dens, tunnels, and animal nests; (v) spot baiting applications to ditch banks; (vi) applications on non-crop land and in non-agricultural areas where no livestock are present; and (vii) baitbox applications and applications in V-shaped above-ground troughs.

*Non-food uses of zinc phosphide:* The Agency has determined that the use of zinc phosphide at the following sites should be classified as non-food use, based on examination of the registered and proposed use patterns: alfalfa (including alfalfa grown for seed), barley, berry production areas, bulbs, corn (no-till), oats, orchards and groves (including macadamia nut and sugar maple orchards), timothy, wheat, and buildings (including outside buildings). The justifications for classifying uses on these crops as non-food uses are presented in Table 4. Although no residue chemistry data are required for reregistration of the non-food uses, label amendments are required to support the non-food use classification of uses on orchards and buildings.

<b>Current Zinc Phosphide Non-Food Uses Sites (no tolerances required)</b>	
<b>Site</b>	<b>Basis for Non-Food Designation</b>
Alfalfa (seed crop)	Applied only underground or in burrow builder.
Alfalfa	Applied only underground, in bait stations, or in burrow builder
Barley, Oats, Wheat	Applied only underground or in burrow builder. Dormant season use only.
Berry Production Areas	Applied only underground, in bait stations, or in burrow builder. Applied in fair weather after harvest while crop is in a nonbearing phase.
Bulbs	Can not be applied in gardens or areas where food or feed may be contaminated.
Corn, no-till	For pre-plant or at-plant application only. May not be applied to areas inhabited by livestock. Animals may not be grazed in treated areas.
Macadamia nut orchards	Bait applied only by broadcast or in burrow builder. Animals can not be grazed in treated areas and bait must be removed from trees prior to harvest. May not be broadcasted over growing crop when bait may lodge in plant.
Maple, sugar	Application is made only in bait stations. Stations must be placed so that the bait will not come in contact with the harvested commodity or tubing that harvests commodity.
Orchards/groves	Is only applied after harvest or any time during the dormant season. Can not be broadcasted over growing crops or bare ground and animals may not be grazed in treated areas.
Timothy	Is applied only during crop dormancy and not over growing crops. Animals may not be grazed in treated areas.



Current Zinc Phosphide Non-Food Uses Sites (no tolerances required)	
Site	Basis for Non-Food Designation
Buildings	The use directions must restrict the use in food/feed handling establishments as specified in Section V.

*Food uses of zinc phosphide:* The Agency has determined that application of zinc phosphide on artichokes (globe), grapes, grasses grown in pastures and rangelands, sugar beets and sugarcane should be classified as food uses based on established policy, as outlined in OPPTS GLN 860.1000 and noted above. The Agency required crop field trials for these food uses and detectable residues were found on grasses, sugar beets and sugarcane. No detectable residues were found on artichokes or grapes. Tolerances were established for all of these crops based on their designation as a food crop, as is Agency policy. The tolerances were set on the actual detected residues or based on the limit of detection.

A label amendment is required to support the use of zinc phosphide on grasses. Although zinc phosphide is not currently registered for use on artichokes (globe), the Zinc Phosphide Consortium has indicated that they wish to reinstate this use and retain the established regional tolerance for artichokes. The use of zinc phosphide on artichokes (globe) may be reinstated provided the application method is restricted to satisfy the requirements for a non-food use site.

Although several time-limited tolerances are in place to allow for emergency exemption (or section 18) applications of zinc phosphide on several crops, these crops were not included in the risk assessment as the corresponding residues are expected to be negligible.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for additional plant metabolism data are waived based on a zinc phosphide radiotracer study which demonstrated that sugarcane will absorb and translocate [<sup>32</sup>P] phosphine, but not as phosphine *per se*. The <sup>32</sup>P was shown to be thermally stable and non-volatile, and was assumed to be translocated through plants as phosphate. Based on this radiotracer study, the Agency has determined that the residue of concern is the unreacted zinc phosphide, measured as phosphine. The current tolerance expression for plants is appropriate and no changes are required.

GLN 860.1300: Nature of the Residue - Livestock

The reregistration requirements for animal metabolism data are waived. The Agency does not expect secondary residues in meat, milk, poultry, and eggs. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorous compounds.

GLN 860.1340: Residue Analytical Methods

The reregistration requirements for residue analytical methods are fulfilled. Acceptable methods are available for enforcement and data collection purposes for plant commodities. The Pesticide Analytical Manual

(PAM) Vol. II lists, under aluminum phosphide, a colorimetric method and a GLC method with flame photometric detection as Methods A and B, respectively, for the enforcement of tolerances. Both methods determine the level of phosphine liberated when zinc phosphide is exposed to dilute acid solutions. Method A remains a lettered method because of variable recoveries observed in an Agency method try-out, however, the method has been determined to be acceptable for enforcement because phosphine gas is highly reactive and finite residues are not expected. Data submitted in support of the established tolerances were collected by one of these two methods.

#### GLN 860.1360: Multiresidue Methods

Because zinc phosphide is an inorganic compound, recovery of residues using FDA Multiresidue Protocols is not expected and the requirement for such data is waived.

#### GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are partially fulfilled. Adequate storage stability data have been submitted to support frozen storage of sugar beet and alfalfa samples for 6 months; these data may be translated to grass forage and sugarcane. Adequate storage stability data have also been submitted to support storage of artichokes for 16 months.

To fully satisfy reregistration requirements, the registrant(s) must provide information concerning the length and conditions of sample storage for grapes, rangeland grass forage, and sugarcane; dates of harvest and analysis are also required for sugarcane. If samples were stored for longer than 30 days (grapes) or 6 months (grass forage and sugarcane) prior to analysis, then additional crop field trial data will be required.

#### GLN 860.1460: Food-Handling

The reregistration requirements for magnitude of the residue in food-handling establishments will be considered fulfilled pending appropriate label revisions in order to reinforce the non-food use classification on/in buildings. The use directions on some tracking powder labels are not sufficiently restrictive to preclude the need for residue data on food-handling establishments. Please see Section V (Actions Required of Registrants) for exact labeling language.

#### GLN 860.1480: Meat, Milk, Poultry, and Eggs

The reregistration requirements for data on magnitude of the residue in animals are waived. There is no reasonable expectation of residues in meat, milk, poultry, or eggs [Category 3 of 40 CFR §180.6(a)]. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds.



#### GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on grapes, grasses, and sugarcane will be considered fulfilled pending resolution of storage stability issues. The available field trial data for these raw agricultural commodities (RACs) have been reevaluated for purposes of tolerance reassessment. Overall, acceptable field trials reflecting the maximum registered use patterns and conditions under which the pesticide could be applied were conducted. The geographic representation for each commodity is generally adequate, and a sufficient number of trials reflecting representative formulation classes was conducted. Refer to "Tolerance Reassessment Summary" section for recommendations with respect to established tolerance levels.

Adequate field trial data are available to support the reinstatement of zinc phosphide use on artichokes (globe) and sugar beets. If the registrant(s) wishes to retain the tolerances with regional registration established for sugar beet tops, and sugar beet root, then they must propose use directions reflecting the use patterns for which adequate residue data from the original tolerance petitions are available.

#### GLN 860.1850: Confined Accumulation in Rotational Crops

Data for confined accumulation in rotational crops has been waived because the physical properties of zinc phosphide precludes transfer of residues to rotated crops.

#### GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in sugarcane processed commodities are fulfilled. A processing study showed no concentration of residues in the processed fractions. Tolerances for sugarcane processed fractions are not required.

No processing data are needed for grapes, provided the field trial samples were analyzed within 30 days of sample collection.

The data requirements for a sugar beet processing study has been waived. The Agency believes that the refining process of sugar beets will remove any unreacted zinc phosphide from refined sugar.

#### **b. Dietary Exposure from Drinking Water**

Zinc phosphide degrades rapidly to phosphine ( $\text{PH}_3$ ) and zinc ions ( $\text{Zn}^{2+}$ ), both of which sorb strongly to soil and are common nutrients in soil. Zinc phosphide and its degradation products appear to have a low potential for ground and surface water contamination. Therefore, dietary exposure is not expected from either ground or surface water fed drinking water.

### c. Dietary Risk Assessment and Characterization

The food crop uses which are being supported for reregistration are grapes, grasses (rangeland), sugarcane, globe artichokes, and sugar beet (roots and tops). These uses have all been designated as food uses, based on the application methods and OPPTS policy GLN 180.1000, and have tolerances.

There were no detectable residues of zinc phosphide in grape and artichoke samples following application of zinc phosphide as bait by hand application (globe artichokes) or to the ground by a spreader (grapes).

Residue studies show there were quantifiable residues in sugarcane, sugar beets, and grasses. Since these crops are not direct human foods, no acute dietary consumption is expected. Also, there is no likelihood of residues of zinc phosphide or phosphine being found through transfer of residues on grasses to meat and milk. The Agency has determined that there is no likelihood of residues of zinc phosphide occurring in any processed commodities.

## 4. Occupational and Residential Exposure, Risk Assessment and Characterization

### a. Occupational and Residential Exposure

At this time, some products containing zinc phosphide are intended primarily for occupational use and some are intended primarily for homeowner use.

#### (1) Handler Exposures and Assumptions

Based on the use patterns and potential exposures described above, several exposure scenarios were identified for occupational and/or homeowner handlers of zinc phosphide: (1) mixing the dry concentrate into wet bait, (2) loading dry bait (granular/pellet) formulation to support aerial and ground equipment applications, (3) applying the wet and dry baits by hand (spoon) as spot treatments, (4) applying tracking powders by hand, (5) applying tracking powders using hand-bulb and bellows-type dusters, (6) applying dry baits by hand as broadcast treatments, (7) applying dry baits with hand-held mechanical baiting device, (8) applying dry baits with cyclone and end-gate seeders, tractor-drawn granular spreaders, and other ground-driven bait dispensing devices, (9) applying dry baits with fixed- or rotary-wing aircraft, (10) applying dry baits with whirly-bird spreaders, (11) applying dry baits with push-type spreader, and (12) flagging for aerial applications.

Although the Agency has not identified any endpoints of concern from which to perform a handler exposure and risk assessment, it is concerned for inhalation exposure of occupational workers to the particulate fines or dust that may be generated from the mixing and loading of the dust-concentrate or wettable-powder formulations and from applying the pellet and bait formulations. The Agency is confident that current labeling restrictions, when combined with those required by this document, are adequate and will require these formulation specific protections for all appropriate products.

#### (2) Post-Applications Exposure and Assumptions

Residential: There is the possibility of post-application exposures, if (1) baits or tracking powders applied indoors are not placed out of reach of children and pets or are not placed in tamper-resistant bait stations, as specified in labeling; (2) baits applied outdoors are not applied underground and deep enough to prevent children and pets from finding and eating the baits; (3) baits are available to homeowners in packages which are not tamper resistant and could be accessible to children or pets prior to application; and (4) baits resemble food (e.g., peanuts), are brightly colored, or are packaged in a way in which they could be appealing to children or mistaken by children for food or candy.

Occupational: The Agency has determined that there is potential for post-application exposure to zinc phosphide in occupational settings, such as workers reentering areas following all of the above-ground applications.

#### **b. Occupational and Residential Risk Assessment/Characterization**

There were no endpoints identified for use in an occupational or residential risk assessments except for accidental ingestion of a bait, however, the Agency has identified several occupational scenarios where inhalation of particulates and/or dusts may occur. In order to minimize these occurrences, the Agency is adopting labeling requirements for several formulations. See Section V for specific labeling requirements.

##### (1) Risk from Post-Application Exposures

Occupational: Because no toxicological endpoints were identified for occupational exposures, a risk assessment was not performed.

Residential: The Agency has performed a risk assessment based on the possibility of accidental ingestion of zinc phosphide. This assessment estimates that a 10 kg child could consume 5 grams of product in one swallow. This provides for an estimated dose of 500 mg/kg. A two percent bait would then result in a dose of 10 mg/kg of active ingredient. For zinc phosphide, a NOEL for accidental ingestion has been set at 5.0 mg/kg. This results in a margin of exposure (MOE) of 0.5. Generally, the Agency considers MOE's of less than 100 as posing an unacceptable risk.

##### Restricted Entry Intervals

There are currently no restricted entry intervals for any zinc phosphide products and the Agency is not requiring any at this time.

