United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA 738-R-98-017 December 1998

Reregistration Eligibility Decision (RED)

AL & MG 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 cases aluminum and magnesium phosphide [Case Numbers 0025 & 0645]. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of this chemical, 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. Please note that an extensive stakeholder involvement process will begin shortly to determine the best methods for reducing the risks associated with these pesticides. Following this process, the Agency will identify specific risk mitigation measures which will need to be implemented in order for these pesticides to be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient 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 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 Bonnie Adler (703) 308-8523. Address any questions on required generic data to the Special Review and Reregistration Division representative Mark Hartman (703) 308-0734.

Sincerely,

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 issuance of final mitigation measures following the conclusion of the stakeholder process.**

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 703-605-6000).

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 Citation of Data**. Complete and sign EPA form 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

Aluminum and Magnesium Phosphide

LIST A

CASES 0025 & 0645

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ALUMINUM AND MAGNESIUM PHOSPHIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

William L. Gross	Herbicide & Insecticide Branch
Alan Halvorson	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Norman B. Birchfield	Environmental Risk Branch I
James A. Hetrick	Environmental Risk Branch I
Richard J. Mahler	Environmental Risk Branch I
Joseph R. Sylvester	Environmental Risk Branch I

Health Effects Risk Assessment

Paul I. Lewis	Risk Characterization and Analysis Branch
Steven A. Knizner	Risk Characterization and Analysis Branch
Julianna F. Cruz	Risk Characterization and Analysis Branch
Stanley B. Gross	Toxicology Branch II
David E. Hrdy	Chemistry and Exposure Branch II
Tracy L. Keigwin	Chemistry and Exposure Branch I
Timothy Leighton	Chemistry and Exposure Branch I
Kelly M. O'Rourke	Chemistry and Exposure Branch I

Registration Support

William W. Jacobs	Insecticide-Rodenticide Branch
Dennis McNeilly	Insecticide-Rodenticide Branch

Risk Management

Mark A. Hartman	Reregistration Branch II

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
HIARC	Hazard Identification and Review Committee
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	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

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
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 for the pesticides aluminum and magnesium phosphide. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products.

Aluminum and magnesium phosphide are registered as fumigants on a wide variety of raw agricultural commodities including stored grain and vegetable crops, stored processed foods and non-food commodities. Typical storage structures include silos, bins and railcars. These pesticides are also registered for use in animal dens and burrows. Both aluminum and magnesium phosphide act as broad spectrum insecticides and as rodenticides for controlling small mammalian pests. Aluminum and magnesium phosphide are formulated as pellets, tablets, impregnated materials and dusts. The Aluminum and Magnesium Phosphide Task Force is supporting the reregistration of all currently registered uses.

Aluminum and magnesium phosphide react with the moisture in the atmosphere to produce phosphine gas which is the substance that is active as a pesticide. For this reason, and given their common use sites and methods of application, the Agency is considering these two pesticides together for the purposes of risk assessment and reregistration.

The Agency has determined that all uses of aluminum phosphide and magnesium phosphide as specified in this document require mitigation of the risks associated with the exposure to these pesticides. The Agency will conduct a public process to identify the best ways to reduce the risks associated with aluminum and magnesium phosphide exposure. This process will include a public comment period and a stakeholder meeting. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing aluminum and magnesium phosphide to be eligible for reregistration.

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA 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 the Agency to consider information concerning the susceptibility of infants and children to pesticide residues in food, and 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. Further, the FQPA amendments require the Agency to apply a 10-fold safety factor to protect infants and children unless reliable data demonstrate that the factor can be reduced or removed.

In determining whether to retain, reduce, or remove the 10X FQPA safety factor for infants and children, the Agency uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base and the nature and severity of the effects observed in pre- and post-natal studies. The data provided no indication of increased susceptibility of rats to in utero or postnatal exposure to aluminum or magnesium phosphide. In addition, exposure assessments do not indicate a concern for a potential risk to infants and children because residues of phosphine are not

expected in food or drinking water and there is only a limited registered residential use at the present time that the Agency has proposed to remove. Given these factors, the Agency determined that an additional 10X safety factor is not necessary to protect infants and children, and that based on reliable toxicology and exposure data, a lesser margin of safety will be safe for infants and children.

Regarding aggregate exposure, the Agency only considered dietary exposure from food because drinking water exposure is not expected and there is only a limited residential use at the present time that the Agency has proposed to remove. Since, as mentioned above, no residues of phosphine gas are expected on food or in drinking water aggregate risk is not a concern. The Agency also considered the possible risks associated with a related pesticide, zinc phosphide, which also generates phosphine gas in this aggregate assessment. The RED for zinc phosphide determined that an aggregate assessment for that chemical for the various possible sources of phosphine from its uses was not warranted because the likelihood of exposure is very low/unlikely. Therefore, the contribution of zinc phosphide to this aggregate assessment was negligible.

The Agency does not have, at this time, available data to determine whether aluminum, magnesium and zinc phosphide have a common mechanism of toxicity with other substances. Additionally, the Agency does not currently have the methodology to conduct a cumulative risk assessment. For the purposes of this assessment, therefore, the Agency has not assumed that aluminum and magnesium phosphide have a common mechanism of toxicity with other substances.

Given the use patterns and environmental fate characteristics of these pesticides, aluminum and magnesium phosphide are not expected to pose a significant ecological risk to non-target organisms or to water resources under most circumstances. The exception is potential risks to some endangered species. Since one of the uses of these pesticides is as a burrow fumigant for the control of rodents there is a concern that several endangered or threatened species, such as the black-footed ferret, could be present in burrows targeted for fumigation.

Given the high toxicity of aluminum and magnesium phosphide and potential risks posed to occupational and residential bystanders, a number of mitigation measures are proposed by the Agency. Aluminum and magnesium phosphide are methyl bromide alternatives. Furthermore, since these pesticides have significant benefits and there are few if any viable alternatives besides methyl bromide, the Agency believes that it is important that a broad stakeholder process be conducted to discuss these measures and/or to develop other workable mitigation measures that adequately protect occupational and residential bystanders. The proposals described in this document constitute the Agency's preliminary thoughts on the best ways to reduce the risks of concern. These measures are to be discussed as part of the public review and stakeholder meeting process mentioned above.

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. 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 ("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 ingredients 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 the 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. The Agency will therefore continue its ongoing reregistration program, while it continues to determine how best to implement the FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of aluminum and magnesium phosphide. The document consists of six sections. Section I is the introduction. Section II describes aluminum and magnesium phosphide, their uses, data requirements, and regulatory history. Section III discusses the human health and environmental assessments based on the data available to the Agency. Section IV presents the reregistration decision for aluminum and magnesium phosphide. Section V discusses the reregistration requirements for aluminum and magnesium phosphide. Finally, Section VI contains 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

This Reregistration Eligibility Decision covers both aluminum and magnesium phosphide. The following table provides an overview of these chemicals:

Table 1: Chemical Overview

	Aluminum Phosphide	Magnesium Phosphide
Common Names	Aluminum Phosphide	Magnesium Phosphide
Chemical Names	Aluminum Phosphide	Magnesium Phosphide
Chemical Family	Inorganic compound	Inorganic compound
CAS Registry Numbers	20859-73-8	12057-74-8
OPP Chemical Codes	066501	066504
Empirical Formula	AlP	Mg_3P_2
Trade and Other Names	Fumtoxin, L-Fume, Tri-Tox Fumiphos, Phostoxin, Fumex, Gastoxin, Quik-Fume	Fumi-Cell, Magnaphos, Magtoxin
Basic Manufacturers	Bernardo Chemical Ltd, Inc. Degesch America, Inc. Inventa Corporation Midland Fumigant, Inc. Pestcon Systems, Inc.	Degesch America, Inc. Inventa Corporation

B. Use Profile

Aluminum and magnesium phosphide are fumigants used primarily for indoor fumigation of raw agricultural commodities, animal feeds, processed food commodities, and non-food commodities in sealed containers or structures to control insects, and for outdoor fumigation of burrows to control rodents and moles in non-domestic areas, noncropland, and agricultural areas. Aluminum and magnesium phosphide also is used to control rodents which can carry various diseases including sylvanic plague. In cases where the purpose of treatment is to control for a vector-borne disease the use would be considered a public health use. The following is information on currently registered uses, with an overview of use sites and application methods. A detailed table of these uses of aluminum phosphide and magnesium phosphide is in Appendix A.

For aluminum phosphide:

Type of Pesticide: Insecticide; Rodenticide

Use Sites:
Nonfood and Related Areas:
Aluminum phosphide is registered for use on the following nonfood items and related areas: temporarily stored nonfeed/nonfood commodities, commercial storage/warehouse premises, silos, seeds, article treatments, agricultural uncultivated areas, non-agricultural uncultivated areas, wide area public health uses (e.g., tires for mosquito control or animal burrows for rodent control), and wood protection treatment to seasoned forest products. It is also registered for use on stored furs, feathers, hair, leather/leather hides, paper, textiles/fabrics/fibers, and tobacco.

Food and Related Areas:
Aluminum phosphide is registered for use on the following food/feed crops: temporarily stored feed/food commodities, barley, buckwheat, corn, millet, oats, rice, wild rice, rye, sorghum, triticale, wheat, peanuts, soybeans, vegetables, dates, figs, almonds, brazil nuts, cashews, filberts, pecans, pistachios, walnuts, grass forage/fodder/hay, popcorn, rape, sesame, cocoa, coffee, legume vegetables, safflower, seeds, and sunflower. It is also registered for use in orchards, commercial transportation facilities and commercial shipping containers, food processing plants (nonfood contact), silos, commercial storehouses/warehouses, and grain/cereal/flour bins and elevators. It is also used on diseased or empty beehives.

Processed Food:
Aluminum phosphide is registered for use on the following processed foods and related areas: candy, cereal flour/bakery mixes, pasta/crackers, cereals, bagged grain/cereal/flour, cheese/cheese byproducts, chocolate/chocolate byproducts, coffee, processed/ground corn, cottonseed, dried egg yolk solids, dried fruits, herbs/spices, livestock feed, malt/malt beverage, dried milk, dried non-dairy creamers, cured meat products, nut meats, oats, rice, soybean flour, starch, sugar, tea, dried vegetables, and yeast. It is also registered for use in commercial transportation facilities and commercial shipping containers, in food processing plants (nonfood contact), silos, commercial storehouses/warehouses, and grain/cereal/flour bins and elevators.

Target Pests: The pests that are controlled by aluminum phosphide are africanized honey bee, almond moth, angoumois grain moth, bean weevil, diseased bees, cadelle, cereal leaf beetle, cigarette beetle, confused flour beetle, dermestid beetles, driedfruit beetle, driedfruit moth, european grain beetle, flat grain beetle, flatheaded grain beetle, fruit flies, granary weevil, greater wax moth, hairy fungus beetle, hessian fly, honey bee, indian meal moth, khapra beetle, lesser grain borer, maize weevil, mediterranean flour moth, mosquitos, pea weevil, pink bollworm, raisin moth, red flour beetle, rice

weevil, rust red grain beetle, rusty grain beetle, sawtoothed grain beetle, spider beetles, tobacco moth, tracheal mite, wax moth, yellow meal worm, chipmunks, gophers, ground squirrels, house mice, marmot, meadow vole, mice, moles, norway rats, prairie dogs, rodents, roof rats, woodchucks, and yellow-bellied marmot.

Formulation Types Registered: dust (57-60%), granular (55%), and pelleted/tableted (55-60%)

Method, Rates and Timing of Application:

The type of formulation and method of application a handler selects are dependent on the commodity and the structure being fumigated. In all cases, the metal oxide is converted to phosphine gas when it reacts with atmospheric moisture. A common method of application is to spread tablets or pellets along the surface of a commodity by hand or to probe to the center through a pipe into the commodity. In this case, tablets are usually preferred to pellets, since typically it takes five times as many pellets as it does tablets to generate an equal quantity of phosphine gas (Allen 1993). Pellets may also be distributed into a commodity using a dispensing machine. Dusts are used when pellets or tablets are prohibited (such as in processed foods or when fumigating a large enclosure and a substantial amount of product is necessary). Tablets and pellets may be prohibited by some processors due to a white dusty residue of aluminum oxide that remains following the fumigation. Dusts are usually contained in paper sachets or pouches. These pouches are often linked in blanket form or belt form. A typical blanket contains 100 pouches which are unrolled by the applicator before application. Trays may also be used to avoid aluminum oxide residues. In such cases, tablets or pellets are placed in trays near the commodity and, hence, any residues following the generation of the phosphine gas will remain in the tray. Frequency of fumigation varies widely, and is dependent on the function of a given facility or holding area, pest pressure, and length of storage. Rates of application vary by pest and use sites with the highest rate being 5.847 lb. per 10,000 cubic feet on a variety of use sites.

Use Practice Limitations:

Some current labels include statements prohibiting application directly to water or wetlands, to areas where surface water is present or to intertidal areas below the mean high water mark. Some labels also require that the product be kept out of lakes, streams, ponds, tidal marshes, and estuaries. Some also contain an endangered species restriction. Many labels also prohibit the contamination of water, food or feed.

For magnesium phosphide:

Type of Pesticide: Insecticide; Rodenticide

Use Sites:
Nonfood and Related Areas:
Magnesium phosphide is registered for use on the following nonfood items and related areas: agricultural uncultivated areas, non-agricultural uncultivated areas, wide area public health uses, wood protection treatment to seasoned and unseasoned forest products, and tobacco. It is also registered for use on stored furs, feathers, hair, leather/leather hides, paper, textiles/fabrics/fibers, and nonfood article treatment.

Food and Related Areas:
Magnesium phosphide is registered for use on the following food/feed crops: temporarily stored food/feed commodities, barley, field corn, millet, oats, rice, rye, sorghum, triticale, wheat, peanuts, soybeans, vegetables, dates, almonds, brazil nuts, cashews, filberts, pecans, pistachios, walnuts, pop corn, sesame, cocoa, coffee, safflower, sunflower, and grass forage. It is also registered for use in commercial transportation facilities, empty or full commercial shipping containers, in food processing plants and on processing plant equipment, in empty containers used for processed feed/food or raw agricultural commodities, in food marketing, storage and distribution premises, and equipment/utensils therein. Further, it is used in empty or full grain/cereal/flour bins/elevators/storage areas as well as used on diseased or empty beehives.

Processed Food:
Magnesium phosphide is registered for use on the following processed foods and related areas: temporarily stored food/feed commodities, candy, cereal flour/bakery mixes, pasta/crackers, cheese/cheese byproducts, chocolate/chocolate byproducts, processed coffee, processed corn, cottonseed, dried egg yolk solids, dried fruits, herbs/spices, livestock feed, malt/malt beverage, dried milk, dried non-dairy creamers, cured meat products, nut meats, oats, rice, soybean flour, sugar, tea, dried vegetables, and yeast. It is also registered for use in commercial transportation facilities, empty or full commercial shipping containers, in food processing plants and on processing plant equipment, in empty containers used for processed feed/food or raw agricultural commodities, in food marketing, storage and distribution premises, and equipment/utensils therein as well as in empty or full grain/cereal/flour bins/elevators/storage areas.

Target Pests: The pests that are controlled by magnesium phosphide are africanized honey bee, almond moth, angoumois grain moth, bean weevil, diseased bees, cadelle, cereal leaf beetle, cigarette beetle, confused flour beetle, dermestid beetles, driedfruit beetle, driedfruit moth, european grain beetle, flat grain beetle, fruit flies, grain weevil, granary weevil, greater wax moth, hairy fungus beetle, hessian fly, honey bee, indian

meal moth, khapra beetle, lesser grain borer, maize weevil, millers, mosquitos, pink bollworm, raisin moth, red flour beetle, rice weevil, rust red flour beetle, rust red grain beetle, rusty grain beetle, sawtoothed grain beetle, spider beetles, tobacco moth, tracheal mite, yellow meal worm, chipmunks, gophers, ground squirrels, meadow vole, mice, moles, norway rat, prairie dogs, roof rat, woodchuck, and yellow bellied marmot.

Formulation Types Registered: impregnated material (56-66%) and pelleted/tableted (66%)

Method and Rates of Application:

Refer to the discussion above regarding aluminum phosphide for information about application methods. Rates of application vary by pest and use site, with the highest rate being 3.197 lb. per 10,000 cubic feet on a variety of use sites.

Use Practice Limitations:

Some current labels include statements prohibiting discharge of effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or public water, and prohibiting discharge of effluent containing this pesticide into sewage systems without notifying sewage treatment plant authorities. Some labels also prohibit application directly to water or wetlands.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of aluminum and magnesium 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, and variability in using data from various information sources.

Based on available pesticide survey usage information for 1987 through 1996, estimated annual usage of aluminum phosphide is about 1.6 million pounds active ingredient (a.i.). Major uses include fumigation of wheat, peanuts and stored corn. Other sites treated include various other commodity sites, and numerous commercial and industrial sites. Usage estimates for this chemical are not precise due to scarcity of usage data sources for post-harvest agriculture and non-agriculture uses/sites.

Based on available pesticide survey usage information for 1987 through 1996, estimated annual usage of magnesium phosphide is more than the 2 to 3 thousand pounds active ingredient (a.i.) used in California. (Usage data in terms of pounds a.i. are not available for sites other than in California.) Major uses include fumigation of almonds and other food commodities. Various commercial and industrial sites are also treated. Detailed usage analysis of this chemical is not possible, because of a scarcity of both post-harvest agricultural

usage data and non-agricultural usage data.

Available use data for aluminum phosphide is presented in Table 2 below. No tabular data is provided for magnesium phosphide given the scarcity of use information for this chemical, as mentioned above.

Table 2: Estimated Annual Use of Aluminum Phosphide

Site	Units Grown (000)	Units Treated (000)		% of Crop Treated		Lb AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ unit/yr	#appl / yr	lb ai/unit /appl	(% of total lb ai used on site)
Almonds (1000 acres)	404	-	-	-	-	9	14	-	-	-	CA: 100%
Almonds (*)	-	-	-	-	-	10	15	-	-	-	CA: 100%
Corn for Consumption											
-empty bin (mill lb.)	48,272	3,379	4,827	7%	10%	27	39	0.008	1.0	0.008	-
-binned (mill lb.)	48,272	17,378	21,722	36%	45%	209	261	0.012	1.0	0.012	-
Food Processing Indoor	-	-	-	-	-	16	24	-	-	-	-
Non Classified	-	-	-	-	-	1	1	-	-	-	-
Oats for Consumption											
-binned (mill lb.)	2,528	253	379	10%	15%	6	9	0.03	1.0	0.03	
Peanuts, stored (1)										-	-
- Oklahoma (tons)	206,900	33,104	49,656	16%	24%	-	-	-	1.0	-	-
- Texas	-	-	-	17%	26%	-	-	-	1.0	-	-
Pistachios	-	-	-	-	-	3	5	-	-	-	CA: 100%
Recreational, Outdoors	-	-	-	-	-	0	1	-	-	-	-
Residential Outdoor	-	-	-	-	-	1	1	-	-	-	-

Site	Units Grown (000)	Units Treated (000)		% of Crop Treated		Lb AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ unit/yr	#appl / yr	lb ai/unit /appl	(% of total lb ai used on site)
Rice, binned (mill lb.)	19,778	593	890	3%	5%	15	22	0.02	2.5	0.01	CA: 20%
Walnuts (1000 acres)	172	-	-	-	-	0	1	-	-	-	CA:100%
Wheat for Consumption (mill lb)											
- Empty bin (1)	51,180	3,583	5,118	7%	10%	29	41	0.008	1.0	0.008	
- Binned	51,180	19,193	23,031	38%	45%	576	691	0.030	2.5	0.012	
- Warehouses Operations (1)	51,180	8,189	10,748	16%	21%	90	118	0.011	1.0	0.011	
Whsale/Manuf/Hosp, Outdoor (*)	-	-	-	-	-	17	26	-	-	-	-
Whsale/Manuf/Other, Indoor (*)	-	-	-	-	-	15	23	-	-	-	-
CALIFORNIA ONLY											
Alfalfa (*)	-	-	-	-	-	1	1	-	-	-	-
Apples (1000 acres)	35	-	-	-	-	1	1	-	-	-	-
Dry beans	-	-	-	-	-	0	1	-	-	-	-
Commodity fumigation (*)	-	-	-	-	-	17	26	-	-	-	-
Fumigation, other (*)	-	-	-	-	-	37	55	-	-	-	-

Site	Units Grown (000)	Units Treated (000)		% of Crop Treated		Lb AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ unit/yr	#appl / yr	lb ai/unit /appl	(% of total lb ai used on site)
Grape (1000 acres)	652	-	-	-	-	4	6	-	-	-	-
Landscape maintenance (*)	-	-	-	-	-	13	20	-	-	-	-
Nursery/Greenhouse (*)	-	-	-	-	-	0	1	-	-	-	-
Prunes (*)	-	-	-	-	-	3	5	-	-	-	-
Right-of-Way (*)	-	-	-	-	-	4	6	-	-	-	-
Safflower (*)	-	-	-	-	-	0	1	-	-	-	-
Storage area/ process equipment (*)	-	-	-	-	-	2	2	-	-	-	-
Structural pest control (*)	-	-	-	-	-	5	8	-	-	-	-
Sudangrass (*)	-	-	-	-	-	1	2	-	-	-	-
Vertebrate pest control (*)	-	-	-	-	-	6	9	-	-	-	-
Wheat, forage (*)	-	-	-	-	-	1	1	-	-	-	-
TOTAL						1,122	1,683				

COLUMN HEADINGS

Wtd Ave = Weighted average, with the most recent years and more reliable data weighted more heavily.

Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA

(*) Units available for treatment and units treated, if given, are measured as volume, weight, area and/or miscellaneous units of the commodity/site.

(1) Usage is in terms of phosphine, which consists of mostly aluminum phosphide but possibly also some magnesium phosphide.

- A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.
- Usage data primarily covers 1987 - 1996.
- Calculations of the above numbers may not appear to agree because they are displayed as rounded:
  to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500.)
  to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%.)
- Small usage (<500 lbs a.i.) is indicated in sources for the following total U.S. sites: office/retail and government, outdoor.
- Small usage (<500 lbs a.i.) is indicated in sources for the following CA sites: animal husbandry premises; apricots; artichokes; asparagus; avocados; barley; beans, green; beehives; Bermuda grass; beverage crops; blackberries; bushberries; carrots; cherries; Chinese leafy vegetables/greens; clover; commercial/institutional areas; corn, forage/sweet; cotton; county agriculture commission sales; feed/food storage; figs; flavoring/spices; food handling; forage/fodder grasses; fruits, dried; garlic; grapefruit; grasses, rye; kiwifruit; lemons; lettuce; nectarines; olives; onions; oranges; orchards; ornamental turf; pasture; peaches; pears; peas; pecans; persimmons; plums; public health pest control; rangeland; raspberries; research commodities; rye; soil application; sorghum; strawberries; sugarbeets; sunflower; sweet potatoes; tangerines; uncultivated areas; and vegetables, misc.

SOURCES --

- Proprietary EPA data, 1987-1996
- CA Use Reports, 1993-1994
- USDA/NASS, 1990-1995
- Commercial/Certified Pesticide Applicators Survey (CCPAS), Research Triangle Instit., 1993 data
- Oklahoma State Univ., Current Management Practices and Impact of Pesticide Loss in the Hard Red Wheat Post-Harvest System, 1992 data
- Oklahoma State Univ. and Texas A&M Univ., Use of Pest Management in Stored Peanuts in OK and TX, 1994 data
- Kevric Company, Market Analysis of Postharvest Pesticide Use, December 1997

D. Data Requirements

Data required for the reregistration of aluminum and magnesium phosphide are outlined in 40 CFR 158.150 through 158.740 for those uses supported by the registrant. There have been two (2) data call-ins (DCI) for this chemical. The first issued on August 6, 1990, required product chemistry data. The second was issued April 6, 1993 for sub-chronic neurotoxicity, chronic toxicity/oncogenicity, reproductive toxicity, rat dominant lethality, and usage data. Appendix B includes all data requirements identified by the Agency which are required to support reregistration of currently registered uses.

E. Regulatory History

Aluminum Phosphide

Development of aluminum phosphide as a source of phosphine gas for fumigation was pioneered by the German company Degesch. Aluminum phosphide first was registered as a pesticide in the U.S. in 1958 to Hollywood Termite Control Company, Inc. Although the registrant's name was changed subsequently, the original U.S. aluminum phosphide registration remains active. Currently there are 23 products containing aluminum phosphide as the active ingredient registered as pesticides in the U.S. All of these aluminum phosphide products have been classified as restricted use due to "Inhalation Hazard to Humans" (40 CFR, §152.175).

In October of 1981, EPA issued a Pesticide Registration Standard which discussed safety data and labeling for products containing aluminum phosphide. EPA also issued a data call-in associated with the Registration Standard for aluminum phosphide. Subsequently, EPA's Office of Pesticide Programs issued PR Notice 84-5, a "LABEL IMPROVEMENT PROGRAM FOR FUMIGANTS" and PR Notice 85-6, which partially revised PR Notice 84-5, but did not alter the portions of PR Notice 84-5 that pertained to aluminum phosphide.

In February of 1986, EPA announced an "Amended Reregistration Standard Process" for pesticides containing aluminum phosphide as the active ingredient. That action was precipitated by the Agency's having completed review of the data developed in response to the data call-in associated with the 1981 Registration Standard. In October of 1986, EPA announced another "Amended Reregistration Standard Process" which was intended to supersede the 1981 Registration Standard, PR Notices 84-5 and 85-6, and the amended standard for aluminum phosphide issued earlier in 1986. The second amended standard issued in 1986 required additional data submissions and labeling changes for aluminum phosphide and magnesium phosphide products.

40 CFR §180.225 identifies tolerances in raw agricultural commodities for residues of phosphine gas resulting from postharvest applications and preharvest burrow treatments with aluminum phosphide. 40 CFR §185.200 and §186.200 identify tolerances in processed foods and animal feeds for phosphine resulting from use of aluminum phosphide.

Magnesium Phosphide

Magnesium phosphide was first registered as a pesticide in the U.S. in 1979. Currently, there are four pesticide products containing this active ingredient registered in the U.S. All pesticide products containing magnesium phosphide as an active ingredient have been classified for restricted use due to "Inhalation Hazard to Humans" (40 CFR, §152.175).

In 1982, EPA announced a Registration Standard for magnesium phosphide. PR Notice 84-5 included labeling statements that were to be incorporated into the labeling of magnesium phosphide products. PR Notice 85-6 did not alter these statements.

In February of 1986, EPA announced an "Amended Reregistration Standard Process" for Magnesium Phosphide. The "Amended Reregistration Standard Process" of October 1986, which pertained to magnesium phosphide as well as to aluminum phosphide, superseded the documents for the individual chemicals issued earlier in the same year, and imposed additional data and labeling requirements for both metallic phosphides.

40 CFR §180.375 identifies tolerances in raw agricultural commodities for residues of phosphine gas resulting from postharvest applications and preharvest burrow treatments with magnesium phosphide. 40 CFR §185.3800 and §186.3800 identify tolerances in processed foods and animal feeds for phosphine resulting from use of magnesium phosphide.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

Aluminum and magnesium phosphide are fumigants used primarily for indoor fumigation of raw agricultural commodities, animal feeds, processed food commodities, and non-food commodities in sealed containers or structures to control insects, and for outdoor fumigation of burrows to control rodents and moles in non-domestic areas, noncropland, and agricultural areas. The empirical formula, molecular weight, CAS Registry number, and Shaughnessy number for aluminum phosphide and magnesium phosphide are provided in Table 3.

Table 3. Product Chemistry Description of Aluminum Phosphide and Magnesium Phosphide

	Aluminum Phosphide	Magnesium Phosphide
Empirical Formula	AlP	Mg_3P_2
Molecular Weight	57.96	134.9
CAS Registry Number	20859-73-8	12057-74-8
OPP Chemical Number	066501	066504

2. Identification of Active Ingredient

Aluminum and magnesium phosphide are formulated with inert ingredients to form grayish green or black to yellow granular or powdered solids with a carbide/garlic odor and melting point of >1000 ^{O}C. Aluminum and magnesium phosphide are relatively stable if protected from moisture, but readily release phosphine gas upon contact with moisture from the air, water, or acids. Formulated solid aluminum and magnesium phosphide are insoluble but highly reactive in water and most solvents, and decompose releasing phosphine gas in acidic and alkaline media. Since pure aluminum and magnesium phosphide is not stable, product chemistry data has been waived in these cases.

3. Manufacturing-Use Products

There are no manufacturing-use products (MPs) registered under Shaughnessy Nos. 066501 and 066504. The Agency has identified 28 aluminum phosphide end-use products (EPs), and four magnesium phosphide EPs. The Agency has determined that because there are no registered MPs containing aluminum or magnesium phosphide as the sole active ingredient (TGAI), all registered EPs containing aluminum or magnesium phosphide as the sole active ingredient are subject to a reregistration eligibility decision.

Additional product-specific data are required to fulfill product chemistry data for aluminum phosphide and magnesium phosphide EPs. The registrants must submit the data required for the aluminum phosphide 55-60% EPs and magnesium phosphide 56-66% EPs, and either certify that the suppliers of beginning materials and the manufacturing processes for the aluminum and magnesium phosphide EPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages.

B. Human Health Assessment

1. Hazard Assessment

The available toxicological database for aluminum and magnesium phosphide is adequate and will support reregistration eligibility for currently registered uses. The

test material of concern is phosphine gas which is the material with pesticidal properties, when either aluminum or magnesium phosphide are used. Exposure assessments do not indicate a concern for a potential dietary risk because residues of phosphine are not expected in food or drinking water. Therefore, the typical toxicological database for a food use chemical is not required.

Since the route of exposure of concern is inhalation many values are expressed in ppm while others are reported in mg/L. The following table should be used as a reference for conversion between these two units.

Table 4. Conversion of Parts per Million to Milligrams per Liter

Parts per Million		Milligrams per Liter	
0.2	ppm	0.0003	mg/L
0.3	ppm	0.0004	mg/L
1	ppm	0.001	mg/L
1.25	ppm	0.002	mg/L
2.5	ppm	0.0035	mg/L
3	ppm	0.0042	mg/L
4.5	ppm	0.006	mg/L
4.8	ppm	0.0068	mg/L
5	ppm	0.0071	mg/L
5.5	ppm	0.008	mg/L
6.7	ppm	0.009	mg/L
7.5	ppm	0.011	mg/L
10	ppm	0.014	mg/L
13	ppm	0.018	mg/L
15	ppm	0.021	mg/L
18	ppm	0.025	mg/L
20	ppm	0.028	mg/L
23	ppm	0.032	mg/L
30	ppm	0.042	mg/L
40	ppm	0.057	mg/L
83	ppm	0.117	mg/L

a. Acute Toxicity

Phosphine gas produced from aluminum and magnesium phosphide has been tested for acute toxicity by the inhalation route of exposure. No significant exposure to phosphine gas are expected via the oral or dermal routes. Results of the acute inhalation toxicity study (MRID# 41377001) found that the LC_{50} is greater than 11 ppm (approximately 0.014 mg/L), placing it in Toxicity Category I. This was the highest dose tested. The results obtained in this study satisfy the acute toxicity data requirements since

inhalation exposure is the route of concern. In addition, a study by Waritz and Brown (1969) showed phosphine to be a highly toxic gas with a 4-hour LC_{50} = 0.014 mg/L (approximately 11 ppm). Given aluminum and magnesium phosphide's use patterns and chemical characteristics, the other 81-series guideline studies were waived for this chemical. Additional information regarding these waivers is provided in the table below which summarizes the results of the acute toxicology studies.

Table 5. Acute Toxicity of Phosphine Gas

Guideline No.	Study Type	MRID	Results	Toxicity Category
81-1	Acute Oral	No study	--	NA
81-2	Acute Dermal	No study	--	NA
81-3	Acute Inhalation	41377001	$LC_{50>}$ = 11 ppm (hdt)	I
81-4	Primary Eye Irritation	No study	--	NA
81-5	Primary Skin Irritation	No study	--	NA
81-6	Dermal Sensitization	No study	--	NA

NA = not applicable

b. Subchronic Toxicity

A 90-day inhalation study (MRID 41413101) was conducted with male and female Fischer 344 rats exposed via inhalation to phosphine using the following three different exposure regimens: I) 0, 0.3, 1.0 or 3.0 ppm, 6 hours/day, 5 days/week for 13 weeks; II) initiated on study Day 48 at 0 or 10 ppm (after 3 days of exposure 4 of 10 females died and therefore this group was terminated); and III) initiated on study Day 75 with additional groups of rats at 0 or 5 ppm for 15 days; exposure was terminated on study Day 90. For each exposure regimen, recovery groups were included in the study and these groups were sacrificed after 4 weeks of post-exposure observations.

In the 5 ppm for 15-day exposure regimen (regimen III), there were no treatment-related effects on survival, body weight, food consumption, ophthalmological or hematological parameters. No treatment-related histopathological lesions were seen in either sex. Males exhibited statistically

significant increases in alkaline phosphatase activity and blood urea nitrogen. These increases, however, were not considered to be biologically significant since: 1) similar increases were not seen in females ; 2) there were no corroborative histopathological lesions in the kidneys; and 3) the effect did not persist after recovery.

In rats exposed at 10 ppm for 3 days (regimen II), there was 80% mortality in females but no mortality in males. Both sexes of rats exhibited coagulative necrosis in the tubules of the kidneys and pulmonary congestion was observed in the females that died. A LOEL of 10 ppm for four weeks was based on lethality (80% deaths for females) due to the sharp dose-response curve for acute toxicity.

In the 13-week exposure regimen (regimen I), there was no mortality in either sex at any concentration tested. There was a transient decrease in body weight gain accompanied by decreased food consumption. Red blood cell counts, hemoglobin concentration, and hematocrit values were slightly decreased in males at 3.0 ppm (at 4 weeks only), but no effects were observed in these males at 13 weeks or in females at either interval. No exposure-related gross or histologic findings were observed at levels up to and including 3.0 ppm. A LOEL for subchronic exposure (13 weeks) was not established in this study. The NOEL was 3 ppm (the HDT).

c. Chronic Toxicity and Carcinogenicity

Two year rat feeding study

In a two-year rat feeding study (Hackenberg, accession nos. 26937, 26938, 6000), diets were treated with aluminum phosphide pellets at 48 and 90 gm/metric ton, fumigated for 48 hours and 72 hours, mixed for 2 hours, and then aerated for one hour. The feed was then stored frozen in small sealed containers until used as laboratory rat feed. Sixteen separate batches of feed were treated utilizing this methodology over the two-year period. Samples of diet were taken to determine phosphine at the time the feed was removed from the freezer. Phosphine levels ranged from 0.2 to 7.5 ppm and averaged approximately 1 ppm. The amounts of phosphine that remained in the feed offered to the rats as food was not measured (but would be expected to be less because of dissipation). Therefore, the actual dosages in this study are unknown. Two groups of 60 rats each (30 males and 30 females) were used, one as the treatment group and the other as controls. Rats were observed for effects on growth, food consumption, survival, morbidity, hematology, blood chemistry and gross and microscopic pathology. No differences were seen between the controls and the treated animals for any toxicity parameter. No evidence of carcinogenicity was seen.

The study was not considered an acceptable guideline study since toxicity, resulting from phosphine residues, is not possible when aeration is adequate. However, the study is acceptable for showing that toxic levels of residues were not achieved even with the high fumigation treatment rates with adequate aeration.

Two year rat inhalation study

In a chronic toxicity/carcinogenicity study (MRID 44415101), Charles River Fischer CDF Rats (60/sex/group) were exposed to phosphine under dynamic chamber conditions at levels of 0, 0.3, 1, or 3 ppm of phosphine. The rats were kept under standard laboratory conditions, observed twice daily, and sacrificed (10/sex/group) during week 52 of the study. Body weights (weekly), food consumption (weekly), routine hematologic, serum biochemical, and urinary analyses were all similar to control animals.

There were no adverse effects observed for the initial twelve month period. Body weights (taken weekly); food consumption (weekly); routine hematologic, serum biochemical, and urinary analyses were all similar to control animals. Ophthalmological observations, gross pathology, organ weights, and histopathology indicated no adverse effects from the phosphine exposures.

These results are based on an interim report for a two-year study which should be completed by November 1998. Thus, the study is considered upgradable, pending receipt and favorable review of the remaining data. The NOEL for the 52-week period was 3.0 ppm, the HDT.

d. Developmental Toxicity

In a developmental study (MRID 41377002), CD derived Sprague Dawley mated female rats (24-27/dosage group) were exposed in inhalation chambers to concentrations of phosphine gas at 0, 0.03, 0.3, 3.0, 5.0, or 7.5 ppm, 6 hours per day on gestation days 6 through 15. The highest exposure group (7.5 ppm) was terminated after 10 days of exposures due to high mortalities (14/24). Treated females were observed twice daily for toxicity; and body weights and food consumption were monitored throughout the study. At day 20 post-coitus, females were sacrificed and examined for corpora lutea, implantations, live and dead fetuses, and early and late resorptions. Pups were identified, sexed, and examined for external malformations and visceral and skeletal defects.

The females and their fetuses from the high dose group were not examined for developmental effects. The only abnormalities observed were

increased absorptions in litters (16 litters, 76 pups). Increased resorptions were not seen in the 0.3, 3.0, or 5.0 ppm groups. All other observations were comparable to the control females and pups. The maternal NOEL is 5 ppm and the maternal LOEL is 7.5 ppm, based on the high incidence of maternal deaths. The study was classified as acceptable and satisfies the requirements for developmental toxicity in rats.

e. Reproductive Toxicity

This study, a requirement for a food-use pesticide, was waived since residues of phosphine are not expected in food or drinking water.

f. Mutagenicity

Gene Mutations

In a *Salmonella typhimurium* reverse gene mutation assay (MRID 41434301), the test was negative with hydrogen phosphide (PH_3) in all strains up to cytotoxic concentrations ($\geq$488 ppm/plate +/-S9).

Chromosome Aberrations

In an *in vitro* cytogenetic assay with Chinese hamster ovary (CHO) cells (MRID No. 41434302) phosphine was positive at 2500 and 5000 ppm without S9 activation. This resulted in a significant, but not dose-related increases in the frequency of cells with structural chromosome aberrations. Significant clastogenic effects were also noted at 2500 ppm with S9 activation, but not at the highest dose tested (5000 ppm). Although there are limitations in this study, it is considered acceptable for regulatory purposes because of the apparent induction of chromosomal damage by phosphine at non-cytotoxic doses.

Other Genotoxic Mechanisms

In an *in vivo* unscheduled DNA Synthesis (UDS) in primary rat hepatocytes (MRID No. 42788101), the test was negative in male Fischer rats exposed via inhalation to phosphine gas doses of 0, 4.8, 13, 18, or 23 ppm (equiv. to 0, 11.4, 30.8, 42.6 or 54.5 mg/m^3, respectively) for 6 hours. Overt toxicity (i.e., difficulty in breathing), but no target cell cytotoxicity, was observed at the highest dose tested.

Occupational Exposure Mutagenicity Studies

In a human genotoxicity study (Garry et al, 1989), an analysis of chromosome aberrations and sister chromatid exchanges (SCE) in peripheral

lymphocytes in workers was conducted. The following groups were studied:

a) workers exposed to phosphine alone;
b) workers exposed to phosphine and other pesticides;
c) workers exposed to other pesticides and fumigants;
d) state grain workers, and;
e) controls.

Lymphocytes were also exposed to phosphine *in vitro* at different concentrations and chromosome aberrations were analyzed at different times after exposure.

Male fumigant applicators who, 6 weeks to 3 months earlier, were exposed to phosphine and other pesticides had significantly increased stable chromosome rearrangements, primarily translocations in G-banded lymphocytes. There was no increase in sister chromatid exchanges due to fumigation activities. Less stable aberrations, including chromatid deletions and gaps, were significantly increased only during the application season, but not at this later time point. During fumigant application, measured exposure to phosphine exceeded accepted national standards.

Several limitations are noted in this study. First, the mix of exposures in the different groups was not adequately documented. Second, there was no effort to account for whether mitosis was halted in early phases of division or after several mitotic cycles. This is important because many types of chromosome alterations are unstable in that they are lost during the process of cell division, and/or the cells containing the aberration fail to divide or are otherwise killed. Third, there were no SCE differences in the exposure groups. SCE damages should have paralleled chromosomal aberrations.

Based on the findings reported by Garry et al. (1989) that pesticide applicators exposed to phosphine had increased levels of chromosome damage, the Agency sponsored a series of acute (Kligerman et al.1994a) and subacute (Kligerman et al.,1994b) inhalation cytogenetic studies with phosphine. A summary of these studies follows.

(a) Phosphine was negative for the induction of micronucleated polychromatic erythrocytes (MPE) in bone marrow cells and splenocytes and negative for the induction of sister chromatid exchange or chromosomal aberrations in splenocytes of CD-1 male mice exposed by inhalation to 0, 5, 10 or 15 ppm for 6 hours. Overt toxicity, manifested as lethargy and shallow breathing, was seen at the highest dose tested. There was a dose-related and significant reduction of splenocyte cell cycling at all levels, which indicates that phosphine was cytotoxic to splenocytes. There was, however, no adverse effect on bone marrow cells (MRID 43315103).

(b) As part of the Research Triangle Park-sponsored studies, male B6C3F1 mice and male F344 rats were exposed by inhalation to 0, 1.25, 2.5 or 5.0 ppm phosphine, 6 hours/day, 5 days/week over a 11-day period. Bone marrow cells and/or peripheral blood lymphocytes were harvested and examined for sister chromatid exchanges and chromosomal aberrations (mouse and rat peripheral blood lymphocytes) and for MPEs (rat bone marrow and mouse bone marrow and peripheral blood lymphocytes). In addition, B6C3F1 males were exposed via inhalation to 0 or 5 ppm as above over a 12-day period and mated with untreated females in a dominant lethal assay. Results show that phosphine was not genotoxic at any endpoint. While there was no evidence that the test material reached the target sites in potentially genotoxic concentrations, dosing was considered adequate based on the data from other submitted guideline studies (MRID 43315101).

Non-guideline studies

Additional *in vivo* data summarized below were available for review:

a) Following subchronic inhalation exposure (0, 0.3, 1.0 or 4.5 ppm, 6 hours/ day, 5 days/week for 13 weeks) but not acute inhalation exposure (0 or 5.5 ppm, 2 weeks, 6 hours/day, 5 days/week for 2 weeks), phosphine at 4.5 ppm caused a statistically significant increase in MN induction in the spleen lymphocytes and bone marrow cells of Balb-c male and female mice. There was, however, no increase in gene mutations at the HPRT locus in the recovered spleen lymphocytes (MRID 43315102).

b) After 6 hours of inhalation exposure, phosphine, at the highest dose tested (19 ppm), induced a significant increase in chromosomal aberrations in the bone marrow of Sprague Dawley male rats, but not in the female rats. The effect is considered equivocal because increased chromosomal aberration frequencies were only seen in high-dose males with severely reduced mitotic indices (MIs). Females did not show increased chromosome aberrations and did not have decreased MIs. There was also no effect on peripheral lymphocytes (MRID No. Not assigned).

c) In an Australian study of workers exposed to phosphine (Barbosa, 1994), 31 phosphine fumigators and 21 controls, all employed at the New South Wales Grain Corporation, were examined for micronucleus incidence in peripheral blood lymphocytes and their concentrated urine was assessed for mutagenicity in TA100 and TA98 strains of *S. typhimurium*. In addition, serum bile acids were measured. The subjects, all males, were matched for medication, X-ray exposure within the past year, and smoking habits. There was no indication how often the fumigators were exposed, the most recent exposure date, or the length of employment of the various fumigators. No individual data were presented to identify if certain individuals showed

unusually high micronuclei incidence, or presence of mutagens in the urine.

For analysis, urine samples were concentrated 75-fold and the procedure of Yamaski and Ames (1977) was used to test mutagenicity to TA100 and TA98 in the presence or absence of metabolic activation (S9). No increase in the mutagenicity of urine from the fumigators (N=-27) vs controls (N=-19) in this assay was observed. Similarly, no changes related to phosphine exposure were observed in serum bile acids. Cholesterol and some liver enzymes (gamma-glutamyl transferase) were elevated in the exposed group.