##### Incident Reports

The American Association of Poison Control Centers reported a total of 106 exposures to zinc phosphide in 1996. Six of these cases were suicide attempts. Approximately 80% of exposures occurred in residences and 62% of all cases involved children younger than 6 years of age. Ingestion was reported as the route of exposure in 60.5% of these cases inhalation 18.4%, dermal 14%, ocular 2.6% and unknown in the remaining

3.5%. Excluding the suicide attempts, 13% reported symptoms that were considered potentially related to their exposure when they first contacted the Poison Control Center.

The Agency also consulted four incident databases and searched available literature. The OPP Incident Data System reports incidents submitted to the Agency since 1992 from various sources, including: registrants, other federal and state health and environmental agencies and individual consumers. The California Environmental Protection Agency (formerly the California Department of Food and Agriculture) has collected uniform data on suspected pesticide poisonings since 1982. In California, physicians are required to report all occurrences of illness suspected to be related to pesticide exposure; the majority of these occurrences involve occupational workers. The National Pesticide Telecommunications Network (NPTN) is a toll-free information service supported by OPP that includes incident reporting.

The limited information on human incidents is difficult to interpret. Many cases have been documented by the WHO, all prior to 1967. The high dosage associated with all of these cases (ten were fatal, ten non-fatal) would seem to indicate suicide or suicide attempts. The animal incidents identified by the databases are predominantly due to misuse or accidental exposure, with many of the exposures resulting in the death of the exposed animal.

On the list of the highest 200 chemicals for which NPTN received calls from 1984-1991, zinc phosphide was reported to be involved in 16 human incidents and nine animal incidents. Zinc phosphide ranked 165th in a ranking of 200 chemicals by the number of calls received.

Incident data from Poison Control Centers was collected for 1989 and compared to the number of containers in U.S. homes in 1990. Of 83 compounds examined, zinc phosphide ranked 21st for number of exposures per million containers in homes, which was not unexpected for a bait product. None of the top ten compounds were rodenticide baits. For the 12 zinc phosphide cases where the exact product name was provided and an outcome determined, 2 cases reported minor and 1 case reported moderate effects. There were no major life threatening cases. No childhood deaths have been reported due to zinc phosphide since 1983 when the Poison Centers began systematic data collection.

#### Other Rodenticide Incidents

Data collected by the American Association of Poison Control Centers (AAPCC) for 1995 show 17,187 human exposures to all rodenticides. Of concern to EPA is the number of exposures to children younger than six years-old; in 1995, these totaled 14,900 or approximately 87% of all exposures. Of the total number of human exposures to rodenticides, almost 6500 were significant enough to result in treatment at a health care facility. Even though these reports do not identify zinc phosphide *per se* and most of the incidents are reported to have occurred with anticoagulant rodenticides, the Agency is concerned about the use pattern. The Agency would anticipate higher incidences of zinc phosphide poisoning if it were more widely used in residential settings.

Data collected by the AAPCC for 1996 indicate that 17,601 exposures occurred to humans. Of these exposures, over 13,000 occurred in children younger than six years of age. Approximately 5,300 exposures resulted in people seeking treatment at a health care facility.

## 5. Food Quality Protection Act Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFCDA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(c) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have common mechanisms of toxicity. EPA does not believe “accidental ingestion” of baits should be included in the FQPA determination for tolerance setting.

The FQPA amendments to section 408(b)(2)(C) require the EPA to apply an additional 10-fold uncertainty factor (safety) unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) established factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources, including drinking water, as well as non-occupational exposures such as those derived from pesticides uses in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity.

### a. Potential Risks to Infants and Children

In determining whether an additional uncertainty factor is or is not appropriate for assessing risks to infants and children, EPA considers all reliable data and makes a decision using a weight-of-evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

Under the directive of the Food Quality Protection Act (FQPA) recently enacted as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency determined the following:

- 1) The toxicology data base, though adequate for the registration of a non-food use chemical, did not include a two-generation reproductive toxicity study in rats or a developmental toxicity study for a non-rodent species.
- 2) The data provided no indication of increased sensitivity of fetal rats to *in utero* exposure to zinc phosphide. In the prenatal exposure developmental toxicity study in rats, no developmental effects were observed at the highest dose tested (4.0 mg/kg/day) which was shown to be maternally toxic (maternal

deaths, decreased body weight and food consumption during treatment). There was no assessment of *in utero* exposure to non-rodents (rabbits), nor was there an assessment of early postnatal exposure.

The Agency is not requiring these studies because exposure from food sources is expected to be minimal to non-existent. However, an additional uncertainty factor of 10 was applied to the Reference Dose calculation to account for the extrapolation from subchronic to chronic exposure, the lack of reproductive toxicity data, and the lack of chronic toxicity data in a non-rodent species. This additional uncertainty factor will also accommodate the inability to assess the potential for increased sensitivity of infants and children, because of the lack of sufficient animal data on *in utero* and early postnatal exposure to zinc phosphide (a prenatal developmental toxicity study in rabbits and a two generation reproductive toxicity study in rats).

Although residue studies show there were quantifiable residues in sugarcane, sugar beets, and grasses; these commodities are not direct human foods and no dietary consumption is expected. Also, there is no likelihood of residues of zinc phosphide or phosphine being found through transfer of residues on grasses to meat and milk. The Agency has determined that there is no likelihood of residues of zinc phosphide occurring in any processed commodities.

#### **b. Aggregate Exposure**

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and other exposure for which there is reliable information. These other exposures may include drinking water and non-occupational exposure, such as from pesticides used in and around the home, but do not include accidental ingestion.

The Agency also believes that in aggregating exposures it is appropriate to include exposures from other chemicals, metabolites, degradates that are the same as the substance of toxic concern. For example, if chemical A and chemical B both produce the same metabolite of concern, C, then a risk assessment aggregating all exposures to metabolite C will be conducted. As noted earlier, the compound of toxic concern with zinc phosphide is phosphine. Two fumigants, aluminum and magnesium phosphide, also act by generating phosphine. Tolerances for all three pesticides are expressed in terms of phosphine which would suggest that an aggregate exposure/risk assessment for phosphine is appropriate. However, the Agency did not aggregate exposures of phosphine from the diet, drinking water or residential uses of zinc phosphide because the likelihood of exposure is so low. Actual residues of phosphine were only found in rangeland grasses, sugar beets and sugarcane. None of these commodities are consumed directly by humans. There is no expectation of the transfer of phosphine residues to meat and milk as any phosphine residues would be metabolized to naturally occurring phosphorous compounds and processing of sugarcane and sugar beets would remove any zinc phosphide/phosphine residues.

An aggregate exposure assessment for the various possible sources of phosphine from the uses of zinc phosphide is not warranted, because as discussed above, the likelihood of exposure is so low/unlikely. The Agency has not yet evaluated exposures from the use of aluminum and magnesium phosphide. However, when it conducts a tolerance reassessment for aluminum and magnesium phosphide, the Agency will only aggregate exposures from those uses as the zinc phosphide uses will have no effect on the aggregate exposure as



discussed above. Consequently, if a reasonable certainty of no harm finding cannot be made, action will be taken only on the aluminum and/or magnesium phosphide tolerances, not the zinc tolerances. For the purposes of this decision, all zinc phosphide tolerances are assumed to be reassessed.

### c. Cumulative Risk

Section 408(b)(2)(d)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanisms of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanisms of toxicity with any other substances, EPA does not at this time have the methodologies to resolves the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanism increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Zinc phosphide, aluminum phosphide and magnesium phosphide all generate phosphine gas. The Agency believes the generation of phosphine should be considered as part of its aggregate assessment. Other chemicals may share a common mode of toxicity with phosphine gas. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. However, with respect to zinc phosphide tolerance reassessment, any future cumulative risk determination regarding other chemicals that have a common mode of toxicity with phosphine will not include the uses of zinc phosphide discussed in this document because the exposures to phosphine from zinc phosphide are so unlikely.

### C. Environmental Assessment

The environmental fate and effects database on zinc phosphide is adequate and will support reregistration eligibility. Since contamination of the aquatic environment is likely from broadcast bait applications by either air or ground, additional toxicity data for aquatic organisms is required. To support broadcast applications, the following ecological effects studies are required:

72-1a	Acute Fish Toxicity (bluegill sunfish)
72-1c	Acute Fish Toxicity (rainbow trout)
72-2	Acute Aquatic Invertebrate Toxicity

Additionally, the Zinc Phosphide Consortium must consult with EPA prior to initiating these studies to ensure agreement on the appropriate test material and test protocols. These data are necessary to adequately evaluate the risk of zinc phosphide to aquatic organisms.

## 1. Environmental Fate

The environmental fate assessment for zinc phosphide is based on a review of data available in the open literature. The Agency reviewed these data and considers the studies submitted by USDA/APHIS (MRIDs 43466302 and 43466303) adequate to define the environmental fate and transport of zinc phosphide for its current uses. The hydrolysis requirement was previously fulfilled (MRID 00068028). No additional environmental fate data are required at this time.

### a. Environmental Chemistry, Fate and Transport

#### (1) Degradation

**Hydrolysis (161-1):** Hydrolysis is reported to be the major route of dissipation, resulting in the formation of volatile phosphine and zinc ions. The rate of hydrolysis is believed to be pH dependent, with the fastest degradation rate occurring in acid solutions. The rate of hydrolysis of the degradation product, phosphine, appears to be pH and soil moisture dependent, with the rate increasing as the pH increases or decreases from neutrality.

**Photodegradation in Water (161-2):** Since data indicate that zinc phosphide has no chromophoric groups, it is expected to degrade by hydrolysis prior to photolysis. Therefore, photolysis is not expected to be a route of dissipation for zinc phosphide.

**Photodegradation on Soil (161-3):** The data indicate that zinc phosphide does not degrade by photolysis before degrading by hydrolysis, however, zinc phosphide in bait formulations appears to decompose slowly when exposed to either ambient soil moisture or dried soil. Bait formulations exhibited only 12 to 39% reduction of parent material due to climatic conditions during exposure periods of 21 to 27 days. It is likely that hydrolysis was the principal decomposition mechanism and that the sluggish decomposition rate was due to protection of zinc phosphide by formulation additives and packaging. In addition, experiments conducted with UV-C light wavelengths show  $\text{PH}_3$  photolysis produces phosphates under oxygen-enriched conditions or hydrogen and  $\text{PH}_2$  or  $\text{PH}^{2-}$  radicals under oxygen-deprived conditions. Soil photolysis, such as that occurring through photo-sensitized hydrolysis, is expected to be minor compared to the extensive hydrolysis that occurs in wet soil without exposure to light.

#### (2) Metabolism

**Aerobic Soil Metabolism (162-1):** The data indicate that zinc phosphide at high concentrations may effect the viability of soil organisms, such as soil algae. Soil organisms should be able to utilize the decomposition products of zinc phosphide at the registered application rates, since they are essential



micronutrients for plant life. In addition, the data indicate that parent zinc phosphide at low concentrations is either relatively stable to aerobic soil metabolism or hydrolyzes before any biotic processes occur.

**Anaerobic Soil Metabolism (162-3):** Although microbiological-mediated processes cannot be eliminated in the decomposition of zinc phosphide, no potential mechanism has been proposed. Zinc phosphide degrades by hydrolysis, but appears to be pH (degrading under acid and alkaline pHs) and temperature dependent. Since zinc phosphide is relatively stable at pH 7, it may not readily decompose in fresh or sea water. Degradation in neutral water is believed to be mainly by sediment decomposition. Therefore, zinc phosphide appears to degrade under anaerobic conditions in the presence of moisture, without requiring microorganisms assistance. Furthermore, phosphine does not appear to be toxic (absorbed) in the absence of oxygen.

**Aerobic Aquatic Metabolism (162-4):** Additional data indicated that no discernible residues, including phosphine, were present seven days after aerial broadcast of 2% bait. Data also showed that zinc phosphide baits (1.4% to 3.8%) degraded slowly when submerged in an unknown water for 4 to 10 days ( $\approx 20\%$  decline in 10 days).

### (3) Mobility

**Leaching/adsorption/desorption (163-1):** No data exist on the sorption of parent zinc phosphide, but it is considered relatively non-mobile. In moist soils, zinc phosphide rapidly degrades to phosphine ( $\text{PH}_3$ ) which sorbs to soil and oxidizes to phosphate ions and phosphorus. The sorption of the degradation products appears to increase with temperature, however, sorption of degradation products may not be pH dependent. On dried soil zinc phosphide appears to be moderately persistent (half-lives may be greater than 1 month). Since moisture rapidly degrades zinc phosphide, mobility on dried soil has not been addressed. In addition, based on the degradation processes in aqueous conditions, zinc phosphide is expected to have a low potential for remaining in soil and water environments to cause ground or surface water contamination or creating bioaccumulation hazards.