Micronuclei formation was measured in isolated peripheral blood lymphocytes cultured for 44 hours in the presence of phytohemagglutinin to stimulate mitosis, arrested at metaphase with cytochalasin-B, and harvested by cytocentrifugation after 72 hours in culture. The micronucleus incidence was comparable among the fumigators and the control groups (overall MI for fumigators = 6.9 vs 7.1 for controls).

Conclusion:

Phosphine is not mutagenic in bacteria but is clastogenic *in vitro*. Both the negative Ames test and the positive Chinese hamster ovary cell chromosome assay are consistent with the *in vitro* test results for zinc phosphide. Zinc phosphide also produces phosphine gas as its active agent. Studies conducted *in vivo* indicate that phosphine is not clastogenic in mice or rats and does not cause dominant lethal mutations in mice following acute exposures for up to 2 weeks. There is, however, evidence that inhalation exposures of phosphine for up to 13 weeks induced significant clastogenic and/or aneuploidogenic effects in male and female mice. The biological relevance of this finding cannot be fully ascertained until the results of the 2-year rat inhalation study currently underway are submitted and reviewed. However, a one-year interim report reviewed by the Agency indicated no concerns. The acceptable studies satisfy the pre-1991 mutagenicity initial testing battery guidelines. No further testing is required at this time.

g. Metabolism

No studies were submitted nor required.

h. Dermal Absorption

Because the route of exposure anticipated for aluminum and magnesium phosphide is inhalation, the Agency does not expect significant dermal exposure. Therefore, dermal absorption studies are not required.

i. Neurotoxicity

Acute

In an acute neurotoxicity study (MRID 44139001), 11 Crl:CD®BR VAF/Plus® rats/sex/exposure group were exposed to 0, 20, 30, or 40 ppm of phosphine (1% a.i. in nitrogen) for four hours. Each treatment group was exposed via inhalation on a different day, with the first exposure occurring six days prior to the final exposure. Eleven rats/sex/exposure group were selected for functional observational battery (FOB) and motor activity (MA) testing prior to and following exposure, and on days 7 and 14 post-exposure; six rats/sex/exposure group were perfused for neuropathology.

All animals survived to scheduled termination. There were no exposure-related clinical signs. FOB and MA parameters were characterized by variability both within and among control and exposed groups; this variability (which may be partly due to the unbalanced treatment schedule) confounded interpretation of some of the results.

Palpebral closure was noted in some exposed groups on day 1 and was significant in females exposed to 30 and 40 ppm and in males at 20 and 40 ppm. Body temperatures were significantly lowered for males and females on day 1 in all exposure groups. The remainder of the differences in the FOB parameters were random statistical variations that occurred both pre- and post-test, were not dose related, or were not consistent between the sexes.

Motor activity (horizontal, vertical, total distance, and stereotypic time) was decreased at 20, 30, and 40 ppm, primarily during the 10 and 20 minute post-exposure time intervals (data comparing motor activity for the entire 30-minute assessment period was neither presented nor analyzed). With one exception, these reductions no longer occurred at 7 or 14 days after exposure. For males during the first 10-minute post-exposure interval, horizontal activity decreased significantly by 76.4, 71.7, and 83.8% in the 20, 30, and 40 ppm groups, respectively. Males in the 20 ppm group had the following decreases in horizontal activity: 76.4%, 77.6% (both statistically significant), and 89.4% (non-statistically significant) during the 10, 20, and 30 minute intervals, respectively. For females during the first 10-minute post-exposure interval, horizontal activity decreased significantly by 71.3, 48.0, and 83.5% in the 20, 30, and 40 ppm groups, respectively. Females in the 20 ppm group had the following decreases in horizontal activity: 71.3%, 85.8% (both significant), and 54.1% (non-statistically significant) during the 10, 20, and 30 minute intervals, respectively. Similar decreases occurred for both sexes for vertical activity, total distance, and stereotypic time. No phosphine-related neuropathological changes were observed in any exposure group. Significant increases in absolute and relative (body and brain weights) adrenal gland

weights in males from the 40 ppm group were of questionable biological significance and did not show a concentration-response relationship.

Major deficiencies in study design and reporting, along with the absence of appropriate positive control data, raise questions about the conduct of this study. However, the significant decrease in temperature and motor activity, seen at all exposure levels in spite of the flaws in the study, are considered treatment-related.

The LOEL for neurobehavioral findings is 20 ppm based on decreased body temperatures and decreased motor activity in males and females. For acute neurotoxicity the NOEL is <20 ppm. Based on lack of systemic toxicity, the NOEL for systemic toxicity is 40 ppm. This acute inhalation neurotoxicity study is classified unacceptable and does not satisfy the guideline requirement for an acute inhalation neurotoxicity study (81-8) in rats. However, the study is upgradable. An upgraded study was received by the Agency in September 1998 and is currently being reviewed.

Subchronic

In a subchronic inhalation neurotoxicity study (MRID 44210401), 16 Crl:CD®BR VAF/Plus® rats/sex/exposure group were exposed to phosphine (1% a.i. in nitrogen) for six hours/day, 5 days/week, for approximately 90 days at 0, 0.3, 1, or 3 ppm. An additional six rats/sex were assigned to the 0 and 3 ppm groups for a two-week recovery group. Eleven rats/sex/exposure group were assigned for neurobehavioral evaluations. Six of the eleven rats/sex/exposure group were designated for neuropathological evaluations.

No exposure-related deaths occurred in this study. Body weights were slightly higher in high-concentration males (2.4%) and females (1.2%) after 13 weeks of treatment, and became equal or less than the control body weights after the 2 week recovery period. Palpebral closure was consistently increased in high-concentration animals compared to controls. The increase was significant ($p \leq 0.05$) in high-concentration males at week 4 and was exposure related. The increased palpebral closure in high-concentration females was not significantly different from the control group. The incidence of high-concentration males found sleeping was consistently higher than the controls and was significantly higher ($p \leq 0.05$) at week 4. The sleep incidence in males showed an exposure effect at weeks 4 and 13. A similar trend was seen in females, but the differences were not statistically significant. Body temperatures of high-concentration males were consistently lower than the controls and reached statistical significance ($p \leq 0.05$) at week 13. The decreased body temperature was exposure-related at weeks 4 and 13. Females did not show a treatment-related change in body temperature. The horizontal and vertical motor activities were significantly lower in high-

concentration males than the control group at week 13, and were consistently, but not significantly lower at other time intervals. Motor activity measurements in females were compromised by high variations and significant decreases in the high-concentration group at the pretest interval. There were no treatment-related findings at necropsy or during the neurohistopathological examination of collected tissues.

The effects seen in high-concentration males that could be treatment-related are slight, but are consistent and mutually supportive. Effects in females either did not occur, were not statistically significant, or were compromised by variations in pretest measurements. Due to the equivocal nature of the effects seen in high-concentration males, and the lack of effects seen in females, the tentative NOEL for systemic/neurobehavioral findings is 3.0 ppm for males and females and a LOEL was not determined in this study. Since the procedures used in this study have not been validated, and positive effects may be obscured by insensitive methods, the NOEL is tentative and will be re-evaluated upon receipt of information requested from the sponsor. This subchronic neurotoxicity study is classified unacceptable and does not satisfy the guideline requirement for a subchronic neurotoxicity inhalation study (82-7) in rats. However, the study is upgradable. An upgraded study was received by the Agency in September 1998 and is being reviewed.

j. Epidemiological Information

The following data bases have been searched for the poisoning incident data on the active ingredient aluminum phosphide:

1) OPP Incident Data System (IDS) - This database contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, which have been submitted to OPP since 1992.

2) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin, and respiratory), likelihood of a causal relationship, and number of days off work and in hospital are provided.

3) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive, has been prepared. The total number of calls was

tabulated for the categories; humans, animals, calls, incidents and others.

Detailed descriptions of 166 cases submitted to the California Pesticide Illness Surveillance Program (1982-1994) were reviewed. In 162 of these cases, aluminum phosphide was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. A review of these cases shows that the majority of cases appear to involve illnesses to workers who entered areas previously treated with aluminum phosphide. These areas included buildings, fields, tarps, and chambers. These incidents indicate that aluminum phosphide is capable of causing serious illness after fumigation, including difficulty in breathing, headache, nausea, vomiting, abdominal cramps, and even death. From 1982-1994 aluminum phosphide was ranked 15th as a cause of systemic poisoning, 7th as a cause for hospitalization, and 7th as the most frequent cause of systemic poisoning among agricultural workers. Twenty-one individuals were hospitalized between 1982 and 1994. A large proportion of cases occurred when people returned to fumigated structures to reopen and ventilate. Often, exposure results from lack of proper protective equipment and inadequate ventilation before persons are allowed in or near the treated area. Residential illness or death has largely resulted from accidental exposure, product misuse, and proximity to facilities which regularly fumigate with aluminum or magnesium phosphide. Instructions on proper disposal and storage of these products are critical to prevent explosions and fires that result in damage to health and property.

Coincidental systemic and coincidental eye categories were associated with the majority of the exposures reported in California. Such coincidental cases typically occur when bystanders are accidently exposed. Out of a total of twenty-two systemic coincidental exposures, sixteen workers became ill after their almond sorting building was fumigated the previous day. Symptoms included headache, nausea, vomiting, chills, abdominal cramps, weakness, dizziness, and difficulty breathing. Out of the twenty-five coincidental eye exposures, fourteen workers experienced eye irritation after their storage building was fumigated the previous weekend. Symptoms included red and watery eyes, and nasal secretions. The other eleven workers out of the twenty-five coincidental eye exposures had re-occurring eye irritations while working in an almond/pistachio processing plant.

Detailed review of the types of activities associated with incidents suggests a number of patterns that may be amenable to mitigation through improved label warnings. Improper handling or disposal of aluminum phosphide tablets has resulted in fires and explosions leading to eight incidents involving 19 people. Workers responsible for opening fumigated structures or removing tarps have been involved in 15 incidents. Applications to kill gophers or squirrels have resulted in 13 incidents of poisoning. A detailed

discussion of aluminum phosphide poisoning incidents is presented in Appendix G.

Several specific incidents that have come to the Agency's attention which have been allegedly related to phosphine are of special concern to the agency.

On July 7, 1991, EPA headquarters was notified by Region 8, Denver, Colorado, of a potential grain fumigant use problem in North Dakota. In August, 1989, a woman died that lived in close proximity to a grain fumigation operation. Her husband was treated at a medical facility in October, 1989 for possible organophosphate poisoning. The couple had complained about the fumigation operation since December, 1985. The two cases were based on: (1) a review of epidemiology, environmental, and health case material referred to headquarters from the Denver Regional Toxicologist; and (2) supplemental case files provided by State of North Dakota personnel. Both of these cases were considered possible pesticide poisoning incidents, based on information presented in the files, and using standard rankings terminology for human poisoning incidents. In the first case, Mrs. O'Brien's death, the role of heat and chronic grain dust exposure are unclear and her death could have resulted from other factors. In the second case, possible poisoning, Mr. O'Brien reported symptoms of loss of peripheral motor control (uncontrollable shakiness of the hands and feet), diarrhea, headache, burning gums, lips and teeth, skin irritation, dry mouth and throat, and watering eyes during his hospitalization on October 7, 1989. These reported symptoms were worse when the aerator of the fumigation facility was operating about three hundred fifty feet from their home. October, 1989, had the highest monthly use of aluminum phosphide. Based on the available evidence the Agency concludes that both of these incidents were possibly related to aluminum phosphide.

Garry et al. (1993) reported the suspicious death of a pregnant rural woman who lived 30 yards from a large bunker-type grain storage facility. Reportedly, the facility was not tightly sealed in contrast to standard practice. The woman reportedly was removing laundry in here yard sometime between 8 p.m. and 9 p.m. the evening she died. Upon reentering her home she told her husband that the odor was "real strong tonight". After her husband and child went to bed in an upstairs bedroom the patient remained on the first floor of the structure. Between 10:30 and 11 p.m. she visited her local physician at his home stating to him that she was "dying". The physician noted on examination that the patient was tachycardic, vomiting and lucid. Clear frothy sputum began to emanate from her mouth and nostrils. She was then transferred to a hospital where she suffered from cardiac arrest shortly after midnight and died.

2. Dose Response Assessment

a. Determination of Susceptibility

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA 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 the Agency to consider information concerning the susceptibility of infants and children to pesticide residues in food, and 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.

The FQPA amendments to section 408(b)(2)(C) require the Agency to apply a 10-fold safety factor to protect infants and children unless reliable data demonstrate that the factor can be reduced or removed. In determining whether the safety factor should be retained, reduced, or removed, the Agency considers all reliable data and makes a decision using a weight-of-evidence approach, taking into account the completeness and adequacy of the toxicity database, the nature and severity of the effects in pre- and post-natal studies, and other information such as epidemiological data.

A prenatal inhalation developmental toxicity study in rats (MRID 41377002) to determine susceptibility of infants and children to aluminum and magnesium phosphide showed no increased susceptibility to infants and children. No treatment-related effects were seen in maternal body weight, body weight gain, food consumption, and reproduction parameters at necropsy. Further, no developmental toxicity was seen. Thus it was determined that there is no increased susceptibility following in utero exposure to phosphine gas. (Hazard Identification And Review Committee (HIARC), April 16, 1998 and June 2, 1998 meetings)

The complete toxicology data requirements for a food-use chemical are not required for aluminum and magnesium phosphide since little phosphine exposure is expected from the use pattern (i.e. fumigant). Any phosphine left in fumigated commodities is expected to be removed by adequate aeration of the commodities. Bound reaction products formed by reactions with phosphine and biological materials form innocuous phosphates. Therefore, the Agency determined that additional toxicology studies are not required for this chemical.

The FQPA Safety Factor Committee also addressed dietary (food and water) and residential exposure considerations. Detectable residues in food have been reported in field trials. However, these detections were attributed to misapplication (pellets applied directly to wheat grain resulting in residues

of up to 83 ppm after 24 hours of aeration). Residues of phosphine are not expected with proper use of these chemicals. A drinking water risk assessment was not performed for aluminum and magnesium phosphide since there are no concerns for ground or surface water contamination from the use of these chemicals. This will be discussed in more detail later in this document. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed..

Therefore, the Agency concluded that the 10x factor for increased susceptibility of infants and children (as required by FQPA) should be removed based on the rationale provided below:

(A) there was no indication of increased susceptibility of rats following in utero exposure to aluminum/magnesium phosphide; and

(B) exposure assessments do not indicate a concern for potential risk to infants and children because: 1) residues of phosphine are not expected in food; 2) there is no concern for ground or surface water contamination from this use; and 3) there is a limited registered use at the present time which the Agency has proposed that this use be removed.

b. Toxicological Endpoints for Use in Risk Assessment

Inhalation studies are not normally appropriate for oral (dietary) risk assessments. However, inhalation studies were used in hazard identification for aluminum and magnesium phosphide because: 1) the toxicology database for this chemical was limited to studies conducted via the inhalation route because this is the route of exposure expected for phosphine gas; 2) these are the only studies in which the Agency can quantify the dosage of phosphine exposed to laboratory animals; and 3) use of an inhalation "dose" provides a conservative approach for oral risk assessments. Further, since the oral route of exposure is not of concern, no oral-route studies have been required. (HIARC April 16, 1998 and June 2, 1998 meetings)

(1) Acute Reference Dose (RfD)

The acute dietary endpoint is based upon the results of the 90-day inhalation study (MRID 41413101) described on pages 16-17 of this document. The dose and endpoint for risk assessment was 5 ppm = 0.007 mg/L= 1.8 mg/kg/day based on lack of treatment-related effects following 15 days of exposure in that study. The 5 ppm concentration is appropriate for this acute dietary risk assessment, because: 1) no treatment-related effects were seen at this concentration after 15 days of exposure; 2) no treatment-related effects were seen at a lower concentration (3 ppm) after a longer (13

weeks) duration of exposure; and 3) an oral study was not available in the database because the expected route of exposure is inhalation.

In addition, this concentration (5 ppm) is comparable to the concentration of 6.7 ppm derived by using the LOEL of 20 ppm established in an acute neurotoxicity study in rats and an Uncertainty Factor of 3 for the lack of a NOEL (i.e., 20 ppm ÷3 = 6.7 ppm). The Agency did not elect to use the acute neurotoxicity study since a NOEL was not established in the study; instead, the acute neurotoxicity study was used as a "co-critical" or "support" study. In the acute study (MRID 44139001), Crl:CD rats (11/sex/concentration) were exposed to phosphine at 0, 20, 30, or 40 ppm (1% a.i. nitrogen) for 4 hours. The LOEL for neurobehavioral effects was 20 ppm (the lowest concentration tested) based on decreased body temperature and decreased motor activity in both sexes; a NOEL was not established.

Since an inhalation concentration was selected for oral dietary risk assessment, the following route-to route extrapolation (i.e., inhalation to oral) was used for establishing the acute RfD in mg/kg/day:

To convert the ppm to mg/L/day:

$$\text{mg/L/day @ } 25^0 \text{ C/101 kPa} = \frac{\text{(ppm) x Molecular Weight of Phosphine Gas}}{\text{24,450 (Boyle's gas law)}}$$

$$\text{mg/L/day} = \frac{5 \text{ ppm x } 34 \text{ (MW)}}{24{,}450} = 0.007 \text{ mg/L/day}$$

To convert mg/L/day to mg/kg/day:

mg/kg/day = Concentration (mg/L/day) x Absorption x Conversion Factor x Duration of Exposure x Activity Factor

mg/kg/day = 0.007 mg/L/day x 1.0 x 47.0 x 6 hours x 1.0

Where:

0.007 mg/L/day = Concentration (NOEL)
1.0 = absorption factor (100%, default)
47.0=Conversion Factor [Respiratory Volume (7.15 L/hr) ÷ Body Weight (0.152 kg)].
1.0 = Activity Factor (1, animal default).

An Uncertainty Factor of 100 was applied which included 10X for intra-species variation

and 10X for inter-species extrapolation.

Acute RfD = 1.8 mg/kg/day = **0.018 mg/kg/day**
100 (UF)

(2) Chronic Reference Dose

The chronic reference dose was selected from a 2-year chronic/carcinogenicity inhalation study in rats (MRID 44415101) which is fully described on page 18 of this document. The dose and endpoint for risk assessment was a NOEL = 3 ppm = 0.004 mg/L = 1.13 mg/kg/day. The dose recommended for oral risk assessment is based on an inhalation NOEL. Phosphine has been shown to be toxic via the inhalation route. It is noted that the "dose" recommended is conservative and is recommended as a worst case scenario.

Since an inhalation concentration was selected for oral dietary risk assessment, the following route-to-route extrapolation (i.e., inhalation to oral) was used for establishing the chronic RfD in mg/kg/day:

To convert the NOEL of 3 ppm to mg/L/day:

mg/L/day @ 25^0 C/101 kPa = ppm x Molecular Weight of Phosphine Gas
24,450 (Boyle's gas law)

mg/L/day = 3 ppm x 34 (MW) = 0.004 mg/L/day
24,450

To convert mg/L/day to mg/kg/day:

mg/kg/day = Concentration (mg/L/day) x Absorption x Conversion Factor x Duration of Exposure x Activity factor

mg/kg/day = 0.004 mg/L/day x 1.0 x 47.0 x 6 hours x 1.0

Where:

0.004 mg/L/day = Concentration (NOEL)
1.0 = absorption factor (100%, default)
47.0=Conversion Factor [Respiratory Volume (7.15 L/hr) ÷ Body Weight (0.152 kg)].
1.0 = Activity Factor (1, animal default).

An Uncertainty Factor of 100 was applied which includes 10X for intra-species variation

and 10X for inter-species extrapolation.

Chronic RfD = $\frac{1.13 \text{ mg/kg/day}}{100 \text{ (UF)}}$ = **0.0113 mg/kg/day**

(3) Occupational and Residential Dermal Exposure

Based on the use pattern, the route of exposure of concern is inhalation, not dermal. Consequently, doses and endpoints were not selected for dermal risk assessments. Doses and endpoints were selected only for inhalation exposure risk assessments since this is the route of exposure of concern.

(4) Short Term Inhalation (1 day to 1 week)

The 90-day inhalation study (MRID 41413101) that was also used as the basis of the acute dietary RfD was used as the basis for the short term inhalation risk assessment. The dose selected for risk assessment was 5 ppm based on the lack of treatment-related effects following 15 days of exposure. This concentration is appropriate for the exposure period of concern (i.e., 1- 7 days) since the treatment was for 15 days and no treatment-related effects were observed at this concentration. A margin of exposure (MOE) of 100 (10X for intra-species variation and 10X for inter-species extrapolation) is adequate for occupational exposure via the inhalation route. A risk assessment is not required for residential exposure. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Further, bystander risk is an issue of concern and is addressed as part of the occupational risk assessment.

(5) Intermediate Term Inhalation (7 days to several months)

The 90-day inhalation study (MRID 41413101) was also used as the basis for the intermediate-term inhalation risk assessment. For the sub-chronic exposure (90-days), the NOEL was 3 ppm (0.004 mg/L) based on the lack of treatment-related effects at the highest concentration tested; a LOEL was not established. The study is appropriate for the exposure period of concern because of the duration of exposure (i.e., 90 days) and the NOEL of this study is supported by a similar NOEL established in a 90-day neurotoxicity study in rats (MRID 44210401). In that study, no treatment-related effects were observed in survival, clinical signs, body weights, neurobehavioral effects, or gross and histopathology in male and female Crl:CD rats exposed to phosphine (1% a.i in nitrogen) at 0,

0.3, 1 or 3 ppm, 6 hours/day, 5 days/week for approximately 90 days. The NOEL was 3 ppm (HDT); a LOEL was not established. A MOE of 100 (10X for intra-species variation and 10X for inter-species extrapolation) is adequate for occupational exposure via the inhalation route. A risk assessment is not required for residential exposure. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Further, bystander risk is an issue of concern and is addressed as part of the occupational risk assessment.

(6) Long Term Inhalation (several months to lifetime)

The chronic toxicity/carcinogenicity inhalation study (MRID 44415101) that was used as the basis of the chronic dietary RfD was also used as the basis for the long-term inhalation exposure risk assessment. The NOEL was 3 ppm (0.004 mg/L), the highest dose tested. A MOE of 100 (10X for intra-species variation and 10X for inter-species extrapolation) is adequate for occupational exposure via the inhalation route. A risk assessment is not required for residential exposure. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed.. Further, bystander risk is an issue of concern and is addressed as part of the occupational risk assessment.