**Volatility-Lab (163-2):** The data indicate that in moist soils zinc phosphide degrades to a volatile product, phosphine (maximum concentration 32% of applied). The rate of volatility appears to be dependent on soil moisture and the pH of the system. Appreciable amounts of phosphine were shown to evolve from moist, acidic or basic soils, however, phosphine concentrations from bait use on dried soils or neutral waters appear negligible and are liberated too slowly to be discernible. Under normal use conditions bait formulations may be moderately persistent. Most of the phosphine released during incubation may be reabsorbed and oxidized to the ions.

**Terrestrial field dissipation (164-1):** The field data appear to confirm the laboratory data. Zinc phosphide was reported to dissipate with half-lives of one month or longer in dry soils, which may cause the bait formulations to be moderately persistent under some environmental conditions. In moist soils, zinc phosphide was reported to dissipate with half-lives of less than 1 week. Data indicate that the application rate will generally be low enough that residues will not be detectable in plants or soil after a period of time ( $\approx 1$  to 2

weeks). In addition, the phosphate and zinc ion decomposition products in soil may be utilized by plants as elemental zinc or phosphorus.

**Aquatic field dissipation (164-2):** Zinc phosphide was determined to hydrolyze in aquatic systems. Hydrolysis results in the liberation of phosphine (at most  $\approx 32\%$  of applied) and the release of zinc ions, which may partially convert to zinc phosphate, in suspended or bottom sediments. The rate of dissipation appears to depend on the pH of the aquatic systems. Decomposition of zinc phosphide was reported to increase as the pH strayed from neutrality (from no detection to  $\approx 32\%$  of applied as phosphine). Zinc phosphide was shown to be relatively stable (half-life may be longer than a month in bait formulation) in neutral aquatic systems.

## **b. Environmental Fate Assessment**

The environmental fate assessment is based on the review of available literature and is not supported by guideline studies. The major route of degradation/dissipation of zinc phosphide is hydrolysis, which results in the formation of volatile phosphine and zinc ions. Zinc phosphide and its residues appear to be non-persistent under most environmental conditions and relatively immobile (zinc ions and dissolved phosphorus readily sorb onto soil) in laboratory and field data. When applied to dry soil environments, zinc phosphide may be moderately persistent ( $\approx 40\%$  of applied remaining at 30 days post-treatment). The rates of hydrolysis and volatilization of phosphine appear to be pH and soil moisture dependent with the hydrolysis rate increasing as the pH increases or decreases from neutrality. There are limited data available on the metabolism (microbial mediated processes) of zinc phosphide. It is believed that zinc phosphide hydrolyzes prior to biotic metabolism, however, a potential metabolism process has not been described. It has been noted that in the presence of oxygen, soil organisms appear to utilize the decomposition products when present at low concentrations. Zinc phosphide degrades rapidly to  $Zn^{2+}$  and  $PH_3$ , which sorb strongly to soil and are common nutrients in soil. Zinc phosphide and its degradation products appear to have a low potential for ground water or surface water contamination.

## **2. Ecological Effects**

### **a. Toxicity to Terrestrial Animals**

#### **(1) Birds, Acute and Subacute**

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of zinc phosphide to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below.

Avian Acute Oral Toxicity				
Species	% AI	LD <sub>50</sub> mg/kg	Toxicity Category	MRID
Northern bobwhite quail ( <i>Colinus virginianus</i> )	TGAI	12.9 (12.0-13.9)	High	00006032
Mallard duck ( <i>Anas platyrhynchos</i> )	TGAI	67.4 (56.3-80.9)	Moderate	00006033

Since the LD<sub>50</sub> falls in the range of 12.0 to 13.9 mg/kg, zinc phosphide is Highly Toxic to avian species (Bobwhite quail) on an acute oral basis. The guideline (71-1) is fulfilled. (MRIDs 00006032 and 00006033)

Two subacute dietary studies using the TGAI are required to establish the toxicity of zinc phosphide to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Avian Subacute Dietary Toxicity				
Species	% AI	5-Day LC <sub>50</sub> (ppm)*	Toxicity Category	MRID
Northern bobwhite quail ( <i>Colinus virginianus</i> )	TGAI	469 (356 - 546)	High	00006031
Mallard duck ( <i>Anas platyrhynchos</i> )	TGAI	2885 (1970 - 4329)	Slight	00006025

\* Test organisms observed an additional three days while on untreated feed.

Zinc phosphide, especially at higher doses, repels and has an emetic effect on birds. Mallards are particularly susceptible, indicating that the actual LC<sub>50</sub>s are probably lower than those recorded under laboratory conditions. Since the LC<sub>50</sub> for Bobwhite quail is 468.5 ppm, zinc phosphide is considered to be highly toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled. (MRID 00006025)

## (2) Birds, Chronic

Avian reproduction studies for a chemical are required when any of the following conditions are met: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed, (3) the pesticide is stored or accumulates in plant or animal tissues, and/or, (4) information derived from mammalian reproduction studies indicates reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the product. The preferred test species are mallard duck and bobwhite quail.

Although zinc phosphide bait will eventually degrade in the field, it may be stable under dry conditions at levels known to kill non-target animals for more than a month. Although some species of birds are exposed during their breeding season, any bird that eats the bait is expected to die from acute poisoning. Chronic effects are not expected. Avian reproduction studies are not required at this time.

**(3) Mammals, Acute and Chronic**

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values required for the Agency's human health assessment substitute for wild mammal testing. As reported earlier, zinc phosphide in laboratory rats was shown to have an LD<sub>50</sub> of 21 mg/kg, when administered by gavage. (MRID 00085366)

No studies have been submitted on the acute toxicity of zinc phosphide to wild mammals. Some LD<sub>50</sub>s reported in the literature also have been listed to aid the decision to require acute or chronic mammalian toxicity studies and to help interpret the secondary poisoning studies.

<b>Wild Mammal Toxicity*</b>			
<b>Species</b>	<b>LD<sub>50</sub> (mg/kg)</b>	<b>Species</b>	<b>LD<sub>50</sub> (mg/kg)</b>
Desert kit fox	93.0	Meadow vole	18.0
California ground squirrel	33.1	Nutria	5.55
Black-tailed prairie dog	18.0	Woodrat (LD <sub>100</sub> )	25.0
Northern pocket gopher	6.8	Black-tailed jackrabbit	8.25
Norway rat (wild)	27-40	Polynesian rat	23.0
Roof rat	2.9-40.5		

\* Prevention and Control of Wildlife Damage (Zinc Phosphide, p. G-58), Timm (ed.), 1994

The results from the above studies indicate that zinc phosphide is highly to very highly toxic to small mammals on an acute oral basis. No chronic studies have been reviewed or required. Due to the fatal nature of zinc phosphide poisonings, chronic studies are not necessary.

**(4) Terrestrial Testing**

The Zinc Phosphide Consortium is currently conducting two terrestrial field studies. One study is to determine the residues available on alfalfa following broadcast applications of a 2% bait in flood irrigated and sprinkler irrigated alfalfa fields. The other study is to determine nontarget hazards to

pheasants in alfalfa fields that have been treated with a broadcast application of 2% zinc phosphide. The testing is expected to be completed within a year.

**b. Toxicity to Freshwater Aquatic Animals**

Zinc phosphide has a very low water solubility. When water is acidic or basic, zinc phosphide disassociates rapidly and produces phosphine gas (a toxic degradate that kills the target rodents). Zinc phosphide is believed to be toxic to aquatic organisms, however, it is unclear what agent is responsible for the toxicity. Currently there are no acute or chronic aquatic toxicity data available. Due to the uncertainties, test protocols must be agreed upon before initiation of any aquatic tests.

**(1) Freshwater Fish, Acute**

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of zinc phosphide to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). No acceptable acute freshwater fish studies have been submitted. These data are now required.

**(2) Freshwater Fish, Chronic**

A freshwater fish early life-stage (guideline 72-4) test is not required at this time because the Agency does not expect chronic aquatic exposure from zinc phosphide use. Once the acute toxicity testing is performed, the Agency will determine whether chronic testing is needed. The preferred test species is rainbow trout.

**(3) Freshwater Invertebrates, Acute**

A freshwater aquatic invertebrate toxicity test (guideline 72-2) using technical grade active ingredient is required to establish the toxicity of zinc phosphide to aquatic invertebrates. The preferred test species is *Daphnia magna*. No acceptable studies have been submitted.

### 3. Exposure and Risk Characterization

#### a. Primary Exposure and Risk to Nontarget Terrestrial Animals

Primary nontarget exposure is the ingestion of a toxicant by an animal other than the target species. The following table summarizes three non-guideline studies that address exposure and risk in field uses of zinc phosphide:

Primary Non-Target Exposure and Risk to Animals		
Study Name	MRID	Conclusions
Primary and secondary hazards of zinc phosphide to nontarget wildlife	42306201	Little non-target poisoning
Nontarget hazards to ring-necked pheasants and California quail	43586602	Broadcast application killed Ring-necked pheasants, but not California quail
Hazards to Pheasant and Cottontail rabbits associated with zinc phosphide	00005918	Nontarget mortality occurred

One submitted study reviewed the literature on zinc phosphide use submitted by the Animal and Plant Health Inspection Service of USDA (APHIS). These studies covered various habitats with various zinc phosphide poisoning regimes. Some studies were specifically designed to investigate the effects of zinc phosphide usage while others reported on it as incidental to their primary purpose. Mortality of nontarget rodents during the management of prairie dog and ground squirrel colonies from zinc phosphide applications was documented. Baiting in orchards produced mortality in rabbits, gallinaceous birds, and grain-eating passerine birds. Six birds of a group of 24 found dead in a sugar cane field that was treated with zinc phosphide were found to have eaten the bait. Mortality from zinc phosphide applications also was documented for deer, chickens, upland game birds, waterfowl, and aquatic invertebrates in Hawaii. Canada geese were killed in baited alfalfa enclosures.

The general finding is that after the experimenters put down poison, very few, if any, primary nontarget victims were discovered. Any bodies found were considered to be isolated occurrences of little importance and concluded that the populations were not effected. "Because many species of rodents are associated with prairie dog and ground squirrel colonies, several instances of mortality to these species from zinc phosphide applications have been documented. Most mortality to nontarget rodents, however, has been localized and involved only a few individuals." (MRID 42306201)

In another study, 2% zinc phosphide grain bait was applied by broadcast per label directions in 2-ha enclosures. Ring-necked pheasants were killed, but California quail were not because they did not eat the poisoned grain. The study did not address nontarget hazards to voles, but implies that voles would be killed as a nontarget species if they were in the treated areas. (MRID 43586602)

A separate study baited an orchard with air and ground broadcast equipment at a rate of five to ten pounds of zinc phosphide per acre. Intensive ground searches of 672 acres from day-1 to day-159



revealed that 1 of 5 radio tracked Ring-necked pheasants was killed by zinc phosphide. Four dead rabbits, 3 Deer mice and 1 Blue jay also were found to contain zinc phosphide residues. (MRID 00005918)

Generally the experimenters in the submitted studies distributed poison but didn't find any (or very few) primary nontarget victims. They considered any bodies they found to be isolated occurrences that were of little importance and concluded that the populations were not effected. The Agency does not necessarily agree with these conclusions but will consider the findings of these studies useful in risk assessments.

The reviewed literature suggests that waterfowl and some passerines appear to be relatively sensitive to zinc phosphide. It was also reported that many birds appear capable of distinguishing treated from untreated bait, and prefer untreated grain when given a choice. The study authors suggest several factors that influence the magnitude of effects, including prior exposure to untreated bait, nutritional condition of the bird when provided treated baits, availability of alternate food sources, and ability to regurgitate treated baits.

The Agency has concluded that the studies reviewed (including supplemental and published studies) show that the use of zinc phosphide in agricultural fields will likely kill nontarget birds and mammals. Zinc phosphide is a very toxic substance and will kill most animals to which it is administered. Rodents are more sensitive than carnivores. Although gallinaceous birds (pheasants, turkeys, other large terrestrial birds) are more sensitive than other avian species, some passerines such as Red-winged blackbirds are also sensitive.