(7) Dermal Absorption

Because the route of exposure anticipated for aluminum and magnesium phosphide is inhalation, the Agency does not expect significant dermal exposure. Therefore, dermal absorption studies are not required and no risk assessment is required for this route of exposure.

(8) Classification of Carcinogenic Potential

The carcinogenic potential of aluminum and magnesium phosphide has not been fully evaluated since the results of the two-year carcinogenicity study is expected to be submitted in November, 1998. However, the interim results (52 weeks) do not show any evidence of carcinogenicity even at the highest concentration tested. In addition, the results of a non-guideline two-year feeding study in which no evidence of carcinogenicity was seen in rats fed diets that were treated with aluminum phosphide pellets (Accession nos. 26937, 26938 and 6000). Also, exposure assessments do not indicate a concern for a potential dietary risk because residues of phosphine are not expected in food. Thus the Agency does not believe that

aluminum and magnesium phosphide pose a carcinogenic concern.

A summary of the endpoints for dietary, short-term (inhalation), intermediate (inhalation), and long-term (inhalation) exposures are provided below. The endpoints are the same for both aluminum and magnesium phosphide since they are based upon phosphine gas, the common active agent for both chemicals.

Table 6. Summary of Aluminum and Magnesium Phosphide Endpoints for Risk Assessments

EXPOSURE SCENARIO	CONCENTRATION/ DOSE	ENDPOINT	STUDY
Acute Dietary	1.8 mg/kg/day converted from 5 ppm	No treatment-related effects after exposure for 15 days.	15-Day exposure regimen in a 90-day inhalation - Rat
	UF=100	**Acute RfD =0.018**	
Chronic Dietary	1.13 mg/kg/day converted from 3 ppm	No treatment-related effects after chronic (52 weeks) inhalation exposure.	Chronic Toxicity Inhalation-Rat
	UF=100	**Chronic RfD =0.0113**	
Short-Intermediate or Long-Term (Dermal)	None	The use pattern does not indicate potential exposure via the dermal route. Therefore, dermal risk assessments are not required.	
Short Term (Inhalation)	0.007 mg/L	No treatment-related effects after exposure for 15 days.	15-Day exposure regiment in a 90-day inhalation - Rat
	UF=100		
Intermediate (Inhalation)	NOEL= 0.004 mg/L	No evidence of toxicity at the highest tested concentration.	90-Day Inhalation - Rat
	UF=100		
Long-Term (Inhalation)	NOEL= 0.004 mg/L	No evidence of toxicity at the highest tested concentration.	Chronic Toxicity Inhalation - Rat
	UF=100		

3. Exposure Assessment

a. Dietary Exposure From Food Sources

Tolerances are established, at levels ranging from 0.01 to 0.1 ppm, for residues of the fumigant phosphine in/on several raw agricultural commodities (RACs) from postharvest treatment with aluminum [40 CFR §180.225(a)] and magnesium [40 CFR §180.375(a)] phosphide. Tolerances of 0.01 ppm have been established for residues of the fumigant phosphine in/on all RACs resulting from preharvest treatment of pest burrows in agricultural and non-

cropland areas with aluminum [40 CFR §180.225(b)] and magnesium [40 CFR §180.375(b)] phosphide. Tolerances of 0.01 ppm have been established for residues of phosphine in processed food resulting from the use of aluminum [40 CFR §185.200] and magnesium [40 CFR §185.3800] phosphide. Tolerances of 0.1 ppm were established for residues of phosphine in animal feeds resulting from the use of aluminum [40 CFR §186.200] and magnesium [40 CFR §186.3800] phosphide. Tolerances are based in many cases on field/storage trial residues. In most cases, residues were not detectable and, therefore, limits of detection were used when establishing the tolerances.

GLN 860.1200 (171-3): Directions for Use

There are currently 28 aluminum phosphide and four magnesium phosphide end-use products (EPs) registered under FIFRA Section 3; there are no Special Local Need (SLN) registrations under FIFRA Section 24(c). A list of registered aluminum and magnesium phosphide EPs is presented inAppendix G. (REFS 2/27/97)

Because the use of aluminum and magnesium phosphide results in the release of phosphine, a highly toxic gas, all end-use products containing these active ingredients are classified for restricted use and may be applied only by or under the supervision of a certified applicator.

Registered sites: Aluminum and magnesium phosphide are registered for fumigation of stored food and feed commodities to protect them from damage by insects. Aluminum and magnesium phosphide are also registered for outdoor fumigation of rodent burrows. Aluminum and magnesium phosphide may be blended with bulk commodities which are not directly consumed as foods. Commodities which can be directly consumed as food must not be contaminated by direct contact with aluminum and magnesium phosphide. Fumigation of these items requires the registered product be placed in trays fastened to a support within the area to be fumigated or the use of sachets, belts or blankets, as described in the use profile earlier in this document.

Fumigation treatment period guideline: For all products, the recommended length of fumigation is dependent on temperature. A guide for determining the exposure period at various temperatures is presented in Table 7. In general, a short fumigation exposure period is required at high temperatures. It may be necessary to lengthen the fumigation at lower temperatures and relative humidities (or grain moisture) since insects are difficult to control under these conditions. The lengths of time the target pests are exposed to the phosphine via fumigation, listed in Table 7, are minimum periods and it is recommended they not be shortened for any reason

other than when it may be necessary to abort the scheduled fumigation.

Recommended application rates (current): Phosphine is a mobile gas and will penetrate all parts of the storage structure. Most labels specify dosage rates based upon the total volume of the space being treated (i.e., per 1,000 cu. ft.); some labels also specify dosage rates based on the amount of a commodity the storage structure contains (i.e., per 1,000 bushels). Aluminum and magnesium phosphide may be applied in the form of tablets, pellets, bags, or sachets. The general recommended rates based on formulation class are listed in Table 8. The specific recommended rates based on types of fumigation for aluminum and magnesium phosphide are presented in Tables 9 and 10, respectively.

Aeration of fumigated commodities: The following information pertains what is found on current labels. To ensure that phosphine residues will not exceed the established tolerances, fumigated commodities (except tobacco) should be aerated for 48 hours prior to making them available to consumers. This aeration entails the venting of the structure that has been fumigated to slowly reduce the level of phosphine gas in the structure/commodity. Tobacco should be aerated for at least 72 hours when fumigated in hogsheads or until the phosphine concentration is below 0.3 ppm and for at least 48 hours when fumigated in other containers. The labels examined also specify that under no conditions should the formulations containing the active ingredients be used so that they will contact any processed food (except processed brewer's rice, malt, and corn grits stored in breweries for use in the manufacture of beer). When plastic liners are used, longer aeration periods are required to reduce the phosphine residue level to 0.3 ppm. As an alternative to these aeration periods, each container of a treated commodity may be analyzed for residues using accepted analytical methods. If residues are less than tolerance levels, then the commodity may be shipped to the consumer regardless of the established holding periods.

Aluminum and magnesium phosphide are not to be directly mixed with foods, feed, and raw agricultural products which may be used directly as foods. All labels must include the restriction, "Under no conditions shall food, feed, and/or raw agricultural commodities which may be used directly as foods come into contact with aluminum or magnesium phosphide." The status of reregistration requirements for each guideline topic is based on the use patterns registered by all the registrants of aluminum and magnesium phosphide.

Table 7. Recommended Temperatures and Exposure Periods When Using Aluminum and Magnesium Phosphide.

Temperatures To Which Fumigants and Insects Are Exposed	Minimum Exposure Period For Fumigation By Formulation		
	Pellets	Tablets	Bags or Sachets
Below 40 F (5 C)	Do not fumigate	Do not fumigate	Do not fumigate
40-53 F (4-12 C)	6 days (144 hours)	7 days (168 hours)	14 days (336 hours)
54-59 F (12-15 C)	4 days (96 hours)	5 days (120 hours)	7 days (168 hours)
60-68 F (16-20 C)	3 days (72 hours)	4 days (96 hours)	4 days (96 hours)
Above 68 F (20 C)	2 days (48 hours)	3 days (72 hours)	3 days (72 hours)

Table 8. Recommended General Dosage Rates for Aluminum and Magnesium Phosphide By Formulation.

Formulation	Recommended Dosage (In Terms of Product)	
	Per 1,000 cu. ft.	Per 1,000 Bushels
Pellets [a]	100-725 pellets	120-905 pellets
Tablets [b]	20-145 tablets	25-180 tablets
Bags [c]	2-13 bags	2-16 bags
Sachets [c]	2-13 sachets	--

[a] Each pellet weighs ~0.6 g and releases ~0.2 g of phosphine.
[b] Each tablet weighs ~3 g and releases ~1 g of phosphine.
[c] Bags and sachets each weigh ~34 g and release ~11 g of phosphine.

Table 9. Recommended Dosage Rates For Aluminum Phosphide By Type of Fumigation and Storage.

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (55-60% P/T)	**Tablets [b] (55-60% P/T)**	**Bags [c] (55-57% D) (55-60% P/T) (60% Impr)**	**Sachets [c] (57% Impr)**
Space				
Mills (including cereal and feed mills), warehouses, and food-processing plants	100-300 pellets/1,000 cu. ft.	20-60 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	2-6 sachets/1,000 cu. ft.
Bulk animal feeds (except nuts)	120-300 pellets/1,000 bushels	60-180 tablets/1,000 bushels	--	--
Bagged and packaged commodities (grain, processed foods, etc.) in sealable enclosure	150-300 pellets/1,000 cu. ft.	30-90 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	3-6 sachets/1,000 cu. ft.
Dried and processed fruits (including nuts and dates) and nuts in bags or storage boxes	100-200 pellets/1,000 cu. ft.	20-40 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	2-4 sachets/1,000 cu. ft.
Peanuts	--	60-125 tablets/1,000 cu. ft.	--	--
Stored tobacco	100-200 pellets/1,000 cu. ft.	20-40 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	2-4 sachets/1,000 cu. ft.
Bulk Stored Commodities				
Vertical storage [including large vertical silo bins which are relatively gas tight or well-constructed concrete bins]	120-375 pellets/1,000 bushels or 150-375 pellets/1,000 cu. ft.	40-180 tablets/1,000 bushels or 30-75 tablets/1,000 cu. ft.	2-7 bags/1,000 bushels or 2-6 bags/1,000 cu. ft.	3-5 sachets/1,000 cu. ft.

(continued; footnotes follow)

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (55-60% P/T)	**Tablets [b] (55-60% P/T)**	**Bags [c] (55-57% D) (55-60% P/T) (60% Impr)**	**Sachets [c] (57% Impr)**
Tanks	200-450 pellets/1,000 bushels or 150-450 pellets/1,000 cu. ft.	40-90 tablets/1,000 bushels or 30-90 tablets/1,000 cu. ft.	2-8 bags/1,000 bushels or 2-7 bags/1,000 cu. ft.	4-6 sachets/1,000 cu. ft.
Flat storage	250-900 pellets/1,000 bushels or 250-900 pellets/1,000 cu. ft.	50-180 tablets/1,000 bushels or 50-180 tablets/1,000 cu. ft.	2-16 bags/1,000 bushels or 2-13 bags/1,000 cu. ft.	5-13 sachets/1,000 cu. ft.
Farm bins (including Butler type of bins which are well constructed and reasonably gas tight)	200-900 pellets/1,000 bushels or 350-900 pellets/1,000 cu. ft.	90-180 tablets/1,000 bushels or 70-180 tablets/1,000 cu. ft.	2-16 bags/1,000 bushels or 2-13 bags/1,000 cu. ft.	6-13 sachets/1,000 cu. ft.
Loosely piled commodity stored under temporary, relatively gas-tight covering	270-540 pellets/1,000 bushels	90-180 tablets/1,000 bushels	--	–

(continued; footnotes follow)

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (55-60% P/T)	**Tablets [b] (55-60% P/T)**	**Bags [c] (55-57% D) (55-60% P/T) (60% Impr)**	**Sachets [c] (57% Impr)**
Railcars	200-450 pellets/1,000 bushels or 150-500 pellets/1,000 cu. ft.	40-90 tablets/1,000 bushels or 30-145 tablets/1,000 cu. ft.	2-7 bags/1,000 bushels 2-6 bags/1,000 cu. ft.	3-6 sachets/1,000 cu. ft.
Bunkers and tarped ground storage	200-500 pellets/1,000 bushels or 150-500 pellets/1,000 cu. ft.	40-100 tablets/1,000 bushels or 30-100 tablets/1,000 cu. ft.	2-8 bags/1,000 bushels 2-6 bags/1,000 cu. ft.	3-6 sachets/1,000 cu. ft.
Barges	200-900 pellets/1,000 bushels or 150-725 pellets/1,000 cu. ft.	40-180 tablets/1,000 bushels or 30-145 tablets/1,000 cu. ft.	2-9 bags/1,000 bushels or 2-7 bags/1,000 cu. ft.	3-7 sachets/1,000 cu. ft.
Shipholds	200-413 pellets/1,000 bushels or 100-375 pellets/1,000 cu. ft.	40-83 tablets/1,000 bushels or 30-75 tablets/1,000 cu. ft.	2-7 bags/1,000 bushels or 2-6 bags/1,000 cu. ft.	3-6 sachets/1,000 cu. ft.
Stored beehives, supers, and other beekeeping equipment for wax moth control and Africanized honeybees infested with tracheal mites and foulbrood.	150-225 pellets/1,000 cu. ft.	30-45 tablets/1,000 cu. ft.	3-4 bags/1,000 cu. ft.	--

(continued; footnotes follow)

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (55-60% P/T)	**Tablets [b] (55-60% P/T)**	**Bags [c] (55-57% D) (55-60% P/T) (60% Impr)**	**Sachets [c] (57% Impr)**
Small containers (i.e., spices)	1-2 pellets/1.4-10 cu. ft.	1 tablet/6.9-50 cu. ft.	1 bag/6.9-500 cu. ft.	--
Miscellaneous				
Non-food products	150-450 pellets/1,000 cu. ft.	30-90 tablets/1,000 cu. ft.	--	--
Outdoor fumigation of rodent burrows (agricultural and non-cropland areas)	5-20 pellets/burrow	1-4 tablets/burrow	2-6 bags/burrow	--

[a] Each pellet weighs ~0.6 g and releases ~0.2 g of phosphine.
[b] Each tablet weighs ~3 g and releases ~1 g of phosphine.
[c] The bags and sachets each weigh ~34 g and release ~11 g of phosphine.

(continued; footnotes follow)

Table 10. Recommended Dosage Rates For Magnesium Phosphide By Type of Fumigation and Storage.

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (66% P/T)	Tablets [b] (66% P/T)	Bags [c] (66% P/T)	FUMI-CEL Plate [d] (56% Impr)
Space				
Mills and warehouses	100-300 pellets/1,000 cu. ft.	20-60 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/550-1,650 cu. ft.
Bagged commodities	150-300 pellets/1,000 cu. ft.	30-60 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/550-1,100 cu. ft.
Processed fruits and nuts	100-200 pellets/1,000 cu. ft.	20-40 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/825-1,650 cu. ft.
Stored tobacco	100-200 pellets/1,000 cu. ft.	20-40 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/825-1,650 cu. ft.
Processing machinery and equipment (spot fumigation)	25-50 pellets/1,000 cu. ft.	--	--	--
Bulk Stored Commodities				
Vertical storage	150-375 pellets/1,000 cu. ft.	30-75 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/550-1,100 cu. ft.
Tanks	150-450 pellets/1,000 cu. ft.	30-90 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/470-1,100 cu. ft.
Flat storage	250-900 pellets/1,000 cu. ft.	50-180 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/230-660 cu. ft.
Farm bins	350-900 pellets/1,000 cu. ft.	70-180 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/230-470 cu. ft.
Bunkers and tarped ground storage	150-500 pellets/1,000 cu. ft.	30-100 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/410-1,100 cu. ft.
Railcars	150-400 pellets/1,000 cu. ft.	30-80 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/510-1,100 cu. ft.

(continued; footnotes follow)

Type of Fumigation and Storage	Recommended Dosage (In Terms of Product)			
	Pellets [a] (66% P/T)	**Tablets [b] (66% P/T)**	**Bags [c] (66% P/T)**	**FUMI-CEL Plate [d] (56% Impr)**
Barges	150-500 pellets/1,000 cu. ft.	30-100 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/230-660 cu. ft.
Shipholds	150-375 pellets/1,000 cu. ft.	30-75 tablets/1,000 cu. ft.	2-6 bags/1,000 cu. ft.	1 plate/500-1100 cu. ft.
Small sealable enclosures	1 pellet/1.4-10 cu. ft.	1 tablet/6.9-50 cu. ft.	1 bag/6.9-50 cu. ft.	--
Stored beehives, supers, and other beekeeping equipment	150-225 pellets/1,000 cu. ft.	30-45 tablets/1,000 cu. ft.	3 bags/1,000 cu. ft.	--
Miscellaneous				
Outdoor fumigation of rodent burrows (agricultural and non-cropland areas)	5-20 pellets/burrow opening	1-4 tablets/burrow opening	2-6 bags/burrow opening	--

[a] Each pellet weighs ~0.6 g and releases ~0.2 g of phosphine.
[b] Each tablet weighs ~3 g and releases ~1 g of phosphine.
[c] Each bag weighs ~34 g and releases ~11 g of phosphine.
[d] A FUMI-CEL Plate releases 33 g of phosphine.

(continued; footnotes follow)

GLN 860.1300 (171-4 a,b): Nature of the Residue - Plants and Animals

No additional plant and animal metabolism data are required for purposes of reregistration. The residue of concern is phosphine and the current tolerance expression is appropriate. The original Registration Standards for aluminum and magnesium phosphide reserved the requirements for human health studies until certain uncharacterized residues which resulted from the treatment of food were characterized and evaluated. Subsequent to the issuance of the Registration Standards, the Agency received information which identified these formerly unknown residues as oxidation products of phosphine. Having reviewed these data, the Agency has concluded that these decomposition products of phosphine are toxicologically insignificant at the levels found in the treated commodities. Therefore, the Agency waived the requirements for metabolism, residue, and storage stability data.

GLN 860.1340 (171-4 c,d): 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 (LOD = 0.01 ppm) and a GLC method with flame photometric detection (LOD = 0.001 ppm) as Methods A and B, respectively, for the enforcement of tolerances. Both methods determine the level of phosphine residues. It is noted that 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 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 (171-4 m): Multiresidue Methods

Because aluminum and magnesium phosphide are inorganic compounds, recovery of residues using FDA Multiresidue Protocols is not expected, and the requirement for such data is waived.

GLN 860.1380 (171-4 e): Storage Stability Data

No additional storage stability data are required for the purposes of reregistration. The Agency waived the requirements for this guideline.

GLN 860.1400 (171-4 f,g,h): Water, Fish, and Irrigated Crops

Aluminum and magnesium phosphide are presently not registered for direct use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline.

GLN 860.1460 (171-4 I): Food-Handling

No additional data pertaining to magnitude of the residue in food-handling establishments are required for the purposes of reregistration.

GLN 860.1480 (171-4j): 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 secondary residues of phosphine in meat, milk, poultry, or eggs [Category 3 of 40 CFR §180.6(a)] based on the registered uses.

GLN 860.1500 (171-4 k): Crop Field Trials

No additional data pertaining to magnitude of the residue are required for purposes of reregistration because there are no uses of this type.

Residue data reflecting registered postharvest treatments of stored raw agricultural and processed commodities indicate that, with adequate aeration or further processing after treatment, residues of phosphine dissipate to nondetectable levels. Residue data also suggest that the phosphine released from registered aluminum and magnesium phosphide products are not significantly different. Since aluminum and magnesium phosphide have essentially identical use patterns, the available residue data for aluminum phosphide may be translated to magnesium phosphide. Existing tolerances reflect a 48-hour aeration period. No additional data are required to support the registered uses of aluminum and magnesium phosphide on animal burrows or den entrances for the control of rodents and moles.

GLN 860.1520 (171-4 l): Processed Food/Feed

No additional processing data are required for purposes of reregistration.

GLN 860.1850 (165-1) and 860.1900 (165-2): Confined/Field Accumulation in Rotational Crops

Data pertaining to confined/field accumulation in rotational crops are not required for the purposes of reregistration.

b. Dietary Exposure from Drinking Water

Aluminum and magnesium phosphide are expected to degrade rapidly in the environment to aluminum hydroxide and magnesium hydroxide and phosphine. The Agency has determined that phosphine gas will degrade in days and has a low exposure potential for contaminating ground and surface water. Therefore, the Agency concludes that a dietary exposure assessment from drinking water is not necessary.

The Agency determined that the use of standard models to estimate concentrations of phosphine in surface and ground water are not appropriate for this compound because: the compound is highly volatile and volatilization is not considered as a route of dissipation in the models; the outdoor/field use pattern (i.e. placing aluminum and magnesium phosphide in burrows) does not present a surface water concern because the compound is not applied to the soil surface and would not be expected to runoff in surface water; uses will be localized since the only outdoor application is to rodent burrows; and only a small percent of total use is outdoors.

While it is conceivable that some proportion of phosphine could reach ground water through macropore flow-like processes, the Agency could not estimate with any degree of certainty the concentration that would occur in groundwater, and does not believe it would be a concern, due to the low potential for exposure and the fate characteristics noted above.

c. Occupational and Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if 1) certain toxicological criteria are triggered; and 2) there is potential exposure to handlers (mixer/loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. Use of aluminum and magnesium phosphide triggers both of the above requirements and thus an exposure assessment is warranted.

(1) Application Practices

The application practices, methods and rates are discussed in the use profile presented on pages 2-6 above. Please refer to that section for a complete discussion.

(2) Handler Concerns/Requirements/Restrictions

The primary handler concern from aluminum and magnesium phosphide fumigation is acute inhalation exposure. Although manufacturers of aluminum/magnesium phosphide indicate a delay before dangerous amounts of phosphine are released (usually between 30 and 90 minutes), this time may be significantly decreased if the chemical is handled under warm, humid conditions (Leesch et al., 1995). A National Institute of Occupational Safety and Health (NIOSH) review of grain fumigation with phosphide stated "...substantial exposures to phosphine can and do occur as soon as the original containers of aluminum phosphide are opened" (NIOSH, Zaebst, A., et. al. 1987). Additionally, when released too quickly in a confined area, fire and/or explosions may occur. Under the Agency's "Label Improvement for Fumigants," changes have been made to better define user information and precautionary statements. Revised labels state that at least two trained persons must be present during the principle fumigation. These fumigators should be licensed and present during application and aeration of a structure. Detectors are required to monitor fumigant concentrations as a condition of reentry or transfer of treated grain.