**b. Secondary Exposure/Risk to Nontarget Terrestrial Animals**

If a target animal eats the toxicant and is subsequently eaten by a predator or a scavenger, secondary poisoning may occur to the predator or scavenger. The following table summarizes studies that have been submitted to address the extent of secondary poisoning that occurs with zinc phosphide:

Secondary Exposure and Risk to Animals			
Study Name	MRID	Study Classification	Conclusions
Primary and secondary hazards of Zinc phosphide to nontarget wildlife	42306201	Supplemental	Little nontarget poisoning, no secondary poisoning
Black-tailed prairie dog - domestic ferret secondary poisoning study	41507401	Core	no secondary poisoning, residues in stomach, ferrets regurgitated poison
Responses of Siberian ferrets to secondary Zinc phosphide poisoning	00151407	Core	Non-lethal acute intoxication of Siberian ferrets

One study presents a long list of LD<sub>50</sub> and other toxicity tests done with zinc phosphide. Most of the experimenters conducted informal studies to use up excess specimens or were incidental to other studies. Although few of the LD<sub>50</sub> or LC<sub>50</sub> values are definitive, some may be useful as a guide. (MRID 42306201)

Secondary poisoning experiments have been conducted with a variety of carnivorous mammals and birds. The risk of secondary poisoning is low because zinc phosphide does not accumulate in the tissues of the target animals. The primary source of zinc phosphide to a carnivorous or scavenging animal is the digestive tract of the target animal, where unreacted zinc phosphide may remain. Most animals, when given a choice, refuse to eat the digestive tract of poisoned animals. Even if the digestive tract is eaten, the poison decomposes further in the digestive tract of the second animal. Zinc phosphide has a strong emetic action and frequently causes regurgitation. These studies concluded that, "secondary poisoning is reduced because mammalian predators appear to be less susceptible to zinc phosphide than other species."

One study reviewed studies conducted in various habitats with various zinc phosphide poisoning regimes. Some studies were specifically designed to investigate the effects of zinc phosphide usage while others report it as incidental to their primary purpose. The general finding is that the experimenters distributed poison, but uncovered few if any secondary or nontarget victims. The carcasses found were considered to be isolated occurrences and of little importance. The papers reviewed do not describe how intensively or extensively the experimenters searched for dead animals. None of the papers dealt with the mathematical reasoning behind the choice of poisoning regime, plot extent, or body search plan. (MRID 42306201)

The study comments on several reports of incidents involving zinc phosphide. However, the study authors could not prove that zinc phosphide was responsible for the kill, whether the kill was due to misuse or following outdated label instructions. "Many cases of secondary poisoning have involved cats and dogs, possibly because these species have been noted to consume stomach contents of poisoned animals in laboratory studies, whereas wild carnivores tend to avoid consuming the GI tract."

Matschke and Andrews (1990) found that: (1) No poisoning symptoms were observed in the ferrets that were fed the prairie dogs; (2) 96% of the zinc phosphide residues in the rodents were found in the stomach; (3) the ferrets regurgitated gavaged zinc phosphide; therefore, a good LD<sub>50</sub> was not (and probably cannot) be determined. "The low amounts of zinc phosphide remaining in the carcasses and the absence of mortality, poisoning symptoms or emesis, in spite of the emetic properties of zinc phosphide, suggest that the risk of secondary poisoning from zinc phosphide is low." (MRID 41507401)

Hill and Carpenter's (1982) study demonstrated evidence of acute intoxication of Siberian ferrets fed zinc phosphide-poisoned rats. Overt evidence of acute intoxication was emesis by the ferrets. Subacute zinc phosphide toxicity in the ferrets was indicated by significant decreases in hemoglobin, cholesterol, and triglycerides. The study demonstrates that ferrets, or other species with a sensitive



emetic reflex, may be afforded some degree of protection from secondary acute zinc phosphide poisoning due to its emetic action. However, the study also clearly demonstrates the potential for secondary exposure of nontarget animals to zinc phosphide. The study provides no data indicative of zinc phosphide residues to which predators and scavengers may be secondarily exposed, nor does it provide an indication of the relative sensitivity of Siberian ferrets to zinc phosphide poisoning. (MRID 00151407)

The Agency concludes that predators or scavengers who eat a target animal that has been killed by zinc phosphide will not be killed. They may become ill, listless, and regurgitate. Further studies on secondary poisoning are not necessary.

**c. Exposure and Risk to Nontarget Freshwater Animals**

The Agency presumes that aquatic exposure may occur from aerial and ground broadcasting of zinc phosphide baits, however, risk cannot be assessed until acceptable toxicity data are submitted. No presumption of risk to aquatic organisms is made for hand-placed applications, because minimal exposure of aquatic organisms is expected when baits are placed by hand.

**d. Endangered Species Concerns**

Zinc phosphide was addressed in the "U.S. Fish and Wildlife Service Biological Opinion March, 1993" document. That Opinion is based on zinc phosphide's use for control of rodents in/on orchards, rangeland, forests, vineyards, sugarcane, macadamia nuts, agricultural crops, ornamentals, lawns, golf courses, recreational areas, rights-of-way, animal burrows, and in and around all types of buildings. The Service made a "jeopardy" determination for 35 species that were determined to be potentially exposed from these uses. Of these 35 species, 29 (20 mammalian, 9 avian) were determined to be in a "jeopardy" status. Other species were considered either not at risk of exposure or not likely to be affected. See Section IV for a description of the Agency's Endangered Species Program policy.

**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 zinc phosphide as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing zinc phosphide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of zinc phosphide, 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 zinc phosphide and to determine that zinc phosphide, labeled and used as specified in this document, can be used without resulting in unreasonable adverse effects to humans and the environment. Therefore, the Agency finds that products containing zinc phosphide 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, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of zinc phosphide 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 zinc phosphide, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

## **B. Determination of Eligibility Decision**

### **1. Eligibility Decision**

Based on the reviews of the generic data for the active ingredient zinc phosphide, the Agency has sufficient information on the health effects of zinc phosphide and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that zinc phosphide products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that all products containing zinc phosphide are eligible for reregistration.

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

The Agency has determined that all uses of zinc phosphide, as specified in this document, are eligible for reregistration. These uses include: indoor and outdoor residential and agricultural areas (including in and around homes, lawns, bulbs, in and around outside buildings/barns, rights-of-ways/fencerows/hedgerows), indoor and outdoor commercial or institutional premises and equipment, golf courses, reforestation areas. The following crop uses are eligible and are regarded as non-food uses because the application method and other label restrictions do not result in residues: alfalfa, barley, berries (dormant), oats, sugar maple, wheat, no-till corn, macadamia nut orchards, orchards/groves (post-harvest and dormant), timothy (hay). Food uses for zinc phosphide include: grapes, rangeland grasses and sugarcane. Artichokes and sugar beets have regional tolerances for use in California; currently there are no labels that include use on artichokes.

## **C. Regulatory Position**

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

## **1. Food Quality Protection Act Findings**

### **a. Determination of Safety for U.S. Population**

EPA has determined that the established tolerances for zinc phosphide, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water.

For zinc phosphide, there is little likelihood of residues in water, on food items or processed food items and non-accidental residential exposure will be minimal. Therefore, no acute or chronic dietary, or drinking water, risk assessments were conducted and aggregate risk assessments are not necessary for zinc phosphide at this time.

Zinc phosphide, aluminum phosphide and magnesium phosphide all generate phosphine gas. The Agency believes the generation of phosphine should be considered as part of its aggregate assessment. Other chemicals may share a common mode of toxicity with phosphine gas. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. However, with respect to zinc phosphide tolerance reassessment, any future cumulative risk determination regarding other chemicals that have a common mode of toxicity with phosphine will not include the uses of zinc phosphide discussed in this document because the exposures to phosphine from zinc phosphide are so unlikely. For the purposes of this decision, all zinc phosphide tolerances are assumed to be reassessed.

### **b. Determination of Safety for Infants and Children**

EPA has determined that the established tolerances for zinc phosphide, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of zinc phosphide residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from zinc phosphide residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature and severity of the effects observed, and other information.

The toxicology data base, though adequate for the registration of a non-food use chemical, did not include a two-generation reproductive toxicity study in rats, nor did it include a developmental toxicity for a non-rodent species. The data provided no indication of increased sensitivity of fetal rats to *in utero* exposure to zinc phosphide. In the prenatal exposure developmental toxicity study in rats, no developmental effects were observed at the highest dose tested (4.0 mg/kg/day) that was shown to be maternally toxic (maternal deaths, decreased body weight and food consumption during treatment).

The Agency is not requiring these studies at this time because exposure from food sources is expected to be minimal to non-existent, however, the Agency established an RfD based on the anticipation that a chronic dietary risk assessment would be required. The RfD is 0.0001 mg/kg based on a subchronic oral study that showed no effects at 0.1 mg/kg. The Agency found, in its evaluation of dietary risk for zinc phosphide subsequent to the RfD determination, that no dietary or drinking water exposure will be expected and no risk assessment is necessary. Should a risk assessment be required in the future, due to treated food crops, an additional uncertainty factor of 10 would be applied to the Reference Dose calculation. This uncertainty factor would account for the extrapolation from subchronic to chronic exposure, the lack of reproductive toxicity data, and the lack of chronic toxicity data in a non-rodent species. The RfD of 0.0001 mg/kg reflects this additional uncertainty factor. If food uses showing dietary exposure are proposed for registration, a risk assessment will have to be performed. If risks are unacceptable using the current RfD, which reflects an additional uncertainty factor of 10, further studies will be required.

The Agency does not believe that exposure from the accidental ingestion of baits should be used in making the tolerance safety finding under FQPA. These exposures are accidental in nature and should not be considered as part of the FQPA calculus for non-occupational exposure. The dietary and drinking water contributions from zinc phosphide are negligible.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

EPA may determine, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate. In this case, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

### **c. Effects to the Endocrine System**

EPA is required to develop a screening program to determine whether certain substances (including all active ingredient pesticides and inerts) "may have an effect in humans that is similar to an effect predicted by a naturally occurring estrogen, or such other endocrine effect." The Agency is

currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end-use products.

## 2. Benefits of Rodenticides

Toxic rodenticides are the most efficient available means for controlling existing infestations of large numbers of pest rodents. These agents also may be the method of choice in controlling certain smaller rodent infestations and often are needed to control individuals that cannot be removed by use of traps.

People control rodent pests primarily because these animals (1) are associated with the spread of many types of serious diseases; (2) bite humans; (3) damage private and commercial property; (4) destroy and contaminate millions of tons of agricultural crops annually, both in the field and in storage; and (5) are generally unwelcome in homes, schools, places of business, and other areas occupied or frequented by humans.

The diseases vectored by rodents include: plague, Rickettsial diseases (e.g., murine typhus, Rickettsialpox), leptospirosis, rat bite fever, Salmonellosis, hantavirus, Lyme disease, granulocytic Ehrlichiosis, relapsing fever, and others. Rodents transmit diseases either directly or indirectly, via ectoparasites such as fleas, ticks or mites, or bodily waste products and secretions.

Many rodent-vectored diseases recently have been held in check through the private and public use of toxic rodenticides, along with other pest and disease control and management practices. Government agencies at times conduct rodent control programs in communities or parks, but actions of private citizens may affect the outcomes of such efforts significantly. Improved pest management, including coordination of rodenticide use and other rodent abatement practices, is a principal reason why numbers of cases and deaths associated with many rodent-vectored diseases have been much lower in the latter part of the twentieth century than was the case in prior decades. For example, there were 3,700 reported cases of murine typhus in the U.S. in 1942 but only 12 reported cases in 1987. In recent decades, however, "new" rodent-vectored diseases such as Lyme disease and hantavirus have emerged, primarily in rural and semi-rural areas in the U.S. Of these diseases, the HPS hantavirus strains appear to be the most serious, with a composite fatality rate of approximately 45% for the 170+ human cases reported since 1993.

Approximately 14,000 humans are bitten by rats each year. Recent information on this subject may not be available on a nationwide basis.

Rodents damage structures by gnawing on integral parts and as a result of contamination from bodily waste products and other secretions. Rodents can gnaw through wood, concrete, asphalt, sheet rock, plumbing, and soft metals. Rodent damage to electrical wiring has been cited as the probable

cause for certain fires and explosions, as well as an instance of shutting down the Internet. When buildings, including residences, are heavily infested, poisoning generally is an integral component of successful abatement programs.

"Field" rodents such as ground squirrels, voles, and native mice and rats cause significant damage to crops and rangelands. Certain crops, such as sugarcane, are heavily damaged in the field by commensal rats and mice. Commensal rodent species are primarily responsible for vertebrate pest damage to stored food and feed in the U.S. Zinc phosphide plays an important role in the management of rodents associated with agricultural crops.

Commensal rats and mice are not particularly "liked" by humans. This circumstance may be a factor in rodenticide use, however, disease concerns and desires to protect self and property also are likely to be valid in most cases in which rodenticide baits are used.