According to the current labels, exposure to phosphine must not exceed an 8 hour time-weighted average (TWA) of 0.3 ppm (0.0004 mg/l) for applicators and workers during application. This standard (0.3 ppm) was developed as the permissible exposure limit (PEL) by the Occupational Safety and Health Administration (OSHA). It should be noted that this value does not take into consideration the potential for chronic phosphorus poisoning from prolonged exposure (ACGIH Publication 0206). Application is defined as the time period covering the opening of the first container, applying the appropriate first dosage of fumigant and closing up the site to be fumigated. All persons in the treated site and in adjacent indoor areas are covered by this exposure standard. After application is completed, worker or applicator exposure must not exceed a 0.3 ppm maximum concentration. A NIOSH/MSHA approved full face gas mask/hydrogen phosphide canister combination must be used at concentrations up to 15 ppm. Above this level, or if the concentration is unknown a NIOSH/MSHA approved self-contained breathing apparatus (SCBA) or equivalent must be available at the application site. According to current labels, placarding should not be removed until the treated commodity is aerated down to 0.3 ppm or less.

Since current labels often refer to OSHA standards a brief overview of some OSHA requirements that may be related to the use of aluminum and magnesium phosphide is presented here. The Occupational Safety and Health Act requires employers to establish and maintain a safe and healthy work

place. Therefore OSHA limits the exposure of workers to hazardous chemicals, such as hydrogen phosphide gas. The principal of the 'action level,' which is usually set at half the PEL, is to set a level of hazard that serves as a warning and initiates measures to prevent that hazard from exceeding the PEL. The PEL, in turn is the amount of hazardous substance to which it is believed an average worker may be exposed for eight hours a day, five days a week, for forty years. This regulatory limit assumes that not all workers will be protected by this limit, particularly if they have a pre-existing health condition. Therefore the PEL is not designed or intended to protect bystanders or the public, who may be exposed to an airborne chemical up to 24 hours a day if such a chemical is released into the community air. Nor is the PEL adequately protective of infants, the elderly, sensitive individuals, or the infirm.

The revised PPE Standard was promulgated by OSHA in 1994 and requires employers to evaluate the hazards present or potentially existing in the work place. Based on this assessment, employers must provide all appropriate personal protective equipment to employees to permit them to do their jobs safely. If respirators are required to perform a job, then the employer must have a respiratory protection plan. The plan requires medical clearance, training, fit testing, and proper respirator selection. Employees working with phosphine will need to be trained to monitor the levels of phosphine gas and select a respirator with an appropriate protection factor. Employees will then be expected to clean and maintain their respirator and change chemical cartridges when they are depleted.

Definitions of several OSHA terms used in this document are:

PEL: Permissible Exposure Limit: the amount of chemical permitted to be in the atmosphere of the work environment, based on a time-weighted average [TWA] concentration measured for an eight-hour day. The limits are listed in the 29 CFR 1910.1001 table z-1.

AL: Action Level: The level of contaminant in the work atmosphere at which administrative (e.g. worker rotation, limiting exposure), engineering (e.g. exhaust ventilation, contaminant isolation), or personal protection controls must be implemented. Generally equal to one-half the PEL.

Ceiling Value: A level of contaminant in the work atmosphere which may not be exceeded at any time.

STEL: Short Term Exposure Limit (is supplemental to the PEL or TLV's 8-hr TWA): The level of contaminant in the work atmosphere to which an

average worker may be exposed for 15 minutes without significant health effects. A maximum of four 15-minute periods per eight hour shift, 60 minutes in between each 15 minute exposure, is allowable, as long as the worker does not exceed the daily 8-hr-TWA.

TWA: Time-Weighted Average: The worker's personal cumulative exposure for one shift divided by eight hours.

(3) Handler Exposures and Assumptions

The estimates of exposure in this assessment have been derived from a phosphine chemical specific studyconducted by S.Z. Mansdorf et al. entitled "Phosphine Exposure Monitoring for Applicators, Workers, and Nearby Persons" (MRID 40717201). The Mansdorf et. al. study monitored exposure to fumigators (and helpers); bystanders during and post-fumigation (but before aeration); aerators; and bystanders during and post-aeration. Occupational bystanders/nearby persons have been defined by Mansdorf et. al. as someone with "no direct contact with the fumigant material and/or container during or anytime after fumigation and no direct or indirect contact with spent fumigant container after aeration". The fumigants were applied to concrete upright bins, bulk railcars, railroad box cars, processing plants, tobacco warehouses, farm bins, flat bins, and in spot fumigation situations. Each site had workers in short term (1 to 7 days) and intermediate term (1 week to several months) exposure situations, and many of the sites had chronic situations (5 days/week for 6 months) as well. Note that although some fumigations seem only short-term in nature, the potential for intermediate exposure exists for the commercial applicator. The materials and methods are described in detail below. It should also be noted that this study did not review all possible exposure scenarios that could result from the use of aluminum and magnesium phosphide.

Concrete Upright Bins

Commodity fumigations in concrete upright bins were analyzed at three sites. The first site was a large grain elevator and mill consisting of many cylindrical and rectangular concrete upright bins. The cylindrical bins were connected by interstitial (star-shaped) bins. This facility received and stored several grades of grain. Fumigations occur daily due to the constant movement of grain. Fumigation occurred through the use of automatic dispensers. An applicator would add pellets to the dispenser which in turn added the pellets to the grain at measured intervals. The second site was a mid-size grain elevator and storage bin consisting of more than 40 cylindrical concrete bins. As with the first site, the cylindrical bins were connected by

interstitial bins. Fumigations were much less frequent than at the first site, averaging only 6 per year. Applicators manually added pellets to the grain as it was transferred through the hatch at approximately 100 pellets every 7.5 minutes. The third site was a large grain elevator and storage bin complex consisting of both concrete and flat storage bins. The high volume of grain demanded almost daily fumigation. As with the first site, pellets were added to grain through the use of automatic dispensers.

The duration of exposure from concrete upright fumigation was greater than any other site or complex in the study. Daily fumigant applications could take up to 12 hours depending on the size of the bin being filled. Unlike other facilities where phosphine exposure may be brief (due to rapid fumigation), the study noted that residue concentrations from concrete upright fumigation were probably consistent throughout the day. The daily fumigations/aerations over a 6-8 month season constitutes chronic exposure.

Bulk Railcars and Railroad Boxcars

Four sites examined worker exposure from the fumigation and aeration of bulk railcars and railroad boxcars at large grain elevators, mills, or cereal processing plants. Single car fumigation or aerations usually lasted under 45 minutes; however, the number of cars treated at facilities varied. For example, at one site the fumigation of outgoing railcars took up to 3.5 hours per day. The average appeared to be an applicator treating between 2 and 4 cars/day over a 6 to 8 month "season". This constitutes a chronic use pattern. These findings and potential chronic use patterns were similar to those in another study (Shaheen, Donald G. Letter to Jeff Kempter of Registration Division, 2/20/87). In this study, a survey of processing plants indicated that up to 6-8 phosphine treated railcars/day could be unloaded at breweries, 0 - 1 treated railcars/day unloaded at mills, 3 treated railcars/day unloaded at feed plants, and 1 treated car/day unloaded at cereal plants. Others from industry felt that while the potential for chronic exposure existed, fewer railcars or bulkcars would be treated or aerated than seen by Shaheen or in the Mansdorf et al. study. (Hegele, Fred**.** General Mills. Personal Communication, January 1998.; Sawyer, Glenn. Industrial Fumigants. Personal Communication, January, 1998). Blister pacs (prepac strips) or dust sachets were placed on cardboard discs in the cars and the hatches were sealed. Aerations occurred either in the large indoor rail docks used for fumigation or outside in the switching yard. Fumigations usually involved one applicator or an applicator and assistant. Aerations involved 1 or 2 workers.

Spot fumigation

Spot fumigation occurred at one of the mid-size grain elevators and mill complexes. At this facility mill, equipment was fumigated every third weekend and took approximately one hour. Aeration and retrieval of unused chemical took approximately 1.5 hours, and took place 36 hours after fumigation.

Tobacco Warehouses

The facility examined in the Mansdorf et al. study used prepac blister strips. Each warehouse was sealed with polyethylene sheeting prior to fumigation. The fumigation crew of 8 to 10 applicators started at the front end of the warehouse, opened the pouches and placed the pesticide strips in a zig-zag pattern on metal trays and worked their way towards the exit. The exit was a slit in the plastic sheeting and was sealed after all the crew had exited.

The tobacco warehouse in the Mansdorf et al. study represented ideal fumigation and aeration practices and the resulting data should be considered a "best case scenario" (EPA memo dated 1992). Actual data from other facilities could potentially show greater exposure. Shaheen found off-gassing problems most notably in tobacco warehouses where the combination of hogsheads of tobacco and tobacco packaging of polyethylene sheeting result in the retention of phosphine for periods considerably longer than the 72-hour aeration.

Farm and Flat Storage Bins

Many of the sites analyzed were farm and flat storage bins from a series of farms and small town storage facilities. The farm bins were usually made of bolted steel and were cylindrical in shape with conical roofs. The small town sites had facilities with welded steel cylindrical tanks or large rectangular structures. These are called "flat storage bins". They have a larger storage capacity than the farm bins. These fumigations were conducted by a professional fumigation company. Workers from the team reported approximately 20 fumigations per year. The methods of application varied from shaking the fumigant material onto the surface of a commodity, to submerging a flask 2-3 inches below the commodity surface, to using a probe (pipe) to pour the fumigant into the center of the commodity. The most common method of application in these sites was shaking the fumigant material onto the surface of the commodity without tarping or powered aeration.

Commodity Transfers

At three sites, samples were collected on "post-aeration" workers at a finished product packaging line and while transferring fumigated grain to bulk railcars. The reduced replicate number and conflicting use information in this study has in part determined how exposure and risk was estimated (as discussed later in this assessment). Despite these deficiencies, the Agency has determined that this study represents the best available data for assessing exposure to aluminum and magnesium phosphide.

The residue of phosphine gas per liter of air drawn through the sampling media was calculated with the following formula:

$$\text{Residue (mg/l)} = (A_s \div t \times f) \div 1000$$

where:

A_s = amount of phosphine collected on the sample tube in micrograms

t = sample time in minutes
f = average pump flow rate in liters of air per minute

Table 11 summarizes the mean concentration and concentration range for each specific facility and handler function. Data from different sites for the same function and facility (e.g. bulk railcar fumigations) were pooled in order to maximize the number of replicates for each function.

(4) Animal Burrow Treatment

A study entitled *Exposure of Persons to Phosphine Gas from Aluminum Phosphide Application to Rodent Burrows* was conducted by Rex O. Baker, Professor at California State Polytechnic University in 1992. Worker exposure was assessed for two methods of applying aluminum phosphide tablets to rodent burrows: hand and mechanical application. At the end of the workday, phosphine levels on gloves, shirts, and pants were measured by sealing each garment in a plastic bag with approximately 1.5 cubic feet of air. The air concentration within the bags was measured with direct reading detector tubes after approximately 30 minutes. The mechanical applicators were found to have less residue than the hand applicators on the shirts (0.07 ppm and 0.29 ppm, respectively), pants (0.167 ppm and 0.875 ppm, respectively), and gloves (0.59 ppm and 2.11 ppm, respectively). Measurements, using the procedure above, were taken on the same garments the next morning, prior to the start of work, to determine whether overnight aeration is a sufficient method of cleaning the work clothes. One shirt out of

56 was found to have residual levels of phosphine after overnight aeration. In addition, two pairs of pants and six pairs of gloves were found to have residual levels of phosphine, however, these levels occurred in weather that was near freezing (24º to 48º F). The gloves used in this study were made of smooth leather; during the initial stages of the study, it was found that phosphine gas dissipated from leather gloves much more readily (after approximately 4 hours) than from cotton gloves (approximately 20 hours).

Air concentrations in the breathing zone were measured with monitoring badges clipped to the collars of the workers' shirts. These badges were worn for the entire workday (i.e., 8-hours), and the exposures were calculated on a time-weighted-average (TWA) basis. Four of the 21 measurements for hand applicators had detectable levels of phosphine gas. The total exposures ranged from 0.1 ppm to 0.8 ppm, which equate to TWAs of 0.012 ppm to 0.1 ppm. None of the 21 measurements for mechanical applicators had detectable levels of phosphine gas.

Table 11. Summary Table of Inhalation concentrations

Site	Scenario	Activity	Mean Concentration (mg/l)	Concentration Range (mg/l)
Concrete upright facility	Fumigation	Fumigator	1.4 x 10-4	4.4 x 10-6 to 6.3 x 10-4
	Fumigation	Bystander	1.1x 10-4	2.7 x 10-6 to 8.5 x 10-4
	Post fumigation, before aeration	Bystander	9.9 x 10-5	3.2 x 10-6 to 3.1 x 10-4
	Post aeration	Bystander	5.4 x 10-5	1.9 x 10-5 to 1.4 x 10-4
Bulk railcar	Fumigation	Fumigator	3.9 x 10-4	4.3 x 10-5 to 9.4 x 10-4
	Fumigation	Bystander	2.3 x 10-4	1.1 x 10-4 to 7.1 x 10-4
	Post fumigation, before aeration	Bystander	8.7 x 10-5	8.1 x 10-5 to 9.8 x 10-5
	Aeration	Aerator	9.4 x 10-4	4.8 x 10-4 to 1.6 x 10-3
	Post aeration	Bystander	1.2 x 10-4	7.1 x 10-5 to 2.1 x 10-4
Railroad Boxcar	Fumigation	Fumigator	3.6 x 10-4	3.5 x 10-5 to 1.4 x 10-3
	Fumigation	Bystander	2.5 x 10-4	1.2 x 10-5 to 4.3 x 10-4
	Fumigation, during and post	Bystander	2.0 x 10-4	4.0 x 10-5 to 6.3 x 10-4
	Post fumigation, before aeration	Bystander	2.3 x 10-4	9.7 x 10-6 to 9.1 x 10-4
	Aeration	Aerator	6.3 x 10-4	1.2 x 10-4 to 1.3 x 10-3
	Post aeration	Bystander	6.2 x 10-4	6.2 x 10-4 (1 replicate)
Tobacco Warehouse	Fumigation	Fumigator	2.8 x 10-4	9.5 x 10-5 to 7.2 x 10-4
	Aeration	Aerator	1.3 x 10-4	3.4 x 10-5 to 2.1 x 10-4
	Post aeration	Bystander	5.8 x 10-5	3.2 x 10-5 to 9.7 x 10-5
Flat Bin	Fumigation	Fumigator	7.3 x 10-3	3.9 x 10-5 to 2.5 x 10-2
Farm Bin	Fumigation	Fumigator	1.2 x 10-3	4.9 x 10-4 to 4.1 x 10-3

(continued; footnotes follow)

Site	Scenario	Activity	Mean Concentration (mg/l)	Concentration Range (mg/l)
Spot Fumigation	Fumigation	Fumigator	4.3 x 10-3	3.8 x 10-3 to 4.9 x 10-3
	Aeration	Aerator	8.7 x 10-5	7.8 x 10-5 to 9.6 x 10-5
Commodity transfer-packaging plant	Post aeration	Bystander	1.7 x 10-4	1.9 x 10-5 to 1.2 x 10-3
Commodity transfer-grain transfer	Post aeration	Bystander	4.5 x 10-5	1.9 x 10-5 to 7.0 x 10-5

(continued; footnotes follow)

4. Risk Assessment

There is potential for both dietary (food) and occupational exposure from the use of aluminum and magnesium phosphide. As previously noted, dietary exposure from drinking water is not expected. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Further, the Agency is concerned about the risk to residential bystanders which is included as part of the occupational risk assessment. Dietary exposure occurs via the oral route, while occupational exposure occurs via the inhalation route. Dietary exposure is expected to be short-term (acute) and long term (chronic), while occupational exposure is expected to be short-term, intermediate term and long-term. To assess the acute and chronic dietary risk, the Agency calculated the percent of the reference dose [RfD] (i.e. % RfD) used by the registered uses. To calculate occupational risk, the Agency calculated a Margin of Exposure (MOE).

In examining aggregate exposure, FQPA requires that EPA consider available information concerning exposure from the pesticide residue in food and all other exposure for which there is reliable information. These other sources of exposure of the general population (including infants and children) to pesticides include residues in drinking water and non-occupational exposures to pesticides. Only food source exposure was evaluated. Drinking water exposure is not expected. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed.

a. Dietary Risk Assessment

Dietary exposure to aluminum and magnesium phosphide can potentially occur via residues of phosphine gas remaining in treated commodities. For all data submitted to the Agency for establishment of food tolerances, residues of phosphine gas have been typically reported as non-detectable. However, because the use of aluminum and magnesium phosphide is considered a food use, tolerances for phosphine gas are required. The tolerances are intended for enforcement purposes, i.e., to monitor and safeguard against misuse, not for risk assessment. The tolerances are established based on the limits of quantification of the analytical method for phosphine gas. Anticipated residues were used for the both the chronic and acute dietary exposure analyses.

Section 408(b)(2)(D) of the FQPA 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 aggregate exposures to the pesticide from dietary sources, including drinking water, as well as non-occupational exposures,

such as these derived from pesticide 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.

In examining aggregate exposure, FQPA directs the Agency to take into account available information concerning exposures from pesticide residues in food and other exposures 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.

In the case of aluminum and magnesium phosphide, only food source exposure contributes to the aggregate risk posed by these pesticides. Drinking water exposure is not expected. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Although accidental exposure to bystanders is a concern which will be examined in the occupational exposure section of this document, it does not constitute an exposure scenario that is typical of the proper use of the pesticides and thus is not included as part of the aggregate assessment.

i. Acute Dietary (Food Source) Risk

Estimates of acute dietary exposure were conducted using DEEM™ analysis. The acute DEEM™ analysis evaluates the individual food consumption as reported by respondents in the USDA 1989-1991 nationwide Continuing Surveys for Food Intake by Individuals (CSFII), and accumulates exposure to the chemical for each commodity. In order to conduct a conservative dietary exposure analysis, anticipated residues equal to the highest limit of detection (0.006 ppm) are being used for acute dietary exposure analysis. Additionally the conservative assumption was made that 100% of all commodities included in the DEEM™ data base (except meat/milk/poultry/eggs) would contain residues at that anticipated residue level.

The results of the DEEM™ acute dietary (food) exposure analysis for exposure at the 99.9th percentile in terms of percents of the acute RfD ranged from 22% (U.S. population) to 27% (non-nursing infants). Acute dietary (food) exposure does not exceed the Agency's level of concern. The percent of the acute RfD occupied, at the 99.9th percentile, is less than 30% for the population subgroups examined.

These estimates of acute dietary exposure are partially refined, yet still conservative in that was assumed that all food (except meat/milk/poultry/eggs) consumed by an individual would contain phosphine gas residues at 0.006 ppm. This anticipated residue level is based on the highest limit of detection reported in tolerance petitions. The Agency notes that all tolerances are based upon non-detectable residues in residue field trials. Because phosphine gas will dissipate into the atmosphere, especially as foods are cooked (heated) or prepared, residues are unlikely to be found on food at the time of consumption.

ii. Acute Dietary (Drinking Water) Risk

The Agency has considered the registered uses and the available data on the persistence and mobility of aluminum and magnesium phosphide. The Agency has determined through a qualitative risk assessment that the use patterns associated with aluminum and magnesium phosphide are not expected to impact water resources through labeled uses. In light of this finding, the Agency believes that aluminum and magnesium phosphide use will not impact groundwater or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water. If new uses are added in the future, the Agency will reassess the potential impacts of aluminum and magnesium phosphide on drinking water as part of the aggregate risk assessment process.

iii. Aggregate Acute Dietary (Food Source and Drinking Water) Risk

As noted above, since an acute dietary (drinking water) risk assessment is not required, aggregate acute dietary risk reflects food source risk only. Thus, based on the acute dietary (food) risk assessment, aggregate acute dietary risk does not represent a concern.

iv. Chronic Non-Cancer Dietary (Food Sources) Risk

Estimates ofchronic dietary exposure were conducted using DEEM™ analysis. The chronic DEEM™ analysis evaluates the individual food consumption as reported by respondents in the USDA 1989-1991 nationwide Continuing Surveys for Food Intake by Individuals (CSFII), and accumulates exposure to the chemical for each commodity. In order to conduct a conservative dietary exposure analysis, anticipated residues equal to the highest limit of detection (0.006 ppm) are being used for acute dietary exposure analysis. Additionally the conservative assumption was made that 100% of all commodities included in the DEEM™ data base (except meat/milk/poultry/eggs) would contain residues at that anticipated residue level.

The formula to calculate the percent RfD is:.

$$\% \text{ RfD} = \frac{\text{chronic dietary (food source) exposure (mg/kg/day)}}{\text{RfD (mg/kg/day)}}$$

The results of the DEEM™ chronic analysis are presented in the table below.

Table 12. Chronic Dietary Exposure and % RfD for the General U.S. Population and Sensitive Subpopulations

Subgroup	Exposure (mg/kg/day)	% Reference Dose[1]
General U.S. population	2.6×10^{-4}	2%
Non-nursing infants (< 1 year old)	1.0×10^{-3}	9%
Children (1-6 years old)	4.7×10^{-4}	4%

[1] Chronic RfD = 0.0113 mg/kg/day

As represented in the table above, reassessed tolerance levels residues on commodities result in exposures which are 2% of the chronic RfD for the general U.S. population and 9% of the RfD for non-nursing infants (< 1 year old). Chronic dietary (food) exposure does not exceed the Agency's level of concern based on these %RfDs. The percent of the chronic RfD occupied is less than or equal to 9% for the population subgroups examined.

These estimates of chronic dietary exposure are partially refined, yet still conservative in that was assumed that all food (except meat/milk/poultry/eggs) consumed by an individual would contain phosphine gas residues at 0.006 ppm. This anticipated residue level is based on the highest limit of detection reported in tolerance petitions. The Agency again notes that all tolerances are based upon non-detectable residues in residue field trials. Because phosphine gas will dissipate into the atmosphere, especially as foods are cooked (heated) or prepared, residues are unlikely to be found on food at the time of consumption.

v. Chronic Drinking Water Risk

The Agency has considered the registered uses and the available data on persistence and mobility for aluminum and magnesium phosphide. The Agency has determined through a qualitative risk assessment that the use patterns associated with aluminum and magnesium phosphide are not expected to impact water resources through labeled uses. In light of this finding, the Agency believes that aluminum and magnesium phosphide use will not impact ground water or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water. If new uses are added in the future, the Agency will reassess the potential impacts of aluminum and magnesium phosphide on drinking water as part of the aggregate risk assessment process.

vi. Aggregate Chronic Dietary (Food Sources and Water) Risk

As noted above, since a chronic dietary (drinking water) risk assessment is not required, aggregate chronic dietary risk reflects food source risk only. Thus, based on the chronic dietary (food) risk assessment, aggregate chronic dietary risk does not represent a concern.

vii. Dietary (food source and water) Carcinogenic Risk

The carcinogenic potential of aluminum/phosphide has not been extensively evaluated by the Agency due to a lack of tumor data. The results of a non-guideline 2 year rat feeding study (Ascension nos. 26937, 2693 and 6000), did not indicate a carcinogenic concern. Thus, the Agency does not believe that aluminum and magnesium phosphide suggest a carcinogenic concern. In addition, a combined chronic/carcinogenicity rat inhalation toxicity study is due to the Agency in November, 1998 to provide confirmatory data.

b. Cumulative Risk

The Agency has not yet made a final decision concerning the possible common mechanism of toxicity and the potential for cumulative effects of aluminum and magnesium phosphide and other compounds. Therefore, for the purposes of the tolerance reassessments in this RED document, the Agency has considered only the risks of aluminum and magnesium phosphide.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, the Agency 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, the Agency 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 the Agency as it proceeds with further policy development and rulemaking that may be required.

If the Agency 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 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

The Agency 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 three years from the passage of FQPA (deadline of August 3, 1999) to implement this program. At that time, the

Agency may require further testing of these active ingredients and end use products for endocrine disrupter effects.

d. Occupational and Residential Risk Assessment

The route of exposure of concern for occupational and residential bystander risk is inhalation exposure. Because test data are available where the route of exposure is inhalation, occupational risk was estimated by calculating a route-specific MOE. A route-specific MOE is calculated by dividing the NOEL for the route of exposure in the study by the human exposure level for that same route of exposure. Since the units are the same (mg/kg for oral and dermal; mg/L for inhalation), the units cancel to yield a unitless MOE. The route specific MOE is preferred over a route-to-route extrapolation because there is no need to estimate the percentage of test particle absorption, or adjust for metabolism or any other pharmacokinetic parameters. A route-specific inhalation MOE is calculated as follows:

$$MOE = \frac{NOEL\ (mg/L)\ x\ D_A\ x\ AF_A}{Human\ Airborne\ Concentration\ (mg/L)\ x\ D_H\ x\ AF_H}$$

D_A Duration of daily animal exposure (usually 4 or 6 hours/exposure)
D_H Duration of daily human exposure (hours/exposure)
AF_A Activity Factor for animals (default is 1)
AF_H Activity Factor for humans (accounts for activity-related variations in respiration)

The Science Advisory Panel and the Agency have endorsed the use of route-specific MOEs whenever possible because they are accurate and easy to combine with MOEs from other routes of exposure, even when the MOEs have dissimilar uncertainty factors.

Table 13 represents a summary of the projected short, intermediate and (where applicable) chronic MOEs for each facility and specific handler or bystander/nearby persons for each hour increment up to 8 hours. (Bystanders/nearby persons are not considered to have direct contact with the fumigant material and/or container during or anytime after fumigation, or direct or indirect contact with spent fumigant container after aeration). This level of detail is provided because duration of worker exposure varies with the site and handler function. The table represents MOEs for short term (NOEL=5 ppm= 0.007 mg/L), intermediate term (NOEL=3 ppm=0.004 mg/L) and long term (chronic) (NOEL=3 ppm= 0.004 mg/L) exposure.

The OSHA PEL for aluminum and magnesium phosphide is based on a limited epidemiological study of grain fumigators by Jones et. al. (1962), and corresponds to a NOEL of 0.3 ppm. While much of the Agency's analyses is consistent with OSHA values, the Agency will regulate on NOELs of 0.03 and 0.05 ppm depending upon the length of exposure. These values are an order of magnitude more protective than the OSHA PEL. The reason for this difference is that the OSHA PEL is based upon a very limited epidemiological study conducted in the early 1960's (Jones et. al.), while the Agency has decided to use acceptable guideline studies conducted on animals together with the accepted Uncertainty Factor. The Agency believes that this is a more reliable and defensible basis for regulating the risks associated with these pesticides.

For the purpose of short term risk assessment, the 8-hour MOE should be used as a conservative risk estimate. Although most applications apparently take less than one hour, some applications may take up to 12 hours. Bystanders may be exposed for beyond 12 hours depending on their proximity to the structure. Additionally, some facilities had work days greater than 8 hours (up to 12). Therefore, while conservative, the eight hours should not be considered excessively conservative or unrealistic. MOEs have been estimated at baseline (without PPE, as they are in the Mansdorf et al. study) and with the addition of arithmetically estimated PPE. The protection provided by a NIOSH/MSHA approved full face gas mask/hydrogen phosphide canister combination was estimated at 98%. The protection provided by a NIOSH/MSHA approved Self Contained Breathing Apparatus (SCBA) operating in a negative pressure mode has been estimated at 99.99%. MOEs for use of PPE by nearby persons (occupational bystanders) have also been estimated.

Utilizing either the OSHA PEL or the Agency's endpoint for short-term, intermediate-term, and long–term exposure, short-term MOEs were greater than intermediate or chronic MOEs. MOEs were acceptable for all exposure scenarios with use of PPE/SCBA during an 8-hour application period. However, use of SCBA for an 8-hour application period would be cumbersome.

The acceptability of the MOEs varied with each site, with no one handler function being unacceptable throughout. Risk from phosphine exposure seemed more of a function of the type of fumigation than the specific handler function. Bulk railcar and railroad boxcar aerators had lower MOEs than fumigators, whereas tobacco warehouse and spot fumigators had lower MOEs than their aerator counterparts. Fumigators who performed spot treatment or farm or flat bin fumigation had the lowest MOEs. In many cases,

the full face respirator was not adequately protective when used for more than 1 or 2 hours and was never adequately protective for farm bin, flat bin and spot fumigation. The use of SCBA raised MOEs to acceptable levels in all scenarios.

Most significantly, occupational bystander exposure seems to be a definite concern. Most handler scenarios had unacceptable occupational bystander exposure at the baseline level (no handler scenario had acceptable bystander MOEs for the full 8 hours, and most were not even acceptable at 1 or 2 hours). The use of PPE by a nearby worker could prove to be difficult, especially if heavy physical labor is required. Of additional concern is residential bystander exposure since PPE is not applicable to residential bystanders. As previously discussed, poisoning data corroborate handler and bystander risks, especially residential bystander risks.

Most of the estimated MOEs were greater when calculated with the Mansdorf et al. study mean concentrations than with the OSHA PEL. This is expected since the mean concentrations from the Mansdorf et. al. study were mostly at or higher than the OSHA PEL. Notable exceptions to this were farm and flat bin fumigation, spot fumigation, and bulk railcar aeration.

One of the limitations of the exposure study was the lack of replicates for many of the exposure scenarios. Although it is useful to have information on the many different handler and nearby functions, many scenarios had less than 15 replicates, even with pooled data, and many had less than five. This reduced replicate number makes it difficult to determine if the results are a true estimate of exposure or are biased by the small replicate number. This point becomes a critical issue when MOE estimates for some scenarios prove unacceptable. Although, as Mansdorf et. al. point out, the residues in the study do not reflect the protection afforded the worker by "the proper respiratory protection," in many cases, no protection was worn by the worker.

The study provides some information regarding actual practices by workers. At many of the sites analyzed, fumigators merely opened packaging near an open door or window before application, with cotton gloves as the only other discernible protection worn. Use of respiratory protection with flat bin, farm bin, railroad box or bulk car fumigation was inconsistent, particularly with the bulk or box car fumigators, who did not appear to wear any respiratory protection at all. Therefore, Mansdorf, et. al.'s conclusion that workers will always be exposed to lower concentrations (from wearing the proper PPE) may not always be accurate if workers, in fact, wear the PPE. Data from the Oklahoma Cooperative Extension Service also provides information on actual practices. The Oklahoma Cooperative Extension

Service concludes that only 36% of all grain elevator operators routinely use SCBA and only 56% use canister respirators. Additionally, very few operators were found to test for fumigant or oxygen levels, a legal requirement. Only aerators and the spot fumigators consistently wore respiratory protection of some kind.

Mansdorf et. al. additionally stated that, with the exception of concrete upright facilities, sample times were representative of the concentration a worker would be exposed to for an 8-hour day. This was not consistent throughout the study, with some areas having at least an 8-hour day and often only one fumigator and an assistant. Also, while the sample times representing box or bulk car fumigations were accurate (where one sample time equaled a single car fumigation and according to Mansdorf, a worker's exposure for the day), the number of cars treated/day conflicted with data provided by Shaheen which demonstrated that some facilities treat up to eight cars in one day. This latter case corresponds to an approximate 5-hour exposure/day.

The following tables summarize the results of the Mansdorf study. The vast majority of MOEs for the baseline case are unacceptable. This is significant because the baseline case represents the expected scenario for both occupational and residential bystanders. A smaller but not insignificant percentage of scenarios are unacceptable at the PPE/Full-Face Respirator. These scenarios are: fumigators of railroad boxcars at 8 hours (short term); aerators of railroad boxcars at 8 hours (short term); fumigators of flat bins at 1, 2, 4 and 8 hours (short term); fumigators of flat bins at 2, 4 and 8 hours (intermediate term); fumigators of farm bins at 4 and 8 hours (short term); spot fumigators at 2, 4 and 8 hours (short term); and spot fumigators at 4 and 8 hours (intermediate term), and bystanders during commodity transfer at 8 hours (short term).

Table 13: Summary of Unacceptable MOEs for workers including bystanders

Duration of Exposure	% Unacceptable MOEs Baseline Case	% Unacceptable MOEs PPE Full-Face Respirator Case
1 hour	64%	2%
2 hour	85%	6%
4 hours	98%	11%
8 hours	100%	19%
TOTAL (All scenarios/durations)	87%	10%

Notes:
- Total # of scenarios equals 47
- In baseline case the assumption is that no respirator is worn
- Concentrations vary by scenario per Mansdorf et. al. study

Table 14. Baseline MOEs for Workers and Bystanders

Scenario	1-Hour	2-Hour	4-Hour	8-Hour
Concrete upright facilities: Fumigators (ST)	30	15	8	**4**
Concrete upright facilities: Fumigators (IT/CT)	140	71	36	18
Concrete upright facilities: Bystanders during Fumigation (ST)	22	11	6	3
Concrete upright facilities: Bystanders during fumigation (IT/CT)	180	91	45	23
Concrete upright facilities: Bystanders after fumigation (ST)	62	31	15	8
Concrete upright facilities: Bystanders after fumigation (IT/CT)	200	100	51	25
Concrete upright facilities: Bystanders after aeration (ST)	140	68	34	17
Concrete upright facilities: Bystanders after aeration (IT/CT)	370	190	93	46
Bulk Railcar: Fumigators (ST)	20	10	5	3
Bulk Railcar: Fumigators (IT/CT)	51	26	13	6
Bulk Railcar: Bystanders during fumigation (ST)	27	13	7	3
Bulk Railcar: Bystanders during fumigation (IT/CT)	87	43	22	11
Bulk Railcar: Bystanders after fumigation (ST)	190	97	49	24
Bulk Railcar: Bystanders after fumigation (IT/CT)	230	110	57	29
Bulk Railcar: Aerators (ST)	12	6	3	2

(continued; footnotes follow)

Scenario	1-Hour	2-Hour	4-Hour	8-Hour
Bulk Railcar: Aerators (IT/CT)	21	11	5	3
Bulk Railcar: Bystanders post aeration (ST)	91	45	23	11
Bulk Railcar: Bystanders post aeration (IT/CT)	170	83	42	21
Railroad Boxcars: Fumigators (ST)	14	7	3	2
Railroad Boxcars: Fumigators (IT/CT)	56	28	14	7
Railroad Boxcars: Bystanders during fumigation (ST)	44	22	11	6
Railroad Boxcars: Bystanders during fumigation (IT/CT)	80	40	20	10
Railroad Boxcars: Bystanders during and after fumigation (ST)	30	15	8	4
Railroad Boxcars: Bystanders during and after fumigation (IT/CT)	100	50	25	13
Railroad Boxcars: Bystanders after fumigation (ST)	21	10	5	3
Railroad Boxcars: Bystanders after fumigation (IT/CT)	87	43	22	11
Railroad Boxcars: Aerators (ST)	15	7	4	2
Railroad Boxcars: Aerators (IT/CT)	32	16	8	4
Railroad Boxcars: Bystanders post aeration (ST)	31	15	8	4
Railroad Boxcars: Bystanders post aeration (IT/CT)	32	16	8	4
Tobacco Warehouse: Fumigators (ST)	27	13	7	3

(continued; footnotes follow)

Scenario	1-Hour	2-Hour	4-Hour	8-Hour
Tobacco Warehouse: Fumigators (IT/CT)	71	36	18	9
Tobacco Warehouse: Aerators (ST)	91	45	23	11
Tobacco Warehouse: Aerators (IT/CT)	150	77	38	19
Tobacco Warehouse: Bystanders post aeration (ST)	200	98	49	25
Tobacco Warehouse: Bystanders post aeration (IT/CT)	340	170	86	43
Flat Bin: Fumigators (ST)	1	0	0	0
Flat Bin: Fumigators (IT/CT)	3	1	1	0
Farm Bin: Fumigators (ST)	5	2	1	1
Farm Bin: Fumigators (IT/CT)	17	8	4	2
Spot fumigation: Fumigators (ST)	4	2	1	0
Spot fumigation: Fumigators (IT/CT)	5	2	1	1
Spot Fumigation: Aerators (ST)	200	99	50	25
Spot Fumigation: Aerators (IT/CT)	230	110	57	29
Commodity Transfer- Product packaging line: Bystanders post aeration (ST)	16	8	4	2
Commodity Transfer- Product packaging line: Bystanders post aeration (IT/CT)	120	59	29	15
Commodity Transfer- Transfer of grain to bulk cars: Bystanders post aeration (ST)	270	140	68	34
Commodity Transfer- Transfer of grain to bulk cars: Bystanders post aeration (IT/CT)	440	220	110	56

(continued; footnotes follow)

ST = Short Term
IT = Intermediate Term
CT = Chronic Term

Notes:

- Short term MOEs based on maximum measured concentrations from Mansdorf et. al. study
- Intermediate and chronic term MOEs based on mean concentrations from Mansdorf et. al. study
- MOEs less than 100 are generally considered to be of concern to the Agency

(continued; footnotes follow)

Because the hand application of aluminum and magnesium phosphide to animal burrows resulted in breathing zone exposures greater than the 0.03 ppm standard set forth by this document, it is considered an unacceptable method of application without appropriate respiratory protection. It should be noted that approximately 2 to 4 tablets were used in each application, and that the application activities took place outdoors. Exposures are likely to be significantly higher if the application rate is increased and/or containers are opened in areas other than outside (e.g., inside vehicles or buildings).

e. Additional Occupational/Residential Exposure Studies

The Agency is requiring a study to explore the potential for exposure of applicators, aerators, and occupational and residential bystanders to phosphine gas. The reason the Agency is requesting this data is two-fold. First, a limited amount of exposure data is available for aluminum and magnesium phosphide exposure. Secondly, while the Mansdorf et. al. study is considered the best available data for risk assessment, it uses a limited number of replicates and does not measure all of the important variables regarding potential exposures.

The monitoring data being requested must be captured for all of the phases of fumigation: application; fumigation; and aeration. The exposure levels of the applicator and assistants to phosphine during each of these phases need to be documented. In addition, ambient air concentrations in the immediate vicinity, i.e., where other personnel are working, must be documented during each phase. Further, phosphine concentrations must be measured outside of the structure to the limit of detection or 500 feet away during each phase of fumigation.

f. Short Term Residential Risk

There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Further, the Agency is concerned about the potential risks to residential bystanders, which are addressed in the occupational risk assessment.

C. Environmental Assessment

The Agency has completed its review of the available information regarding the potential impact of aluminum and magnesium phosphide on the environment. The following sections describe this assessment.

1. Environmental Fate and Transport Assessment

The environmental fate and transport assessment is based upon review of selected available literature and is not supported by guideline studies. Because of the physical properties and use patterns of aluminum and magnesium phosphide, the Agency has determined that no environmental fate studies are required at this time.

Aluminum phosphide (AlP) and magnesium phosphide (Mg_3P_2) appear to be non-persistent under most environmental conditions, and are non-mobile in soil because of their instability at atmospheric moisture contents. AlP and Mg_3P_2 react with water or moisture in air to generate the highly toxic gas phosphine (PH_3) which is the active ingredient of these pesticides (Cotton and Wilkerson, 1988; Fluck, 1973; Greenwood and Earnshaw, 1984; and World Health Organization, 1988). Other products of hydrolysis are aluminum and magnesium hydroxides. The reaction can be written as follows:

(1) $AlP + 3H_2O \text{ ----> } Al(OH)_3 + PH_3$ or

(2) $Mg_3P_2 + 6H_2O \text{ ----> } 3Mg(OH)_2 + 2PH_3$

The aluminum and magnesium hydroxide residues can further react to produce mineral phases that are known to occur naturally in the environment (Lindsay, 1979). Inorganic phosphate and other phosphorous oxyacids are expected to be other products formed from the oxidation of PH_3 in soils (World Health organization, 1988; Hilton and Robinson, 1972; EFED one-line, 1998).

Under normal environmental conditions phosphine exists as a gas. The solubility of phosphine in water at normal atmospheric pressure is approximately 340 ppm (World Health Organization, 1988) and the Ostwald solubility constant (the ratio of the concentration in solution to the concentration in the gas phase at equilibrium) is 0.201 (Fluck, 1983). Because of its high vapor pressure (40 mm Hg at -129.4 C) and Henry's Law Constant (0.1 atm m^3/mol), phosphine at the soil surface is expected to rapidly dissipate into the atmosphere (World Health Organization, 1988).

Phosphine in the atmosphere is rapidly degraded (World Health Organization, 1988). The half-life in air is approximately five hours with the mechanism of degradation being photoreaction with hydroxy radicals. The dark half-life is approximately 28 hours. The expected reaction products of phosphine in air are oxyacids of phosphorous and inorganic phosphate which are non-volatile.

Several published laboratory studies suggest that phosphine below the soil surface is quickly adsorbed and degraded (Hilton and Robinson, 1972; Eiseman et. al., 1997; Berck and Gunther, 1970). Gaseous phosphine added to soil headspace at

1000 mg/kg dry soil in closed containers degrades 50% after approximately five days in air dried soil and 11 days in water saturated soil (Hilton and Robinson, 1972). Smaller quantities of phosphine may be removed by soil through a faster mechanism because phosphine added at a lower concentration (0.35 micrograms/kg) was undetectable in 50 minutes (Eiseman, Glindemann, Bergman and Kuschk, 1997). Diffusion through the soil environment is expected to be slow because phosphine is sorbed in seconds when pushed through several types of soil in a nitrogen carrier (Berck and Gunther, 1970). The interaction of phosphine with soil appears to be mixed chemisorption (irreversible) and physisorption (reversible), with the extent of each dependent on soil type.

2. Surface and Ground Water Assessments

Aluminum and magnesium phosphide are expected to degrade rapidly in the environment to aluminum hydroxide and magnesium hydroxide and phosphine. The Agency has determined that phosphine gas will degrade in days, and has a low exposure potential for contaminating ground and surface water. Therefore, the Agency concludes that a dietary exposure assessment from drinking water is not necessary. See the discussion on page 46 for additional discussion.

3. Exposure and Risk Characterization

a. General

Aluminum phosphide and magnesium phosphide are expected to degrade rapidly in the environment to aluminum hydroxide and magnesium hydroxide and phosphine, the toxicant of these pesticides. It appears that phosphine will degrade in days and is at low risk for contaminating ground or surface waters. Phosphine near the soil surface is expected to diffuse into the atmosphere and be removed via photodegradation. Phosphine trapped beneath the soil surface will bind to soil, inhibiting movement, and be oxidized to phosphates.

Given the use patterns of the pesticides and these characteristics, aluminum and magnesium phosphide are not expected to pose a significant ecological risk to non-target organisms or to water resources under most circumstances, with the notable exception of some endangered species as described in the following section.

b. Endangered Species

One use pattern of aluminum and magnesium phosphide, as a burrow fumigant, poses a risk to threatened and endangered species of mammals and

reptiles. The risks posed to these species occur if they are found in a burrow that is fumigated. Because of the high degree of toxicity of phosphine gas, all animals in a treated burrow will be killed.

In 1981, the United States Fish and Wildlife Service (USFWS) determined that use of aluminum and magnesium phosphide as a burrow fumigant may jeopardize the black-footed ferret, the Utah prairie dog, the San Joaquin kit fox, the blunt-nosed leopard lizard, the eastern indigo snake, and the desert tortoise.

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 active ingredients, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing aluminum phosphide and magnesium phosphide active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing aluminum phosphide and magnesium phosphide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of aluminum phosphide and magnesium 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 aluminum phosphide and magnesium phosphide and to determine if aluminum phosphide and magnesium phosphide can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency has determined that all uses of aluminum phosphide and magnesium phosphide as specified in this document require mitigation of the risks associated with the exposure to these pesticides. The Agency will conduct a public process to identify the best ways to reduce the risks associated with aluminum and magnesium phosphide exposure. This process will include a public comment period and a stakeholder meeting. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing aluminum and magnesium phosphide to be eligible for reregistration. Further, 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 aluminum phosphide and magnesium 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. The reregistration of particular products is addressed in Section V.