Rodenticide baits also are used in certain special circumstances, such as managing or eradicating non-native rodent species at sites where such rodents jeopardize the continued existence of certain threatened or endangered species. Control programs of this nature are run by government agencies and typically are limited to offshore islands or other refuge areas.

### **3. Tolerance Reassessment**

Tolerances for residues of zinc phosphide in/on plant commodities [40 CFR §180.284 (a) and (b)] are expressed in terms of phosphine resulting from use of zinc phosphide. The table following the tolerance discussion presents a summary of zinc phosphide tolerance reassessments as well as corrections to definitions of some commodities.

#### Tolerances Listed Under 40 CFR §180.284 (a)

Pending resolution of storage stability issues, adequate data are available to reassess the established tolerances for the following commodities, as defined: grapes, grasses (rangeland), and sugarcane.

Available sugarcane processing data suggest that tolerances for sugarcane processed fractions are not required. No grape processing data will be required, provided grape field trial samples were analyzed within 30 days of collection.

#### Tolerances Listed Under 40 CFR §180.284 (b)

Adequate data are available to reassess the established tolerances with regional registration, in accordance with 40 CFR §180.1 (n), for the following commodities, as defined: artichoke (globe), sugar beet (roots), and sugar beet (tops). Zinc phosphide is not presently registered for use on artichokes. If the registrant(s) wish to retain the tolerances with regional registration established for these commodities, then they must propose use directions reflecting the use patterns for which



adequate residue data from the original tolerance petitions are available. Alternatively, registrant(s) may wish to register zinc phosphide products for non-food uses only with concurrent revocation of existing tolerances. Discussion of non-food uses appears under GLN 860.1200 in Section III of this RED.

Tolerances Needed as a Result of Uses in Food Handling Establishments

Some currently registered uses of zinc phosphide normally require tolerances and supporting data for Food Handling Establishment tolerances. Based on labeling restrictions for those products that are used in these areas, the Agency will waive this requirement provided that all products for use in food-handling establishments sufficiently restrict their application such that the use is considered non-food. Specific requirements have been outlined in Section IIIB and labeling in Section V.

<b>Tolerance Reassessment Summary For Zinc Phosphide</b>			
<b>Commodity</b>	<b>Current Tolerance (ppm)</b>	<b>Tolerance Reassessment (ppm)</b>	<b>Comment */ [Correct Commodity Definition]</b>
<b>Tolerances Listed Under 40 CFR §180.284 (a):</b>			
Grapes	0.01	0.01	
Grasses (rangeland)	0.1	0.1	[Grass, forage]
Grasses (hay)		0.4	[Grass, hay]
Sugarcane	0.01	0.01	
<b>Tolerances Listed Under 40 CFR §180.284 (b):</b>			
Artichoke (globe)	0.01	0.01 **	[Artichoke, globe]
Sugar beet (roots)	0.04	0.04 **	[Sugar beet, roots]
Sugar beet (tops)	0.02	0.02 **	[Sugar beet, tops]

\* All tolerance reassessments are tentative pending adequate resolution of storage stability issues.  
 \*\* If the registrant(s) wish to retain the tolerances with regional registration established for these commodities, then they must propose use directions reflecting the use patterns for which adequate residue data from the original tolerance petitions are available. Alternatively, registrant(s) may register zinc phosphide products for non-food uses only with concurrent revocation of existing tolerances. For discussion of non-food uses see GLN 860.1200 in Section III. RED.

**4. Codex Harmonization**

No Codex MRLs have been established for zinc phosphide; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

**5. Summary of Risk Management Decisions**

**a. Human Health**

**(1) Dietary**

### Acute Dietary

The Agency has determined that acute dietary exposure and risk associated with the use of zinc phosphide is negligible. Of those commodities designated as food uses for zinc phosphide, three were found to have detectable residues after application (grasses, sugar beets, sugarcane). Since these three crops are not direct human food items, acute dietary consumption is not expected.

### Chronic Dietary (including cancer)

The Agency has determined that there will be no chronic dietary exposure or risk associated with the use of zinc phosphide. Residues are not expected on raw food items, as noted above. Also, zinc phosphide will not concentrate during the processing of any commodity because the act of processing will not allow for unreacted zinc phosphide to remain on the fractions. Since chronic exposure and risk associated with the use of zinc phosphide is negligible, no risk of cancer is expected from the use of zinc phosphide.

## **(2) Accidental Residential Exposure**

Rodenticides, when used as currently sold and marketed, are associated with a high number of human incidents and accidental exposures each year. Although the number of incidents attributable to zinc phosphide is limited, EPA is concerned that the small numbers do not reflect a limited risk, but rather a limited market share in residential settings. Therefore, EPA remains concerned about the continued risk of exposure to humans, especially children, from rodenticides used in residential settings. For zinc phosphide, an MOE of 0.5 was determined for accidental ingestion of the bait formulation by a child. This calculation was based on an acute neurotoxicity study and an estimate of how much a child could accidentally ingest. Generally, the Agency considers an MOE of 100 or more to be protective of public health. The Agency has also determined that a single swallow of zinc phosphide bait may be fatal to a young child. There is also considerable trauma and expense associated with medical treatment of children thought to have been exposed to rodenticides. To mitigate the potential risk to children from accidental ingestion of baits, the Agency is requiring several mitigation measures that will be implemented in two phases that will be discussed shortly.

EPA expressed its concern regarding human exposures and incidents to rodenticides used in and around the home in PR Notice 94-7. This Notice, entitled Label Improvement Program for the Revision of Use Directions for Commensal Rodenticides and Statement of the Agency's Policies on the Use of Rodenticide Bait Stations, was issued by the Agency on September 16, 1994, and required registrants of certain rodenticide products that claimed to control commensal rodents to revise the labeling of such products to bear certain statements concerning "tamper-resistant bait stations." The Notice also informed rodenticide registrants, applicants, and other interested persons of EPA's continued concern for the safe use of rodenticides. Moreover, PR Notice 94-7 outlined EPA's policies regarding the isolation of commensal rodenticides from children, dogs, other pets, domestic animals, and non-target wildlife. PR Notice 94-7, in part, stated:



*"Historically, more than 1000 incidents of human exposure to rodent poisons have been reported annually in the U.S. Numbers of human incidents reported have increased greatly in recent years with the advent of a new reporting network. In 1988, more than 10,000 rodenticide incidents were reported in the American Association of Poison Control Center's National Data Collection System. Nearly 90% of these cases involved children under six years of age. Nearly all of such exposures are classed as accidents. The human exposure incidents that are reported may represent less than half of those which occur. Well over 80% of reported human rodenticide exposures involve anticoagulant compounds.*

*Young children thought to have been exposed to rodenticides are often given some medical attention, although symptoms of poisoning usually are not observed, especially in cases involving anticoagulants which act very slowly. Although young children have been killed by rodenticides, most rodenticide-related deaths of humans result from intentional ingestions by persons much older than five years of age.*

*While reports summarizing incidents typically do not indicate exactly how exposures have occurred, it is likely that most accidents are related to improper use rather than to improper storage. Accidents of both types are preventable. EPA believes that the large numbers of exposure incidents provide evidence that current policies for promoting bait protection have not been sufficient and, therefore, that tougher, more explicit policies are needed. EPA has not been persuaded by contentions that the relatively low incidences of serious human illnesses caused by accidental exposures to compounds such as warfarin justify selective relaxations of requirements for bait protection..."*

#### Risk to Household Pets

As with human exposures, EPA is concerned about the increased risk posed to non-target domestic animals to rodenticides used in and around the home. When used as currently sold and marketed, rodenticides account for a high number of non-target animal incidents and accidental exposures every year. PR Notice 94-7 stated in part that:

*"Dog incidents account for more than 80% of the reported exposures of nontarget animals to commensal rodenticides. Most dog exposures are believed to be accidental. The annual number of incidents of animals being exposed to rodenticides is not known, but over 4,000 rodenticide-related inquiries were made to the Illinois Animal Poison information Center in each of the years from 1986 to 1988, with a high of 6,272 inquiries having been made in 1987.*

*Symptoms of rodenticide poisoning are detected more frequently in reported animal cases than in child cases. A larger percentage of asymptomatic exposures of animals may go undetected as pets and livestock generally are not watched as closely as children. Dogs may die as a result of rodenticide exposures, especially if acute poisons are involved.*

*Extended Vitamin K1 therapy may be needed for dogs that have been exposed to certain anticoagulants, such as brodifacoum or diphacinone, which are retained in the body for a relatively long time. For animal exposures reported in 1987 (and probably in other years as well), the animal's owner typically was the source of the rodenticide. Most of these exposures were accidental and occurred in or around human residences."*

In the recent past, poison control centers have enhanced their ability to capture incident data. This improved data collection indicates that the high number of human unintentional or accidental exposures to rodenticides are not going down. From the number of exposures to children, it is clear that children younger than six years of age are at a disproportionately higher risk from the continued use of these products in and around the home. Based on these findings and the additional information on risk to household pets, EPA is requiring the risk mitigation measures in the following discussion.

### **(3) Accidental Residential Risk Mitigation**

The Agency is requiring several risk mitigation measures for zinc phosphide products. The Agency is requiring the identical risk mitigation measures to the registrations of other rodenticide active ingredients such as warfarin and salts, difethialone, vitamin D-3, red squill, as well as those contained in the rodenticide cluster (brodifacoum, bromethalin, bromodiolone, chlorphacinone, diphacinone and salts, and pival and salts). As appropriate, these measures will also be required of registrations of new rodenticide active ingredients to be used in and around the home.

To address the risk concerns posed from the use of rodenticide products and still maintain the benefits afforded by their use, the Agency developed a two-phased approach minimizing exposure that is aimed particularly at protecting infants and children. The first phase is designed to address short-term measures that will aid in identifying when an actual exposure has occurred, to lessen the degree of such an exposure and to monitor exposures. The second phase will reduce the opportunity for exposures in the long term. Ideally, the Agency would have preferred to impose measures to immediately reduce opportunities for exposure, however, it recognizes that technologies may not exist and may need to be developed while maintaining the efficacy of the product. The Agency has developed the following phased approach to allow time for the development and testing of products that deliver bait and are packaged in such a way as to reduce exposure while maintaining sufficient efficacy.

During Phase I the Agency will require all zinc phosphide, non-agricultural products and products covered by the rodenticide cluster to incorporate indicator dye (to help identify whether a child or pet has actually consumed the pesticide) and bittering agents into their formulations. The indicator dye and bittering agent must be incorporated into all zinc phosphide products, other than those used exclusively in agricultural settings. During Phase II EPA will form a stakeholder group (including industry, states, various poison control centers, rodent control experts, the medical community and other interested parties) to develop additional means of significantly reducing exposures to children and pets. It is the Agency's intent that, within nine months or less from the issuance of the RED, the stakeholder group will issue its recommendations. Possible outcomes of this

group include: requiring all rodenticide baits used in residential settings to be placed in disposable, child-resistant bait stations or equivalently protective mechanisms; development of an exhaustive educational and outreach program for consumers and enhanced training for certified applicators; tamper-resistant bait stations; and additional labeling improvements.

#### Indicator Dye and Bittering Agent

All registrants of rodenticides, other than those with products used exclusively at agricultural sites, must incorporate an indicator dye into their formulations. The dye is intended to help identify whether a child or household pet has actually consumed a rodenticide by dyeing their mouth and/or hands a bright color. EPA believes the dye will play a critical role in identifying when an exposure has occurred, thereby helping to determine if treatment is required. Typically, it is very difficult for parents and guardians of children and pet owners to discern whether an exposure or ingestion has actually occurred, which may lead to unnecessary treatment at a medical facility as a precautionary measure. In turn, the Agency believes this measure will also enable parents and guardians of children and pet owners to seek medical or veterinarian attention sooner rather than later and avoid a serious medical episode.

All registrants of rodenticides, other than those with products used exclusively at agricultural sites, must incorporate a bittering agent into their formulations to make the bait unpalatable to humans and household pets. EPA believes that the bittering agent will cause some children to expel the bait if placed in the mouth. The Agency is fully aware that children younger than one year old do not have fully formed taste buds and may not be fully protected by this measure. However, this measure should prevent some exposures to children older than one year of age. Likewise, the EPA is also aware that this measure may not affect exposures to non-target household animals.

The Agency is aware that all mitigation measures required during Phase I may not be feasible within the 8 month timeframe usually accorded by the RED process to submit labeling changes. While registrants will still be required to submit revised labeling as detailed in Section V within the 8 month timeframe, the Agency recognizes that the formulation changes required by the addition of the indicator dye and bittering agent may take longer. The Agency will work with registrants to establish a timeframe for the incorporation of the dye and bittering agent into rodenticide products at a meeting or through other means, prior to the initial stakeholder meeting. At such time, deadlines and submittal procedures for additional efficacy testing, if required, will also be addressed.