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, and the data identified in Appendix B.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients aluminum phosphide and magnesium phosphide, the Agency has sufficient information on the human health effects of aluminum phosphide and magnesium phosphide and on their potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that all uses of aluminum phosphide and magnesium phosphide as specified in this document require mitigation of the risks associated with the exposure to these pesticides. The Agency will conduct a public process to identify the best ways to reduce the risks associated with aluminum and magnesium phosphide exposure. This process will include a public comment period and a stakeholder meeting. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing aluminum and magnesium phosphide to be eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of aluminum phosphide and magnesium phosphide as specified in this document require mitigation of the risks associated with the exposure to these pesticides. The Agency will conduct a public process to identify the best ways to reduce the risks associated with aluminum and magnesium phosphide exposure. This process will include a public comment period and a stakeholder meeting. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing aluminum and magnesium phosphide to be eligible for reregistration.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

The Agency has determined that the established tolerances for aluminum phosphide and magnesium 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, the Agency has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food, and drinking water.

b. Determination of Safety for Infants and Children

The Agency has determined that the established tolerances for aluminum phosphide and magnesium 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 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 phosphine gas residues in this population subgroup.

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

The Agency reviewed a prenatal inhalation developmental toxicity study in rats to determine susceptibility of infants and children to aluminum and magnesium phosphide. No treatment-related effects were seen in maternal body weight, body weight gain, food consumption, or gross pathology. No developmental toxicity was seen. Thus, it was determined that there is no increased susceptibility to *in utero* and/or postnatal exposure to phosphine**.** Aluminum and magnesium phosphide developmental toxicity to the offspring occurred at equivalent or higher doses than maternal toxicity.

The complete toxicology data requirements for a food-use chemical are not required for aluminum/magnesium phosphide, since no phosphine exposure is expected from the use pattern (i.e., fumigant). Any phosphine left in fumigated commodities is expected to be removed by adequate aeration of the commodities. Bound reaction products formed by reactions with phosphine and biological materials form innocuous phosphates. Therefore, the Agency determined that no additional toxicology studies are required for this chemical.

The Agency also addressed dietary (food and water) and residential exposure considerations. Detectable residues in food have been reported in field trials; however, these detections were attributed to food contamination. Residues of phosphine are not expected with proper use of these chemicals. A drinking water risk assessment was not performed for aluminum and magnesium phosphide, since there are no concerns for ground or surface water contamination from the use of these chemicals. There is a limited registered residential use at the present time. However, the Agency has proposed that this use be removed. Further, the Agency has concerns regarding potential risks to residential bystanders as discussed in the occupational exposure and risk assessment sections.

Based on these analyses, the Agency concluded that the 10x safety factor for increased susceptibility of infants and children (as required by FQPA) could safely be removed.

The Agency has not yet made a final decision concerning the possible common mechanism of toxicity and the potential for cumulative effects of aluminum and magnesium phosphide and other compounds. Therefore, for the purposes of the tolerance reassessments in this RED document, the Agency has considered the risks of aluminum and magnesium phosphide only.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, the Agency 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, The Agency 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 the Agency as it proceeds with further policy development and rulemaking that may be required.

If the Agency 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 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

The Agency is required to develop a screening program to determine whether certain substances (including all pesticide active ingredients 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 three years from the passage of FQPA (deadline of August 3, 1999) to implement this program. At that time, the Agency may require further testing of these active ingredient and end use products for endocrine disruptor effects.

2. Alternatives and Benefits Analysis

Integrated pest management of stored grain includes the following: pest-resistant storage facilities, effective temperature, aeration, and moisture regulation, sanitation, rotation of stock, monitoring of pest populations, use of chemical protectants, and fumigation. Chemicals recommended for sanitation of empty grain storage bins include methoxychlor, malathion, chlorpyrifos methyl, cyfluthrin, diatomaceous earth, chloropicrin, and pyrethrins with piperonyl butoxide. Protectants and surface treatments for grain in storage include malathion, chlorpyrifos methyl, diatomaceous earth, Bacillus thuringiensis, DDVP, pirimiphos methyl, pyrethrins with piperonyl butoxide, and methoprene. The above physical and chemical controls are preventative and suppressive of infestations but not effective for disinfesting stored grain once an infestation has started. Once an infestation has begun, fumigation is the only effective treatment for large amounts of stored grain. Aluminum phosphide, magnesium phosphide, methyl bromide, and carbon dioxide are the recommended fumigants. Methyl bromide is scheduled for cancellation in 2001. Carbon dioxide is prohibitively expensive and requires special equipment. Therefore, aluminum and magnesium phosphide can be considered methyl bromide alternatives.

Aluminum and magnesium phosphide also is used to control rodents which can carry various diseases including sylvanic plague. In cases where the purpose of treatment is to control for a vector-borne disease the use would be considered a public health use.

3. Tolerance Reassessment

Tolerances for Aluminum Phosphide Listed Under 40 CFR §180.225 (a) and (b), §185.200, and §186.200 and Tolerances for Magnesium Phosphide Listed Under 40 CFR §180.375 (a) and (b), §185.3800, and §186.3800::

The tolerances established for aluminum and magnesium phosphide are currently expressed in terms of residues of the fumigant phosphine resulting from the use of aluminum and magnesium phosphide, respectively. Since both chemicals have virtually identical use patterns and chemical properties, the Agency has decided to change the current tolerance expressions. The new tolerances will simply be

expressed in terms of residues of phosphine gas. These changes are not intended to change the tolerances for the related compound zinc phosphide because the use patterns for that chemical are substantially different than those for aluminum and magnesium phosphide. These changes will be formally implemented in the near future. At that time, the below tables will be changed to reflect the new tolerance expression.

FQPA stipulates that tolerances for pesticide residues in all types of food (raw or processed) be set under the same provisions of the law. Therefore, the listings of all aluminum phosphide tolerances should be moved under 40 CFR §180.225 and should be subdivided into Parts (a), (b), (c), and (d). Tolerances in Part (a) should be reserved for residues in/on raw agricultural commodities resulting from postharvest fumigation treatment. Tolerances in Part (b) should be reserved for residues in/on raw agricultural commodities resulting from preharvest treatment of pest burrows in agricultural and non-cropland areas. Tolerances in Part (c) should be reserved for residues resulting from fumigation of processed foods (formerly listed under 40 CFR §185.200). Tolerances in Part (d) should be reserved for residues resulting from fumigation of animal feeds (formerly listed under 40 CFR §186.200).

The current end-use product labels for aluminum phosphide were examined for the development of this RED document. The labels are in compliance with the requirements to establish a minimum aeration interval of 48 hours before the fumigated processed foods (except for processed brewer's rice, malt, and corn grits stored in breweries for use in the manufacture of beer) are offered to the consumers. Registrants who would like approval for shorter aeration periods based on forced air ventilation may submit residue data from trials conducted in accordance with the Agency's guidelines. Label restrictions have also been established specifying that under no conditions should the formulations containing aluminum phosphide be used so that they or their unreacted residues come in contact with any processed food.

Adequate data are available to reassess the established tolerances for residues of the fumigant phosphine in/on raw agricultural and processed commodities resulting from postharvest treatment of commodities or preharvest treatment of pest burrows with aluminum phosphide. No adjustments in the established tolerance levels are needed.

Summary

A summary of tolerance reassessments for aluminum and magnesium phosphide is presented in Table 15. The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to this table, some commodity definitions will be corrected. Further, since the tolerances will be combined per the

new tolerance expression mentioned above, several tolerances will become duplicative and thus will be revoked in the near future.

Table 15. Tolerance Reassessment Summary for Aluminum and Magnesium Phosphide.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances for Aluminum Phosphide Listed Under 40 CFR §180.225(a)			
Almonds	0.1	0.1	*[Almond, nutmeat]*
Barley	0.1	0.1	*[Barley, grain]*
Beans, cocoa	0.1	0.1	*[Cacao bean]*
Beans, coffee	0.1	0.1	*[Coffee, bean, green]*
Cashews	0.1	0.1	
Corn	0.1	0.1	*[Corn, field, grain]*
Corn, pop	0.1	0.1	*[Corn, pop, grain]*
Cottonseed	0.1	0.1	*[Cotton, seed, undelinted]*
Dates	0.1	0.1	*[Date, dried]*
Filberts	0.1	0.1	
Millet	0.1	0.1	*[Millet, grain]*
Nuts, Brazil	0.1	0.1	*[Brazil nuts]*
Nuts, pistachios	0.1	0.1	*[Pistachios]*
Oats	0.1	0.1	*[Oats, grain]*
Peanuts	0.1	0.1	*[Peanut, nutmeat]*
Pecans	0.1	0.1	
Rice	0.1	0.1	*[Rice, grain]*
Rye	0.1	0.1	*[Rye, grain]*
Safflower, seed	0.1	0.1	
Sesame seed	0.1	0.1	*[Sesame, seed]*
Sorghum	0.1	0.1	*[Sorghum, grain]*
Soybeans	0.1	0.1	
Sunflower, seed	0.1	0.1	
Vegetables, seed and pod (except soybeans)	0.01	0.01	*[Legume vegetables (succulent or dried group (excluding soybeans)]*
Walnuts	0.1	0.1	
Wheat	0.1	0.1	*[Wheat, grain]*
Tolerances for Aluminum Phosphide Listed Under 40 CFR §180.225(b)			
All RACs resulting from preharvest treatment of pest burrows	0.01	0.01	
Tolerances for Aluminum Phosphide Listed Under 40 CFR §185.200 (c)			

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Processed foods	0.01	0.01	Move to Section 180
Tolerances for Aluminum Phosphide Listed Under 40 CFR §186.200 (c)			
Animal feeds	0.1	0.1	Move to Section 180

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances for Magnesium Phosphide Listed Under 40 CFR §180.375(a)			
Almonds	0.1	0.1	*[Almond, nutmeat]*
Avocados	0.01	0.01	
Bananas	0.01	0.01	
Barley	0.1	0.1	*[Barley, grain]*
Brazil nuts	0.1	0.1	
Cabbage, Chinese	0.01	0.01	
Cashews	0.1	0.1	
Citrus citron	0.01	0.01	
Cocoa beans	0.1	0.1	*[Cacao bean]*
Coffee beans	0.1	0.1	*[Coffee, bean, green]*
Corn	0.1	0.1	*[Corn, field, grain]*
Corn, pop	0.1	0.1	*[Corn, pop, grain]*
Cottonseed	0.1	0.1	*[Cotton, seed, undelinted]*
Dates	0.1	0.1	*[Date, dried]*
Eggplants	0.01	0.01	
Endive (escarole)	0.01	0.01	*[Endive/escarole]*
Filberts	0.1	0.1	
Grapefruit	0.01	0.01	
Kumquats	0.01	0.01	
Lemons	0.01	0.01	
Lettuce	0.01	0.01	
Limes	0.01	0.01	
Mangoes	0.01	0.01	
Millet	0.1	0.1	*[Millet, grain]*
Mushrooms	0.01	0.01	
Oats	0.1	0.1	*[Oats, grain]*
Oranges	0.01	0.01	
Papayas	0.01	0.01	
Peanuts	0.1	0.1	*[Peanut, nutmeat]*
Pecans	0.1	0.1	
Peppers	0.01	0.01	
Persimmons	0.01	0.01	
Pimentos	0.01	Revoke	Covered by the tolerance for peppers.
Pistachio nuts	0.1	0.1	*[Pistachios]*

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Plantains	0.01	Revoke	Covered by the tolerance for bananas.
Rice	0.1	0.1	*[Rice, grain]*
Rye	0.1	0.1	*[Rye, grain]*
Salsify tops	0.01	0.01	*[Salsify, tops]*
Sorghum	0.1	0.1	*[Sorghum, grain]*
Soybeans	0.1	0.1	
Sunflower seeds	0.1	0.1	*[Sunflower, seed]*
Sweet potatoes	0.01	0.01	
Tangelos	0.01	0.01	
Tangerines	0.01	0.01	
Tomatoes	0.01	0.01	
Walnuts	0.1	0.1	
Wheat	0.1	0.1	*[Wheat, grain]*
Tolerances for Magnesium Phosphide Listed Under 40 CFR §180.375 (b)			
All RACs resulting from preharvest treatment of pest burrows	0.01	0.01	
Tolerances for Magnesium Phosphide Listed Under 40 CFR §185.3800 (c)			
Processed foods	0.01	0.01	Move to Section 180
Tolerances for Magnesium Phosphide Listed Under 40 CFR §186.3800 (c)			
Animal feeds	0.1	01	Move to Section 180

4. Codex Harmonization

The Codex Alimentarius Commission has not established maximum residue limits (MRLs) for aluminum and magnesium phosphide residues in/on various commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part 2, FAO CX/PR, 4/91*). However, MRLs have been established for hydrogen phosphide (phosphine gas). At this time there is not harmonization between MCL's and U.S. tolerances. Provided that the registrant submits a petition (with supporting CODEX residue data) requesting that these tolerances be reduced, the Agency anticipates that harmonization between European MCL's and U.S. tolerances will be possible. Harmonization of the Codex MRLs with the U.S. tolerances will be considered as part of the efforts to redefine the tolerance expression as mentioned earlier.

5. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

Acute Dietary

After conducting a conservative acute dietary analysis, the Agency has found that the dietary exposure and risk associated with aluminum and magnesium phosphide is negligible. Phosphine gas will dissipate rapidly into the atmosphere which makes residues on treated commodities very unlikely. Additionally, aluminum and magnesium phosphide may not be directly mixed with foods, feed, or raw agricultural products which may be used directly as foods. Residues also are not expected to be found in meat/milk/poultry/eggs. Further, the endpoint selected for the risk assessment is based upon a NOEL that was the highest dose tested in the study which means that no toxic signs were observed at the dose used for the risk assessment and it is possible that the true NOEL is higher than the dose level used for the risk assessment.

Chronic Dietary

After conducting a conservative chronic dietary analysis the Agency has found that both the chronic dietary exposure and risk associated with aluminum and magnesium phosphide are negligible for the reasons mentioned above.

Cancer

Since chronic dietary exposure and risk associated with the use of aluminum and magnesium phosphide are negligible, no risk of cancer is expected from the use of these pesticides. The final results of the two-year oncogenicity study are expected in November 1998, and will be reviewed to confirm this position.

(2) Worker (Mixer/Loader/Applicator)

Short-Term and Intermediate Term

Upon conducting an extensive risk assessment on over 40 scenarios, the Agency found that the risks posed to workers were

acceptable when full PPE/SCBA was utilized. However, the use of SCBA especially over a full 8-hour application period would be cumbersome. Most MOEs were acceptable when PPE/full face respirators were used for the full 8-hour application period based on measured concentrations. All scenarios had acceptable MOEs using the OSHA PEL. Several scenarios, however, had unacceptable MOEs when based on mean concentrations which, together with the potential problems surrounding the long-term use of SCBA, indicates the need for additional mitigation measures to reduce these worker risks. These concerns are addressed through the risk mitigation efforts outlined in this RED.

Nearly all MOEs were unacceptable at baseline conditions (no PPE). The potential exists for workers who are not directly associated with the fumigation/aeration activities to be near areas where these operations are occurring. These workers may not be aware of these activities and/or may not be wearing the required PPE, thus creating a potentially hazardous situation. This occupational "bystander" risk is discussed below.

Post-Application

The Agency is concerned about potential risks to persons entering treated areas even when following the entry restrictions found on end-use product labels for aluminum and magnesium phosphide.

(3) Bystanders

The Agency is concerned about the potential risks to occupational and residential bystanders with respect to the use of aluminum and magnesium phosphide. Most worker scenarios had unacceptable MOEs for occupational bystanders at the baseline level (no PPE) with no scenario being acceptable for 8 hours and most not acceptable at even 1 to 2 hours of exposure. Since nearby workers not directly involved in the fumigation/aeration activities may not be wearing the PPE required for fumigators and aerators, such exposures are possible and are a concern to the Agency. Of additional concern is the potential for exposure to residential bystanders, since there is little likelihood of those persons wearing any PPE. In some cases, structures and areas undergoing fumigation and aeration may be very near to residential dwellings or other places where residential bystanders are likely to be found. Poisoning incident data supports the Agency's concerns for both occupational and residential bystander

risks.

(4) Public Comment and Stakeholder Meeting Process

Given the high toxicity of aluminum and magnesium phosphide and potential risks posed to occupational and residential bystanders, the Agency has developed a number of mitigation measures which it proposes in order to reduce the risks outlined in this document. However, since aluminum and magnesium phosphide have significant benefits and there are few if any viable alternatives besides methyl bromide, the Agency believes that it is important that a broad stakeholder process be conducted to discuss these measures and/or to develop other workable mitigation measures that adequately protect occupational and residential bystanders. Therefore, the Agency is planning to conduct a public comment and stakeholder process to accomplish this objective.

During the public comment period, commencing with the publishing of a Federal Register Notice, comments and suggestions will be collected and reviewed concerning these measures. Based upon this input, the proposed measures will be revised as needed. These revised mitigation measures will be discussed at a stakeholder meeting that will be held within 9 months from the issuance of this RED at a location to be determined. For this meeting to be most efficient and successful, all interested parties and viewpoints will be welcomed and considered. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing aluminum and magnesium phosphide to be eligible for reregistration. The outcomes of this public comment and stakeholder process will effect all aluminum and magnesium products.

(5) Proposed Risk Mitigation Measures

The following mitigation measures are proposed for all aluminum and magnesium phosphide products. These measures are to be discussed as part of the public review and stakeholder meeting process mentioned above. Following each proposal is a list of generic questions that can be used as a guide for providing input to the Agency on particular proposals.

i. Notification of Authorities and On-site Workers

The Agency believes that it is important that anyone who might be expected to respond to an emergency involving aluminum an magnesium phosphide be well prepared to quickly and effectively respond to such a situation. Hence, the Agency is proposing that applicators would be required to ensure that the local authorities (fire departments, police departments etc.) are notified of the date, time, and location of planned fumigation events at least 24 hours in advance of beginning operations. Further, the Agency is concerned that on-site workers not directly associated with the fumigation could be inadvertently exposed to phosphine since they may frequent areas near fumigated structures. To minimize the potential for inadvertent exposures the Agency is proposing that the applicators would be required to notify any worker or other person who might be expected to be in the proximity of the fumigation/aeration, prior to fumigation.

* what authorities would need to be notified?

* who would be responsible for notification?

* what form or method of notification of both authorities and workers should be employed?

* what is the appropriate timing for notifications?

ii. Requirement for Certified Applicators

The Agency believes that a properly structured certification process provides for a high level of competence in those that are able to complete this process. This level of competence could be difficult to attain without completion of such a process. In order to better ensure the safe conduct of fumigation/aeration operations, the Agency is proposing to require that all persons who conduct these activities be a certified applicator or that certified applicators supervising the activity be within 50 ft of the operation and within clear sight-line of the persons conducting the operation. Current labels allow for non-certified fumigators and aerators to conduct activities under the direct supervision and physical presence of a certified applicator. However, it is possible under this current language for the certified applicator to be a significant distance away from the actual operation, impeding his/her ability to adequately oversee the operations. This potential problem would be solved by requiring certified applicators to be within 50 feet (and within clear sight lines) of persons conducting fumigation/aeration operations.

* when a certified applicator is supervising an operation where should he/she be positioned with respect to the work being done?

iii. Prohibit Aeration of Railcars, Railroad Boxcars, Other Vehicles, and Containers En-Route.

The Agency is concerned about the possibility of exposure to phosphine from aeration of fumigated railcars, railroad boxcars, shipping containers, and other vehicles while in transit. This would especially be of concern during scheduled and unscheduled stops in or near populated areas. To ensure that these exposures do no occur, the Agency is proposing that aeration of fumigated railcars, railroad boxcars, shipping containers, and other vehicles while in transit would be prohibited. Labels would be required to include this prohibition.

* what measures can be taken to prevent exposures from aeration of fumigated railcars, railroad boxcars, shipping containers, and other vehicles while in transit?

iv. Placarding fumigated structures, containers, and vehicles.

The Agency is concerned about potential exposure resulting from improper entrance to fumigated vehicles that have been fumigated prior to/during transit. While the labels require monitoring of such vehicles prior to entry the labels are not always part of the shipment records and the current placards do no necessarily contain this requirement. The Agency also believes it is important that placards contain incident reporting information so that those who might be exposed be better able to report the incident. Currently, labels require the placarding of structures, containers, and vehicles that have been fumigated. The Agency is proposing as a possible requirement that these placards, or some other documentation that accompanies the structure/container/vehicle, clearly state that prior to entering the structure/container/vehicle a certified applicator or trained person under the supervision of a certified applicator (as defined above) must monitor the concentration of phosphine therein. Unloading where exposure to workers or bystanders is possible, or entry must not occur until the measured concentrations are below the pertinent standard unless appropriate PPE is worn. These placards must also contain information for reporting incidents which is consistent with the incident reporting program developed by the registrants.

* how should information be provided to persons prior to entry into a fumigated structure or vehicle to prevent exposure? What should that information be?

* what is the appropriate mechanism for reporting incidents and how should that mechanism be communicated?

v. Establish an Incident Reporting Program.

The Agency believes that, given the toxicity of these chemicals and the incident data currently available, a structured program would need to be developed to ensure that more complete and accurate information regarding incidents is collected and analyzed. Therefore, the Agency is proposing that registrants would be required to establish programs for the comprehensive reporting of incidents to the Agency on an annual basis.

* what mechanisms can be used to report and analyze incidents involving aluminum and magnesium phosphide?

vi. Personal Protective Equipment

Given the high level of toxicity of phosphine and the Agency's concerns regarding the potential for exposure as outlined in this RED, the Agency is proposing to require that all persons involved in fumigation/aeration operations wear respiratory protection during those operations unless it can be verified via monitoring that the concentrations of phosphine are at or below the established standard. PPE would be required to be worn by any person conducting monitoring activities until concentrations are known to be below the established limit. In the event of a spill or leak, SCBA or supplied air would be required to be worn until the spill has been cleaned or the leak has been repaired.

As mentioned previously, a full face respirator is not always adequately protective, and SCBA can be cumbersome and difficult to use over extended periods of time. Supplied air is a possible alternative. Supplied air is defined as a NIOSH-approved full-face or hood respirator to which is supplied uncontaminated air, usually via a hose fed by an electric compressor. The face piece or hood must be maintained under positive pressure to maintain the maximum protection factor.

*what procedures could reduce the potential for exposure during fumigation/aerationoperations?

* what equipment would provide adequate protection under various conditions?

vii. Proposal to require two-man operation for any activity that would involve entry into a fumigated structure.