#### Improved Labeling Requirements

EPA is requiring a number of label revisions to rodenticides used in and around the home. These requirements are set forth in Section V of this RED document and are in addition to those required by PR Notice 94-7 that have already been implemented. The Agency is monitoring the outcome of the requirements in PR Notice 94-7 along with the measures required in this RED document, to determine their effectiveness in reducing the number of incidents and exposures to these pesticides.

### Annual Submission of American Association of Poison Control Centers Data

Under the authority of FIFRA section 3(c)(2)(B), the Agency is requiring registrants of zinc phosphide subject to this RED document, to submit to the Agency annual American Association of Poison Control Centers' (AAPCC) data. The Agency is requiring AAPCC data for the years 1999 through 2009. These data will enable the Agency to determine whether the imposed risk mitigation measures are reducing incidents/exposures to humans, particularly children. AAPCC data obtained by the Agency for 1995 and 1996 will serve as baseline data. Registrants are encouraged to share the cost of generating data, whenever appropriate.

### Stakeholders Meeting

As mentioned above, EPA will initiate a stakeholder meeting to discuss long-term exposure reduction measures (Phase II) and to decide on specific timing and other issues associated with bait dyes, bittering agents, and the content of a special label warning to users of rodenticides that children are particularly vulnerable to ingestion of baits. One such warning could be a large, red stop sign symbol, followed by "Children at risk. Use product only as specified on label." in large, bold lettering. As noted earlier, the stakeholder group may include rodenticide registrants (with zinc phosphide, rodenticide cluster, and new active ingredient products as well as those that may have previously undergone reregistration), states, various poison control centers, rodent control experts, the medical community and other interested parties. The first stakeholders meeting is expected to be held 120 days from the date of the issuance of this RED in Washington, DC. It is the Agency's intent that, within nine months or less from the issuance of the RED, the stakeholder group will conclude with its recommendations.

#### **b. Environmental/Ecological Effects**

Zinc phosphide has a high to very high primary toxicity to birds and small mammals. Field, pen and laboratory studies indicate that some birds and mammals are likely to be poisoned when exposed directly to zinc phosphide. Because of the mode of action, secondary poisoning is expected to be minimal. There is concern for primary exposure to non-targets from the field uses as well as those uses in/around homes and buildings. In an attempt to minimize these exposures the Agency will be requiring that all field uses of zinc phosphide remain classified as Restricted Use. Since data are not available to assess potential risks to aquatic organisms, these data are now required.

The Agency is concerned about zinc phosphide's potential effects on non-target animals, especially from the broadcast use. The Agency has determined that the adverse effects associated with this use are not unreasonable due to the benefits of broadcast applications of zinc phosphide. Many of the tracts of land that are treated with zinc phosphide are vast, making hand baiting infeasible. The Agency also believes that limiting the broadcast uses may indirectly encourage the use of other pesticides that are more hazardous to non-target animals than zinc phosphide. In addition, the available data do not show that hand-baiting will necessarily result in reduced exposure to non-target animals. Rather than impose specific use restrictions at this time, the Agency will continue its

evaluation of the risks associated with hand baiting versus broadcast applications and may impose additional data requirements or label amendments at a later date.

The major route of degradation of zinc phosphide is hydrolysis, which results in the formation of phosphine and zinc ions, common nutrients in soil. Zinc phosphide and its residues do not appear to be persistent or mobile under most environmental conditions. When applied to dry soil environments, zinc phosphide may be moderately persistent. Zinc phosphide and its degradation products appear to have a low potential for ground water and surface water contamination.

**c. Restricted Use Classification**

Based on its toxicity and use patterns, the Agency is maintaining Restricted Use classification for all zinc phosphide products that are currently so classified. This includes all agricultural use and tracking powder products.

**d. Endangered Species Statement**

The Agency has developed a program (the “Endangered Species Protection Program”) to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

Zinc phosphide has been subject to a formal consultation with the Fish and Wildlife Service, as noted in Section III. Additional consultation with the Fish and Wildlife Service and/or the National Marine Fisheries Service may be necessary to determine if steps need to be taken to protect newly listed species or from proposed new uses of these pesticides.

**e. Occupational/Residential Labeling Rationale**

At this time, some products containing zinc phosphide are intended primarily for residential use and some are intended primarily for occupational use. The Worker Protection Standard (WPS) does not cover pesticides applied for control of vertebrate pests such as rodents. Therefore, all of the uses of zinc phosphide are NOT within the scope of WPS.



## 1. Requirements for Handlers

For each end-use product, personal protective equipment (PPE) and engineering control requirements for pesticide handlers are set during reregistration as follows:

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient specific (a.i. specific) handler requirements for end-use products containing that active ingredient. If such risks are minimal, EPA may choose not to establish a.i. specific handler requirements.
- EPA establishes handler PPE requirements for most end-use products, based on each product's acute toxicity characteristics.
- If a.i. specific requirements have been established, they must be compared to the PPE specified for the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product. Engineering controls are considered more stringent than PPE requirements.

For zinc phosphide products, EPA has considered each distinct formulation and is establishing, in this document, formulation-specific personal protective equipment and engineering control requirements for pesticide handlers.

### (a) **Occupational-Use Products**

The Agency has concerns about occupational handlers mixing/loading/applying zinc phosphide tracking powders, concentrates, wettable powders and bait formulations not sold in tamper-resistant bait stations. EPA is concerned that such handlers may inhale fine particles or dusts that may become airborne during the handling and that such handlers may ingest zinc phosphide as a result of hand to mouth transfer of dusts or residues or as a result of swallowing fine particles that may become airborne during handling activities. For specific labeling requirements refer to Section V.

### (b) **Homeowner-Use Products**

EPA is not establishing PPE requirements for homeowner handlers for zinc phosphide. In general, the Agency does not consider PPE requirements for homeowners to be practical or reliable risk-mitigation measures.

## 2. Post-Application/Entry Restrictions

EPA is not establishing post-application entry restrictions for any zinc phosphide end-use products.

### 3. Other Labeling Requirements

All products intended for use at residential sites must have label restrictions limiting their use to either outdoor underground sites or in areas that are inaccessible to children and pets.

The Agency is not requiring the same restrictions for uses of zinc phosphide in agricultural settings as for residential settings. The Agency does not anticipate the same types of exposures to children and pets in the agricultural areas; therefore, the current label restrictions are adequate and will be maintained.

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

## V. ACTIONS REQUIRED OF 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 zinc phosphide for the eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain and data are still required:

61-, 62- and 63- series product chemistry data	
72-1a	Acute Fish Toxicity (bluegill sunfish) <sup>1</sup>
72-1c	Acute Fish Toxicity (rainbow trout) <sup>1</sup>
72-2	Acute Aquatic Invertebrate Toxicity <sup>1</sup>
171-3	Directions for Use <sup>2</sup>
171-4e	Storage Stability <sup>3</sup>
171-4k	Crop Field Trials <sup>4</sup>

The Agency is also requiring zinc phosphide registrants, as well as registrants of other rodenticides, to submit annual American Association of Poison Control Centers (AAPCC) data. The Agency is requiring AAPCC data for the years 1999 through 2009, which must be submitted to the Agency within one-year after the end of the reporting year. For example, 1999 AAPCC data must be submitted to the Agency on or before December 31, 2000. The American Association of Poison Control Centers is located at 3201 New Mexico Avenue, Suite 310, Washington, D.C. 20016. They

can be reached by telephone on (202) 362-7217 and by fax on (202) 362-8377. The Agency encourages registrants to share the costs associated with data generation, whenever possible.

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

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained in the table at the end of this section.

### **B. End-Use Products**

#### **1. Formulation Changes**

All registrants of rodenticides must incorporate an Agency-approved indicator dye and bittering agent into their formulations. The Agency recognizes that the formulation changes required by the addition of the indicator dye and bittering agent may take longer than the eight months usually provided by the RED. The Agency will work with registrants to establish a timeframe for the incorporation of the dye and bittering agent into rodenticide products at a meeting, or through other means, prior to the initial stakeholder meeting. At such time, deadlines and submittal procedures for additional efficacy testing, if required, will also be addressed.

#### **2. Stakeholder Meetings**

The Agency is planning to hold the initial stakeholders meeting within 120 days from the issuance of this RED in Washington, DC. As mentioned earlier, these meetings will provide an open forum to develop workable mitigation measures to adequately protect children from accidental rodenticide exposures. For these meetings to be most efficient and successful, all interested parties and viewpoints will be welcomed and considered. The outcomes of these meetings will effect all rodenticide products with residential uses, including those that were previously reregistered and those that have been registered more recently and, hence, not subject to reregistration.

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

#### **4. Timeframes**



Phase One mitigation requirements include: (a) incorporating bittering agents and dyes into all end-use formulations, (b) submitting revised labeling reflecting revisions as discussed below. The Agency recognizes that the formulation changes required by the addition of the indicator dye and bittering agent may take longer than the eight months usually provided by the RED. The Agency will work with registrants to establish a time frame for the incorporation of the dye and bittering agent into rodenticide products at a meeting or through other means. At the same time, deadlines and submittal procedures for additional efficacy testing, if required, will also be addressed. The Agency expects these issues to be resolved prior to the initial stakeholder's meeting. Revised labeling and other product-specific data is due to the Agency within the regular 8-month time frame.

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

All end-use products should have clear, concise and complete labeling instructions. Proper labels can improve reader understanding, thereby reducing misuse and the potential for incidents. Towards this end, the Agency is requiring the following:

### Directions for Use:

Directions for Use must be stated in terms that can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. It must be presented in a format that is easy to understand and follow. The Directions for Use section of a pesticide label must provide the necessary information to answer four major categories regarding the use of the pesticide. These four questions are:

- 1) Why is the pesticide being used? For what pest(s) or problem?
- 2) Where is the pesticide applied? (Where should it not be applied?)
- 3) How is the pesticide applied (what special precautions must the user take? how much should they use?)
- 4) When should the pesticide be applied?

In addition, the Agency encourages the use of graphic symbols whenever possible, to clarify the written label.

### National Pesticide Telecommunications (NPTN) Hotline Number

All zinc phosphide labels must refer consumers to the NPTN number for additional information. This reference must bear the labeling contained in the table at the end of this section.

### First Aid (Statement of Practical Treatment)

The Agency is requiring that all labels with Statement of Practical Treatment sections be amended so that these sections are entitled, "First Aid." First aid statements must be brief, clear, simple and in straightforward language (conforming to the labeling required by the Agency) so that the

average person can easily and quickly understand the instructions. These statements should be appropriate for all ages or, when necessary, should include distinctions between the treatments for different ages.

#### PR Notice 94-7

All end-use products intended for use in residential settings must include the labeling language as outlined in PR Notice 94-7. When the label requirements imposed by this RED, or those imposed by PR Notice 94-7, are redundant or inconsistent with currently accepted labels those conflicts should be resolved in consultation with the Agency.

#### **(1) Formulation Specific PPE Requirements for this Active Ingredient:**

The Agency is establishing formulation-specific PPE for all occupational uses of zinc phosphide end-use products. Remove any conflicting PPE requirements on the current labeling by eliminating the less stringent requirement.

#### **(2) Placement in Labeling**

The personal protective equipment requirements must be placed on the end-use product labeling in the section titled: "Hazards to Humans (and domestic animals)" immediately following the precautionary statements. The exact language listed in the table at the end of this section must be used.

##### **a. Products Intended for Use on Field Crops, Orchards or Vineyards**

Products labeled for all crop uses regarded as non-food uses because of application methods and timing of applications must include all restrictions, rates, etc. as outlined in the labeling table below. All State and Local Needs products must contain specific information regarding use sites and use directions to help avoid inappropriate use of these products.

#### **C. Required Labeling Changes Summary Table**

The following table summarizes the labeling requirements being imposed by this RED for all zinc phosphide products. Any use instructions on current labels that conflict with the below should be removed.

**Summary Table of Required Labeling Changes for Zinc Phosphide Products**

Description	Required Labeling	Placement
Manufacturing use		
	“Only for formulation into a rodenticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	
Products Intended Primarily for Homeowner/Residential Use (generally, not marketed for use by professional applicators)		
Indoor sites	“Do not contaminate human or pet food preparation items or areas. Do not place near or inside ventilation duct openings.”	Use Restrictions section in Directions for Use
Products Intended Primarily for Occupational Use (generally, not marketed for use by homeowners)		
	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. Keep all other persons out of the treated area during application.”	Use Restrictions section in Directions for Use
	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p> <p>“Any person who retrieves carcasses or unused bait following application of this product must wear gloves.”</p>	Hazards to Humans (and domestic animals)

**Summary Table of Required Labeling Changes for Zinc Phosphide Products**

Description	Required Labeling	Placement
Concentrate formulations that must be diluted prior to use (includes wettable powders and dusts, but does not apply to tracking powders)	<p>“All handlers (including mixers, loaders and applicators) must wear:</p> <ul style="list-style-type: none"> <li>-- long-sleeve shirt and long pants,</li> <li>-- shoes plus socks,</li> <li>-- gloves, and mixers and loaders must wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) and protective eyewear.”</li> </ul>	Hazards to Humans (and domestic animals)
Tracking powder formulations	<p>“All handlers, including mixers/loaders and applicators, must wear:</p> <ul style="list-style-type: none"> <li>-- long sleeve shirt and long pants,</li> <li>-- shoes plus socks,</li> <li>-- gloves,</li> <li>-- a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), and</li> <li>-- protective eyewear.”</li> </ul>	Hazards to Humans (and domestic animals)
Tracking powder formulations	<p>“Tracking powder must be placed in locations not accessible to children, pets, domestic animals or non-target wildlife. If using this product in agricultural buildings where livestock feeds are stored, or in commercial food service, food manufacturing or food processing establishments, limit treatments to concealed, inaccessible places such as spaces between floors and walls. Do not apply tracking powder along walls, in corners or in open floor areas of rooms in which food or feed is handled or stored. Do not place tracking powder in areas where there is a possibility of contaminating water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment or surfaces that come in direct contact with food. Do not place near or inside ventilation duct openings.”</p>	Use Restrictions section in Directions for Use
Pellets or bait formulations	<p>“All handlers, including loaders and applicators, must wear:</p> <ul style="list-style-type: none"> <li>-- long sleeve shirt and long pants,</li> <li>-- shoes plus socks, and</li> <li>-- gloves.</li> </ul> <p>In addition, persons loading the pellets or baits into aircraft or mechanical ground equipment and persons loading/applying with a hand-pushed or hand-held equipment, such as a push-type spreader or cyclone spreader, must wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) and protective eyewear.”</p>	Hazards to Humans (and domestic animals)

**Summary Table of Required Labeling Changes for Zinc Phosphide Products**

Description	Required Labeling	Placement
Products mixed or applied via equipment	“Do not contaminate water when disposing of equipment wash water or rinsate.”	Environmental Hazard Statement
For use in indoor commercial establishments (does not apply to tracking powders)	“Do not use in edible product areas of food or feed processing plants, restaurants or other areas where food or feed is commercially prepared or processed. Do not contaminate food/feed or food/feed handling equipment or place near or inside ventilation duct openings.”	Use Restrictions section in Directions for Use
Products with Crop Uses (required to maintain non-food classification)		
State and Local Needs (SLN) products	Must contain specific information regarding use sites and use directions	Use Restrictions section in Directions for Use
Alfalfa (seed crop)	“Apply only underground or in burrow builder.”	
Alfalfa	“Apply only underground, in bait stations, or in burrow builder.”	
Barley, Oats, Wheat	“Apply only underground or in burrow builder. Dormant season use only.”	
Berry Production Areas	“Apply only underground, in bait stations, or in burrow builder. Apply bait in fair weather after harvest only while crop is in a nonbearing phase.”	
Bulbs	“Do not apply in gardens and areas where food or feed may be contaminated.”	
Corn, no-till	“For pre-plant or at-plant application only. Do not apply to areas inhabited by livestock. Do not graze animals in treated areas.”	
Macadamia nut orchards	“Apply only by broadcast or in burrow builder. Do not graze animals in treated areas. Bait must be removed from trees prior to harvest. Do not broadcast over growing crop when bait may lodge in plant.”	
Maple, sugar	“Apply only in bait stations. Stations must be placed so that the bait will not come in contact with the harvested commodity or the tubing that harvests the commodity.”	
Orchards/groves	“Apply after harvest or anytime during the dormant season, but before tree growth begins in the Spring. Do not broadcast over non-orchard/non-grove crops. Do not graze animals on treated areas.”	

**Summary Table of Required Labeling Changes for Zinc Phosphide Products**

Description	Required Labeling	Placement
Timothy	“Apply only during crop dormancy. Do not apply over growing crops. Do not graze animals in treated areas.”	Use Restrictions section in Directions for Use
Products with Crop Uses that Require a Tolerance		
Grapes Broadcast, ground	Must be applied at a rate of 0.12 - 0.2 lb a.i./A  “Do not apply by air. Do not apply over growing crop when bait may lodge in plant. Do not graze animals on treated areas. Do not broadcast over growing crops other than sugarcane or over bare ground.”	Use Restrictions section in Directions for Use
Grapes Broadcast aerial	Must be applied at a rate of 0.08 - 0.19 lb a.i./A  “Apply during the non-bearing season. Do not apply over growing crop when bait may lodge in plant. Do not graze animals on treated areas. Do not broadcast over growing crops other than sugarcane.”	
Grasses, rangeland Broadcast bait Hand bait	Must be applied at a rate of 0.06 - 0.12 lb a.i./treated swath acre or 1 tsp/burrow at a maximum of 1 application/year  “Apply only to rangeland with <50% ground cover.”	
Grasses, rangeland Hand bait (edge of mound/burrow or adjacent feeding area)	Must be applied at a rate of 1 tsp (4 g)/mound or burrow at a maximum of 1 application/year  “Do not use in areas inhabited by livestock. Do not graze animals in treated areas. Do not apply where plants are grown for food or feed.”	
Grasses, pasture Hand bait (edge of mound or adjacent feeding area)	Must be applied at a rate of 1 tsp (4 g)/mound or burrow at a maximum of 1 application/year  “Do not use in areas inhabited by livestock.”	

**Summary Table of Required Labeling Changes for Zinc Phosphide Products**

Description	Required Labeling	Placement
Grasses (reseeding of rangeland/reforestation) Broadcast/aerial /gnd 20' swaths Hand baiting Trail builder	Must be applied at a rate of 0.11 - 0.18 lb a.i./A  "Do not apply in areas where plants are being grown for food or feed or areas inhabited by livestock."	Use Restrictions section in Directions for Use
Sugarcane Broadcast Aerial/ground	Must be applied at a rate of 0.1 lb a.i./A with a maximum number of applications of 4 in a 36-month period. A 30-day pre-harvest interval is required.  "Do not graze animals in treated areas."	
Sugarcane Broadcast Aerial/ground	Must be applied at a rate of 0.1 lb a.i./A with a maximum number of applications of 4 per 2-year cycle and 2 per 1-year cycle. A 90-day pre-harvest and a 30-day retreatment intervals are required.	
All Products		
	"For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1-800-858-7378."  "Do not apply this product by any method not specified on this label."	Directions For Use
	"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."  "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."	User Safety Recommendations (directly below Hazards to Humans)
	"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark."  "Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait."	Environmental Hazard Statements



#### D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell zinc phosphide products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.



## **VI. APPENDICES**





























































































































## **GUIDE TO APPENDIX B**

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

The data table is organized in the following format:

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

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

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

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





# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Zinc Phosphide

REQUIREMENT	USE PATTERN*	CITATION(S)	
<b><u>PRODUCT CHEMISTRY for</u></b> <b>HACCO 61282-13</b>			
61-1	Chemical Identity	ALL	43452401, Data Gap
61-2A	Start. Mat. & Mnfg. Process	ALL	43452401
61-2B	Formation of Impurities	ALL	42986201
62-1	Preliminary Analysis	ALL	42986201, 43549801
62-2	Certification of limits	ALL	43549801
62-3	Analytical Method	ALL	42986201, 43549801
63-2	Color	ALL	42986202
63-3	Physical State	ALL	42986202
63-4	Odor	ALL	42986202
63-5	Melting Point	ALL	42986202
63-6	Boiling Point	ALL	N/A
63-7	Density	ALL	43452401
63-8	Solubility	ALL	42986202
63-9	Vapor Pressure	ALL	N/A

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

<b>REQUIREMENT</b>		<b>USE PATTERN*</b>	<b>CITATION(S)</b>
63-10	Dissociation Constant	ALL	N/A
63-11	Octanol/Water Partition	ALL	N/A
63-12	pH	ALL	N/A
63-13	Stability	ALL	43452402, Data Gap
63-14	Oxidizing/Reducing Action	ALL	N/A
63-15	Flammability	ALL	N/A
63-16	Explodability	ALL	42986202, Data Gap
63-17	Storage stability	ALL	42986202
63-18	Viscosity	ALL	N/A
63-19	Miscibility	ALL	N/A
63-20	Corrosion Characteristics	ALL	43452402
<b><u>PRODUCT CHEMISTRY for</u></b>			
<b>Bell Laboratories 12455-24</b>			
61-1	Chemical Identity	ALL	43125501, 44227301
61-2A	Start. Mat. & Mnfg. Process	ALL	43125501, 44227301
61-2B	Formation of Impurities	ALL	43125501
62-1	Preliminary Analysis	ALL	43125502, 44227301

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

REQUIREMENT	USE PATTERN*	CITATION(S)
62-2	Certification of limits	43125501, 44227301
62-3	Analytical Method	44227301
63-2	Color	41250602
63-3	Physical State	41250602
63-4	Odor	41250602
63-5	Melting Point	41280602
63-6	Boiling Point	N/A
63-7	Density	41250602, 43125503, 44227302
63-8	Solubility	41250602, 43125503, 44227302
63-9	Vapor Pressure	N/A
63-10	Dissociation Constant	N/A
63-11	Octanol/Water Partition	N/A
63-12	pH	N/A
63-13	Stability	41250602, 43787801, 44227302
63-14	Oxidizing/Reducing Action	N/A
63-15	Flammability	N/A
63-16	Explodability	41250602

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

REQUIREMENT	USE PATTERN*	CITATION(S)	
63-17	Storage stability	ALL	41250602
63-18	Viscosity	ALL	N/A
63-19	Miscibility	ALL	N/A
63-20	Corrosion Characteristics	ALL	Data Gap
<b><u>ECOLOGICAL EFFECTS</u></b>			
71-1A	Acute Avian Oral- Quail/Duck	A,B,C,J,K	00006031, 00006032
71-2A	Avian Dietary - Quail	A,B,C,J,K	00006025, 00006031
71-4B	Avian Reproduction - Duck		Not Required
72-1A	Fish Toxicity Bluegill	A,B,C,J (broadcast uses)	Data Gap
72-1C	Fish Toxicity Rainbow Trout	A,B,C,J (broadcast uses)	Data Gap
72-2A	Invertebrate Toxicity	A,B,C,J (broadcast uses)	Data Gap
72-4A	Early Life Stage Fish		Not Required
124-1	Terrestrial Field		Not Required
141-1	Honey Bee Acute Contact	A,B,C,J,K	Waived
141-2	Honey Bee Residue on Foliage	A,B,C,J,K	Waived

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

REQUIREMENT	USE PATTERN*	CITATION(S)
141-5      Field Test for Pollinators	A,B,C,J,K	WAIVED
<b><u>TOXICOLOGY</u></b>		
81-1      Acute Oral Toxicity - Rat	ALL	00085366
81-2      Acute Dermal Toxicity - Rabbit/Rat	ALL	00006030
81-3      Acute Inhalation Toxicity - Rat	ALL	Waived
81-4      Primary Eye Irritation - Rabbit	ALL	00029247
81-5      Primary Dermal Irritation - Rabbit	ALL	00006029
81-6      Dermal Sensitization - Guinea Pig	ALL	Waived
81-7      Acute Delayed Neurotoxicity - Hen		Not Required
82-1A     90-Day Feeding - Rodent	ALL	43436601
82-1B     90-Day Feeding - Non-rodent		Not Required
82-2      21-Day Dermal - Rabbit/Rat		Not Required
82-3      90-Day Dermal - Rodent		Not Required
82-4      90-Day Inhalation - Rat		Not Required
82-5A     90-Day Neurotoxicity - Hen		Not Required
82-5B     90-Day Neurotoxicity - Mammal	ALL	43903801, 43903802

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

<b>REQUIREMENT</b>		<b>USE PATTERN*</b>	<b>CITATION(S)</b>
83-1A	Chronic Feeding Toxicity - Rodent	ALL	Waived
83-1B	Chronic Feeding Toxicity - Non-Rodent	ALL	Waived
83-2A	Oncogenicity - Rat	ALL	Waived
83-2B	Oncogenicity - Mouse	ALL	Waived
83-3A	Developmental Toxicity - Rat	ALL	43083501
83-3B	Developmental Toxicity - Rabbit	ALL	Waived
83-4	2-Generation Reproduction - Rat	ALL	Waived
84-2A	Gene Mutation (Ames Test)	ALL	42987301
84-2B	Structural Chromosomal Aberration	ALL	42987303
84-4	Other Genotoxic Effects	ALL	42987302
85-1	General Metabolism	ALL	Waived
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>			
132-1A	Foliar Residue Dissipation		Not Required
132-1B	Soil Residue Dissipation		Not Required
133-3	Dermal Passive Dosimetry Exposure		Not Required

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

<b>REQUIREMENT</b>	<b>USE PATTERN*</b>	<b>CITATION(S)</b>
133-4 Inhalation Passive Dosimetry Exposure		Not Required
<b><u>ENVIRONMENTAL FATE</u></b>		
161-1 Hydrolysis	A,B,C,J,K	00068028
161-2 Photodegradation - Water	A,B,J	43466302, 43466303
161-3 Photodegradation - Soil	A,B,J	43466302, 43466303
161-4 Photodegradation - Air		Not Required
162-1 Aerobic Soil Metabolism	A,B,C,J,K	43466302, 43466303
162-2 Anaerobic Soil Metabolism	A,B,C	43466302, 43466303
162-3 Anaerobic Aquatic Metabolism		Not Required
162-4 Aerobic Aquatic Metabolism	J	43466302, 43466303
163-1 Leaching/Adsorption/Desorption	A,B,C,J,K	43466302, 43466303
163-2 Volatility - Lab	A,B	43466302, 43466303
164-1 Terrestrial Field Dissipation	A,B,C,K	43466302, 43466303
164-2 Aquatic Field Dissipation		43466302, 43466303
165-1 Confined Rotational Crop	A,B,C	43466302, 43466303
165-2 Field Rotational Crop		Not Required

**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

<b>REQUIREMENT</b>	<b>USE PATTERN*</b>	<b>CITATION(S)</b>	
<b><u>RESIDUE CHEMISTRY</u></b>			
171-3	Directions for Use	ALL	Data gap
171-4A	Nature of Residue - Plants	A,B	00006047, 00005999, 05007787
171-4B	Nature of Residue - Livestock		Not Required
171-4C	Residue Analytical Method - Plants	A,B	00006044, 05007610
171-4D	Residue Analytical Method - Animal		Not Required
171-4E	Storage Stability	A,B	Data Gap, 41035001
171-4I	Magnitude of Residues - Food Handling		Not Required
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	Waived
171-4K	Crop Field Trials		
	Artichokes	A,B	40962501
	Sugarbeet roots and tops	A,B	41035001
	Grapes	A,B	00006044, 00006045



**Data Supporting Guideline Requirements for the Reregistration of  
Zinc Phosphide**

REQUIREMENT	USE PATTERN*	CITATION(S)
Grasses	A,B	00005950, 00005951, 00005952, 00005962, 00005965, 00005968, 00005969, 00005970, 00082533, 00082535, 00082538, 00082540, 00082541, 00082542, 00082550, 00082553
Sugarcane	A,B	00005921, 00005922, 00005923, 00005924, 00005925, 00005926, 00005927, 00005928, 00005929, 00005930, 00005931, 00005932, 00005933, 00005936, 00005938, 00005939, 00005940, 00005941, 00005947, 00005948, 00005949, 00006058, 00019919
171-4L Corn (no-till)	A,B	43903802
171-4L Processed Food		
Beets, sugar	A,B	Waived
Grapes	A,B	00006044
Sugarcane	A,B	see studies under 171-4k

\* Use patterns are based on the General Use Patterns as cited in 40 CFR part 158 for each guideline, except for the toxicity guidelines which are listed for all uses



## GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC  
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

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

- Section I - Why You are Receiving this Notice
- Section II - Data Required by this Notice
- Section III - Compliance with Requirements of this Notice
- Section IV - Consequences of Failure to Comply with this Notice
- Section V - Registrants' Obligation to Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries and Responses to this Notice

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Citation Forms

## **SECTION I. WHY YOU ARE RECEIVING THIS NOTICE**

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

## **SECTION II. DATA REQUIRED BY THIS NOTICE**

### **II-A. DATA REQUIRED**

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

## II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

## II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

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

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

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

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

## **SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE**

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

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

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

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

#### 1. Generic Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

#### a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option.

Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

- (i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;
- (ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- (iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.



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

a. Voluntary Cancellation

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

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

b. Satisfying the Product Specific Data Requirements of this Notice.

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

c. Request for Product Specific Data Waivers.

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

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

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

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

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and



Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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

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

### Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

### Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 6. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

#### Option 4. Submitting an Existing Study

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of 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 documents available from NTIS). A study not

conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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

#### Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

#### Option 6. Citing Existing Studies

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citation of Data and EPA Form 8570-35 Data Matrix.

#### 2. Product Specific Data

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

- (1) I will generate and submit data within the specified time-frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)



- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

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

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

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

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

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

#### 1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume/minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume/minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume/minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

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

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

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

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data

requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

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

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.



You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

## 2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

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

### IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - 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 generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

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

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2) and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

#### Attachments

The Attachments to this Notice are:

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



## ZINC PHOSPHIDE DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

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

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 Zinc phosphide. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Citation Forms in replying to this Zinc phosphide Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Zinc phosphide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Zinc phosphide are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Zinc phosphide products.

### INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

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

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

**RE: Zinc phosphide**

## ZINC PHOSPHIDE DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

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

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Zinc phosphide. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Citation Forms in replying to this Zinc phosphide Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Zinc phosphide are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Zinc phosphide are needed. These data are needed to fully complete the reregistration of all eligible Zinc phosphide products.

### INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dana Lateulere at (703) 308-8044.

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

Susan Jennings, Chemical Review Manager  
Reregistration Branch 3  
Special Review and Registration Division (H7508W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460  
RE: Zinc phosphide



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

### INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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

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

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
- Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
- Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.
- Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources

are registered), you may not claim a Generic Data Exemption and you may not select this item.

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

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

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

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

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

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

- Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.
- Item 9. **ON BOTH FORMS:** Enter the date of signature.
- Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

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

**INTRODUCTION**

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

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

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

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









## INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

### Generic and Product Specific Data Call-In

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.
- ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.
- Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
- ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.
- Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.
- Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

## INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

### Generic and Product Specific Data Call-In

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

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

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

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

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

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

**ON THE PRODUCT SPECIFIC DATA FORM:** The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

**However, for Product Specific Data,** I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

- Option 3. **ON BOTH FORMS: (Offer to Cost Share)** I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

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

- Option 4. **ON BOTH FORMS: (Submitting Existing Data)** I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.
- Option 5. **ON BOTH FORMS: (Upgrading a Study)** I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

**However, for Product Specific Data,** I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Citation Requirements" form.

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

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

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

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

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

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for

this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

- Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.
- Item 11. **ON BOTH FORMS:** Enter the date of signature.
- Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

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NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these

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## EPA'S BATCHING OF PRODUCTS CONTAINING ZINC PHOSPHIDE AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient zinc phosphide, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4),

Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient zinc phosphide.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	769-741	zinc phosphide ... 94%	powder
	61282-3	zinc phosphide ... 93%	powder
2	769-656	zinc phosphide ... 80%	solid
	769-743	zinc phosphide ... 80%	solid
	4221-11	zinc phosphide ... 80%	solid
	12455-24	zinc phosphide ... 80%	solid
	61282-13	zinc phosphide ... 82%	solid
3	769-756	zinc phosphide ... 62%	solid
	56228-6	zinc phosphide ... 63.2%	solid
	56228-9	zinc phosphide ... 63.2%	solid
	ID91001800	zinc phosphide ... 63.2%	solid
	TX95000200	zinc phosphide ... 63.2%	solid
4	7173-197	zinc phosphide ... 10.3%	solid
	12455-16	zinc phosphide ... 10.0%	solid
5	4-152	zinc phosphide ... 2%	solid

4-285	zinc phosphide	... 2%	solid
30-25	zinc phosphide	... 2%	solid
192-204	zinc phosphide	... 2%	solid
192-205	zinc phosphide	... 2%	solid
322-8	zinc phosphide	... 2%	solid
358-165	zinc phosphide	... 2%	solid
814-9	zinc phosphide	... 2%	solid
2393-185	zinc phosphide	... 2%	solid
2393-521	zinc phosphide	... 2%	solid
2393-522	zinc phosphide	... 2%	solid
4271-16	zinc phosphide	... 1.82%	solid
5887-179	zinc phosphide	... 2%	solid
7122-124	zinc phosphide	... 2%	solid
7173-195	zinc phosphide	... 1.88%	solid
12455-17	zinc phosphide	... 2%	solid
12455-18	zinc phosphide	... 2%	solid
12455-30	zinc phosphide	... 2%	solid
12455-59	zinc phosphide	... 2%	solid
12455-85	zinc phosphide	... 2%	solid
13808-6	zinc phosphide	... 2%	solid
36029-10	zinc phosphide	... 2%	solid
36029-12	zinc phosphide	... 2%	solid

36029-13	zinc phosphide ... 2%	solid
56228-3	zinc phosphide ... 1.82%	solid
56228-14	zinc phosphide ... 2%	solid
61282-14	zinc phosphide ... 2%	solid
61282-20	zinc phosphide ... 2%	solid
CA89002600	zinc phosphide ... 1%	solid
CA89002700	zinc phosphide ... 2%	solid
HI96000700	zinc phosphide ... 2%	solid
IL97000100	zinc phosphide ... 2%	solid
IN83000300	zinc phosphide ... 2%	solid
KS97000100	zinc phosphide ... 2%	solid
KY96000500	zinc phosphide ... 2%	solid
MO96001400	zinc phosphide ... 2%	solid
MT89000900	zinc phosphide ... 2%	solid
MT95000300	zinc phosphide ... 2%	solid
NE97000100	zinc phosphide ... 2%	solid
OH85000100	zinc phosphide ... 2%	solid
OR95002100	zinc phosphide ... 2%	solid
TX95000200	zinc phosphide ... 2%	solid
VT90000200	zinc phosphide ... 2%	solid
WA91000300	zinc phosphide ... 2%	solid
WA91001800	zinc phosphide ... 2%	solid

WA95002200	zinc phosphide	... 2%	solid
WY92000200	zinc phosphide	... 2%	solid
WY92000300	zinc phosphide	... 2%	solid

There was no "No Batch" group for this RED.

The following is a list of available documents for Zinc phosphide that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the internet using WWW (World Wide Web) at [www.epa.gov/REDS](http://www.epa.gov/REDS).

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for zinc phosphide.

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

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.
2. EPA Acceptance Criteria



## 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.

**Attachment 1. List of All Registrants Sent This Data Call-In (insert) Notice**

## 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.









United States Environmental Protection Agency  
 Washington, D.C. 20460  
**Certification of Offer to Cost  
 Share in the Development of Data**

Form Approved  
 OMB No. 2070-0106,  
 2070-0057  
 Approval Expires  
 3-31-99

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-233, 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 firms on the following date(s):

Name of Firm(s)	Date of Offer
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**Certification:**

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

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







**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.  
 Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it 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	Date	Typed or Printed Name and Title
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date		EPA Reg No./File Symbol			Page	of																																																																													
Applicant's/Registrant's Name & Address		Product																																																																																	
Ingredient																																																																																			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note																																																																														

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

**File Copy**

**Public**





## INSTRUCTIONS FOR DATA MATRIX

**INSTRUCTIONS:** Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

**Ingredient:** Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

**Guideline Reference Number:** Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

**Guideline Study Name:** For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

**MRID Number:** For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

**Submitter:** Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

**Status:** Enter one of the following codes for each study cited, as appropriate:

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

- 0 Required to support the broadcast applications. The consortium must consult with EPA prior to initiating studies to ensure agreement on the appropriate test material and test protocols.
- 0 Required to retain artichoke (globe), sugar beet tops, and sugar beet roots uses. Proposed use directions must reflect the use patterns contained in the adequate residue data from the original tolerance petitions.
- 0 Data are required concerning the length and conditions of sample storage for grapes, rangeland grass forage and sugarcane. Dates of harvest and analysis are also required for sugarcane.
- 0 Required for grapes, grass forage and sugarcane if samples in field trial studies were stored for longer than 30 days (grapes) or 6 months (grass forage and sugarcane) prior to analysis.