Due to the acutely toxic effects of inhaling phosphide gas the Agency is proposing that a minimum of two qualified persons would be needed to carry out any fumigation requiring entry into a structure. By implementing a two-man rule, if an applicator is unable to remove oneself from a dangerous exposure situation the second person can then assist in the safe removal of that person from danger. One person would be required to be a certified applicator and one person would need to be trained in the use of monitoring equipment and the health effects of phosphine gas. Although phosphine gas is considered to have good 'warning properties' because of a foul odor detectable by smell as low as 0.02 ppm, not all persons have the same sense of smell. Because some persons may have a poor sense of smell, and due to the capacity for the sense of smell to be fatigued after prolonged exposure, the fumigation workers should rely upon chemical detecting instruments.

*what steps can be taken to ensure that an applicator is able to exit a dangerous situation safely?

* what qualifications should the person who is acting as the second person have?

viii. Establish 500 foot buffer zone and restricted area around all fumigated structures

The Agency is concerned about the possibility of bystander exposure to phosphine especially in residential areas especially considering the toxicity of phosphine. Based upon a review of incidents, the Agency is proposing to prohibit the fumigation and aeration of structures that are within 500 feet of residential areas. Further, a 500 foot restricted area would be implemented for all areas/structures undergoing fumigation/aeration. These steps would be taken primarily to prevent exposure to residential bystanders. Prior to entry to this area monitoring would need to be conducted to ensure

that the concentrations of phosphine in the atmosphere is less than the 0.03 ppm standard established in this RED or the limit of detection of the best available technology. Entry would not allowed above that concentration unless appropriate PPE is worn. Placarding would be required to occur around the perimeter of the 500 foot restricted zone. Efforts would need to be made to request permission for placarding where placarding of the perimeter would involve other people's property.

* what size buffer zone, if any, would provide adequate protection to residential bystanders?

* what alternative measures could be put in place to achieve protection w/o a buffer zone?

* what would be the impact on the ability to fumigate various structures if a 500 foot zone was put in place?

* what measures could be put in place regarding railcars, shipping containers and other vehicles to prevent bystander exposure?

ix. Institute More Thorough Monitoring Around the Commodity

The Agency is concerned about the possibility of exposure resulting from entry into a structure where phosphine gas pockets have developed which normal monitoring would not detect. Therefore, the Agency is proposing to require stringent monitoring when unloading or otherwise disturbing a commodity that has been fumigated, since the level of phosphine gas may be higher at the core of the commodity than in the surrounding air. Monitoring at the door or hatch is insufficient in some cases. Therefore, concentrations would be required to be monitored at the top, middle, and bottom levels of the commodity/storage facility, where feasible, because of stratification of gasses and vapors (similar to monitoring in confined spaces, OSHA 29 CFR 1910.146).

* what steps can be taken to ensure that there are not "pockets" of phosphine gas within a given structure or commodity prior to entry?

* what are the technical limitations to conducting this type of monitoring, if any?

x. Require Seal/Leak Testing for Fumigated Structures

The Agency believes that one potential exposure scenario would involve leakage of phosphine, especially into adjacent structures where people may be working/residing. For this reason the Agency is proposing that, prior to fumigation, the structure would undergo seal/leak testing using established methods to ensure that leakage during fumigation will not occur or is significantly minimized. Record of seal/leak tests must be retained by the certified applicator. Leaks would need to be repaired prior to fumigation. Fumigation would prohibited in cases where substantial leaks are discovered and cannot be sealed.

* what methods are available for conducting effective leak tests and how costly are these methods?

* what other steps could be taken to reduce the possibility of significant leaks?

* how can substantial leakage be defined?

xi. Establish a Minimum Distance from Residences for Burrow Use and PPE for Applicators During these Applications.

The Agency is concerned about the possibility of unintended exposure to residents or other bystanders that might result from rodent control uses near homes or other commercial facilities such as hospitals, schools, and nursing homes. Therefore, the Agency is proposing that treatment of burrows for rodent control be prohibited within 100 feet of a residence. Note that current labels have a restriction of 15 feet, which may not be protective if burrow tunnels extend toward residences (basements). Applicators involved in the fumigation of animal burrows would be required wear respiratory protection during the course of the operation. These actions would eliminate the residential uses of aluminum and magnesium phosphide but would allow for rodent control to continue under other circumstances. In cases of public health, where no other alternatives can be found, exceptions to this item may be made.

* how can exposures to bystanders be prevents when burrows are treated in a residential or school/hospital setting?

* what, if any, size buffer zone around residential and other

related structures would provide adequate protection from inadvertent exposure?

* what is the potential for seepage of phosphine into basements during a burrow treatment?

xii. Notification of Local Residents

The Agency believes that it is important to notify local residents near fumigated structures so that they can take actions if they choose to protect themselves from possible phosphine exposure. This is especially germane given the Agency's commitment to community right to know. Therefore, the Agency is proposing to require notification so that residents in adjoining properties can make decisions regarding temporarily leaving their property during fumigation. Such notification would also be required for commercial and industrial sites that are near a planned fumigation operation. The Agency proposes that the certified applicator would be required to ensure that all residents are notified within 750 feet of the fumigated structure.

* what is the most appropriate means of informing the public of impending fumigation\aeration operations?

* how should the local area be defined for purposes of notification? Is 750 ft. appropriate?

xiii. Requirement for Improved Training for Certified Applicators

The Agency believes that effective training and certification programs are needed to ensure that applicators are prepared to conduct fumigation operations safety. Since fumigation is a relatively unique operation when compared to other agricultural and non-agricultural pest control practices, the Agency believes that a fumigation-specific certification program may be necessary. Although current labels state the need for applicators to have training in phosphine fumigation, existing training programs appear insufficient given the high incident rate. The Agency is proposing to require that the registrants work with the appropriate personnel in the Agency and in the States to develop a fumigator-specific certification program that adequately addresses all risks associated with the use of these chemicals. These programs would stress the highly toxic nature of the chemicals, fumigation/aeration-specific issues, and the importance of

understanding and following label language exactly. Also, those requirements that result from the outcomes of the stakeholder meetings, must be emphasized. This effort would also include consideration of the most effective method of delivering this training.

* is there a need for a fumigation-specific training program?

* what elements should a fumigation-specific certification program contain?

* could existing programs be improved upon to meet these needs or does a new program need to be developed?

* can reciprocity or standardization be achieved? should they be achieved?

xiv. Monitoring Methods to Minimize Exposure

The Agency is concerned about exposures to phosphine given its high toxicity. Therefore, the Agency is proposing to require additional monitoring of areas around fumigated structures in order to reduce the potential for occupational and residential bystander exposure to phosphine. The Agency is further proposing to require that no fumigated structure be entered until it can be verified that the concentrations of phosphine present are at or below the 0.03 ppm standard unless appropriate PPE is worn. A certified applicator or other competent person (industrial hygienist etc.) Would be required to conduct the monitoring. All fumigation/aeration operations would be covered by this requirement including outdoor operations.

The Agency recognizes that current technology is not capable of detecting phosphine at the 0.03 ppm level. Therefore, the best available technology would be used with the limit of detection acting as the standard until new technology becomes available at which time the 0.03 standard would be required. The Agency is aware of a "real-time" direct-read device technologies with a limit of detection of 0.05 ppm that are currently available. These devices can be equipped with audible alarms and data loggers.

Further, there is evidence that the human sense of smell can "detect" phosphine at 0.02 ppm levels (See also ix). In cases where an employee smells the gas it will be assumed that the concentrations are above the standard and proper precautions/actions taken. Under

no circumstances should a person consider smell as a monitoring option in lieu of device monitoring.

* what are the impacts of using the .03 ppm regulatory standard?

* are there scientifically valid alternatives to the .03 ppm standard?

* what would an appropriate monitoring scheme include?

* is it appropriate to monitor "outdoor" operations? why or why not?

xv. Establish and Define Applicable Exposure Limits for the Label

The Agency believes that it is important that users of this pesticide be aware of all applicable workplace standards regarding phosphine. Therefore, the Agency is proposing to require that these standards appear on the label. It would be clearly stated that actions that are required currently based upon the OSHA PEL, STEL and action levels will now be required to occur based upon the 0.03 ppm standard established by this document.

* same questions as above.

b. Environmental/Ecological Effects

Aluminum phosphide and magnesium phosphide are expected to degrade rapidly in the environment to aluminum hydroxide and magnesium hydroxide and phosphine, the toxicant of these pesticides. It appears that phosphine will degrade in days and is at low risk for contaminating ground or surface waters. Phosphine near soil surface is expected to diffuse into the atmosphere and be removed via photodegradation. Phosphine trapped beneath the soil surface will bind to soil, inhibiting movement, and be oxidized to phosphates which are common in the natural environment. Therefore, aluminum and magnesium phosphide and their residues do not appear to be persistent or mobile under most environmental conditions.

Given the characteristics aluminum and magnesium phosphide and their use patterns, these pesticides are not expected to pose a significant ecological risk to non-target organisms or to water resources under most circumstances, with the exception of some endangered species. Since one of

the uses of these pesticides is as a burrow fumigant for the control of rodents, there is a concern that several endangered or threatened species could be present in burrows targeted for fumigation. Since phosphine gas is highly toxic any animals in a fumigated burrow are expected to be killed. See the discussion below on the endangered species statement for additional information regarding this issue.

c. Restricted Use Classification

Based on its toxicity and use patterns, the Agency is maintaining Restricted Use classification for all aluminum and magnesium phosphide products.

d. Endangered Species Statement

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

Aluminum and magnesium phosphide have been subject to a formal consultation with the Fish and Wildlife Service, as noted in Section III of this document. Additional consultation with the Fish and Wildlife 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 Labeling Rationale

At this time, products containing aluminum and magnesium phosphide are intended primarily for occupational use (e.g. mixed, loaded, and applied by commercial applicators only;). The WPS does not cover the currently labeled uses of these pesticides. Therefore, the uses of aluminum and magnesium phosphide are NOT within the scope of WPS. A limited

registered use for treatment of rodent burrows may involve applications at residential sites. Exposure to residential bystanders is an issue of concern as mentioned earlier.

Occupational-Use Products

The Agency is proposing a.i.-specific requirements for all occupational handlers of aluminum and magnesium phosphide. The MOE's for inhalation exposure were less than 100 for all occupational categories at the baseline and for aerators, fumigators, and bystanders in a number of scenarios where PPE was used. The Agency is proposing active-ingredient-based protections for handlers of aluminum and magnesium phosphide in all exposure situations.

Other Labeling Requirements

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

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

There are no manufacturing-use products (MPs) registered under Shaughnessy Nos. 066501 and 066504. There are 28 aluminum phosphide end-use products (EPs) and four magnesium phosphide EPs. The Agency has determined that because there are no registered MPs containing aluminum or magnesium phosphide as the sole active ingredient (TGAI), all registered EPs containing aluminum or magnesium phosphide as the sole active ingredient are subject to a reregistration eligibility decision. This being the case, the Agency is planning to require a bystander exposure monitoring study as confirmatory data. This air monitoring study is considered a non-guideline, or “special” study, and as such will be forwarded to the registrant in a separate Data Call-In after review and clearance by the Office of Management and Budget (OMB).

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. 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.

2. 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. Therefore, 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 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 problems?
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 aluminum and magnesium phosphide labels must refer consumers to the NPTN number for additional information. This reference must bear the specific label language contained in the table at the end of this section.

C. Required Labeling Changes Summary Table

The following table summarizes the labeling requirements being imposed by the RED

for all aluminum and magnesium phosphide products. Any use instructions on current labels that conflict with those language below should be removed.

Table 16: Risk Mitigation Labeling Changes for Aluminum and Magnesium Phosphide		
Description	**Required Labeling**	**Placement**
Labeling for All Products		
NPTN Phone Number	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.	Directions for Use
Statement of Practical Treatment	Symptoms of overexposure are headache, dizziness, nausea, difficult breathing, coughing, shortness of breath, vomiting and diarrhea. Breathing difficulty may not appear until several hours after exposure has ceased.	Statement of Practical Treatment
Statement of Practical Treatment	People who show signs of overexposure to phosphine gas, or are given any first aid treatment due to phosphine gas, must be taken directly to a doctor or emergency treatment facility, along with a copy of the label, the applicator's manual and/or the MSDS, which will be provided to the attending physician.	Statement of Practical Treatment
Definition of Well -Ventilated Area	Example(s) of a "well ventilated area" per OSHA guidelines must be included on the label.	Applicator Worker and Exposure Guideline
Respiratory Protection	The certified applicator must ensure that those who require respiratory protection are part of a Respiratory Protection Program per OSHA standards contained in 29 CFR 1910.134.	Respiratory Protection
Restriction	"Under no circumstances shall food, feed, and/or raw agricultural commodities which may be used directly as foods come into contact with aluminum or magnesium phosphide."	Directions for Use
Prevention of Explosions	"Hydrogen phosphide-air mixtures at concentrations above the lower flammable limit may ignite spontaneously. Ignition of high concentrations of hydrogen phosphide can produce a very energetic reaction. Explosions can occur under these conditions and my cause severe personal injury. **Never allow the buildup of hydrogen phosphide to exceed explosive concentrations**. Do not confine spent or partially spent dust from metal phosphide fumigants as the slow release of hydrogen phosphide from this material may result in formation of an explosive atmosphere. Monitoring will ensure that explosive concentrations are not exceeded."	Recommended Dosage Rates

Table 16: Risk Mitigation Labeling Changes for Aluminum and Magnesium Phosphide		
Leakage from Fumigated Sites	"Adjacent, enclosed areas likely to be occupied must be examined to ensure that significant leakage has not occurred."	Leakage from Fumigated Sites
Piling of Tablets, Pellets or Bags	Piling of tablets, pellets or bags or the addition of liquid to the product is prohibited.	Safety Recommendations and Requirements

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 aluminum and magnesium 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

APPENDIX A - Table of Use Patterns Subject to Reregistration

Appendix A is 87 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Aluminum and Magnesium Phosphide covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Aluminum and Magnesium 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 Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
PRODUCT CHEMISTRY for Pestcon Systems (5857-1 and 5857-2)			
61-1	**Chemical Identity**	ALL	00078353, 00144543, Data Gap
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00078353, 00144543, Data Gap
61-2B	**Formation of Impurities**	ALL	00078353, 00144543
62-1	**Preliminary Analysis**	ALL	00078353, Data Gap
62-2	**Certification of Limits**	ALL	00078353, 00144543, Data Gap
62-3	**Analytical Method**	ALL	00078353, 00144543, Data Gap
63-2	**Color**	ALL	00078354, 00144543
63-3	**Physical State**	ALL	00078354, 00144543
63-4	**Odor**	ALL	00078354, 00144543
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	00078354, 00144543
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Letter 4/26/93
63-15	**Flamability**	ALL	00144543
63-16	**Explodability**	ALL	Letter 4/26/93
63-17	**Storage Stability**	ALL	00144543
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap

PRODUCT CHEMISTRY for Midland Fumigant Company(30574-1 and 30574-4)

61-1	**Chemical Identity**	ALL	40607901
61-2A	**Start. Mat. & Mnfg. Process**	ALL	40607901, Data Gap
61-2B	**Formation of Impurities**	ALL	40607901
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	40607901, Data Gap
62-3	**Analytical Method**	ALL	40607901, Data Gap
63-2	**Color**	ALL	40607901
63-3	**Physical State**	ALL	40607901

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-4	**Odor**	ALL	40607901
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	40607901
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flamability**	ALL	40607901
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage Stability**	ALL	40607901
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap

<u>PRODUCT CHEMISTRY</u> for Midland Fumigant Company(30574-9, 30574-10 and 30574-11)

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
61-1	**Chemical Identity**	ALL	00153941, 40610401
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00153941, 40610401, Data Gap
61-2B	**Formation of Impurities**	ALL	00153941, 40610401
62-1	**Preliminary Analysis**	ALL	00153941, Data Gap
62-2	**Certification of Limits**	ALL	40610401, Data Gap
62-3	**Analytical Method**	ALL	00153941, 40610401, Data Gap
63-2	**Color**	ALL	40610401
63-3	**Physical State**	ALL	40610401
63-4	**Odor**	ALL	40610401
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	40610401
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	40610401
63-15	**Flamability**	ALL	40610401
63-16	**Explodability**	ALL	00153941

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-17	**Storage Stability**	ALL	00153941
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	00153941
PRODUCT CHEMISTRY for Midland Fumigant Company(30574-5, 30574-6, 30574-7 and 30574-8)			
61-1	**Chemical Identity**	ALL	Data Gap
61-2A	**Start. Mat. & Mnfg. Process**	ALL	Data Gap
61-2B	**Formation of Impurities**	ALL	Data Gap
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	Data Gap
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	Data Gap
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	Data Gap
63-8	**Solubility**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flamability**	ALL	Data Gap
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage Stability**	ALL	Data Gap
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap

PRODUCT CHEMISTRY for Degesch America Inc.(40285-1, 40285-3,40285-13 and 40285-14)

61-1	**Chemical Identity**	ALL	41421201
61-2A	**Start. Mat. & Mnfg. Process**	ALL	41421201
61-2B	**Formation of Impurities**	ALL	41421201
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	41421201

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
62-3	**Analytical Method**	ALL	41421201, Data Gap
63-2	**Color**	ALL	41421201
63-3	**Physical State**	ALL	41421201
63-4	**Odor**	ALL	41421201
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	41421201
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	41421201
63-15	**Flamability**	ALL	41421201
63-16	**Explodability**	ALL	41421201
63-17	**Storage Stability**	ALL	41421201
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
PRODUCT CHEMISTRY for Casa Bernardo (43743-1,43743-2, and 43743-3)			
61-1	**Chemical Identity**	ALL	40418701, Data Gap
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00115159, 40418701
61-2B	**Formation of Impurities**	ALL	00115158, 00115159, 40418701
62-1	**Preliminary Analysis**	ALL	40418701
62-2	**Certification of Limits**	ALL	40418701, Data Gap
62-3	**Analytical Method**	ALL	00115158, 00115159, 40418701, Data Gap
63-2	**Color**	ALL	00115158, 00115159, 40418701
63-3	**Physical State**	ALL	00115158, 40418701
63-4	**Odor**	ALL	00115158, 00115159, 40418701
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	00115158
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Letter 5/25/93
63-15	**Flamability**	ALL	00115158, 40418701
63-16	**Explodability**	ALL	40418701
63-17	**Storage Stability**	ALL	00115158, 40418701
63-18	**Viscosity**	ALL	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	00115158
PRODUCT CHEMISTRY for Inventa Corporation (59209-1, 59209-2, and 59209-3)			
61-1	**Chemical Identity**	ALL	40954901, 40954902
61-2A	**Start. Mat. & Mnfg. Process**	ALL	40954901, 42912901, Data Gap
61-2B	**Formation of Impurities**	ALL	40954901
62-1	**Preliminary Analysis**	ALL	40954902, Data Gap
62-2	**Certification of Limits**	ALL	40954901, 40954902, Data Gap
62-3	**Analytical Method**	ALL	40954902, Data Gap
63-2	**Color**	ALL	40954903
63-3	**Physical State**	ALL	40954903

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-4	**Odor**	ALL	40954903
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	40954903
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	40954903, Data Gap
63-15	**Flamability**	ALL	Data Gap
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage Stability**	ALL	40954903
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap
PRODUCT CHEMISTRY for Inventa Corporation (59209-8)			
61-1	**Chemical Identity**	ALL	00126205, Data Gap

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00126205, 41723901
61-2B	**Formation of Impurities**	ALL	00126205, 41723901
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	00126205, Data Gap
62-3	**Analytical Method**	ALL	00126205, Data Gap
63-2	**Color**	ALL	00126205
63-3	**Physical State**	ALL	00126205
63-4	**Odor**	ALL	00126205
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	00126205
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flamability**	ALL	00126205
63-16	**Explodability**	ALL	00126205
63-17	**Storage Stability**	ALL	00126205

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	00126205
PRODUCT CHEMISTRY for Inventa Corporation (59209-8)			
61-1	**Chemical Identity**	ALL	00126205, Data Gap
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00126205, 41723901
61-2B	**Formation of Impurities**	ALL	00126205, 41723901
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	00126205, Data Gap
62-3	**Analytical Method**	ALL	00126205, Data Gap
63-2	**Color**	ALL	00126205
63-3	**Physical State**	ALL	00126205
63-4	**Odor**	ALL	00126205
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	00126205
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flamability**	ALL	00126205
63-16	**Explodability**	ALL	00126205
63-17	**Storage Stability**	ALL	00126205
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	00126205
<u>PRODUCT CHEMISTRY</u> for Inventa Corporation (59209-9, 59209-10, 59209-11, and 59209-12)			
61-1	**Chemical Identity**	ALL	00126205, Data Gap
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00126205, Data Gap
61-2B	**Formation of Impurities**	ALL	00126205
62-1	**Preliminary Analysis**	ALL	Not Applicable
62-2	**Certification of Limits**	ALL	00126205, Data Gap
62-3	**Analytical Method**	ALL	00126205, Data Gap

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-2	**Color**	ALL	00126205
63-3	**Physical State**	ALL	00126205
63-4	**Odor**	ALL	00126205
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	00126205
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flamability**	ALL	00126205
63-16	**Explodability**	ALL	00126205
63-17	**Storage Stability**	ALL	00126205
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	00126205

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
PRODUCT CHEMISTRY for Degesch America Inc.(40285-8 and 40285-12)			
61-1	**Chemical Identity**	ALL	41421202
61-2A	**Start. Mat. & Mnfg. Process**	ALL	41421202
61-2B	**Formation of Impurities**	ALL	41421202
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	41421202
62-3	**Analytical Method**	ALL	41421202, Data Gap
63-2	**Color**	ALL	41421202
63-3	**Physical State**	ALL	41421202
63-4	**Odor**	ALL	41421202
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable
63-7	**Density**	ALL	41421202
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-14	**Oxidizing/Reducing Action**	ALL	41421202
63-15	**Flamability**	ALL	41421202
63-16	**Explodability**	ALL	41421202
63-17	**Storage Stability**	ALL	41421202
63-18	**Viscosity**	All	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap

PRODUCT CHEMISTRY for Inventa Corporation(59209-4 and 59209-6)

61-1	**Chemical Identity**	ALL	43024001
61-2A	**Start. Mat. & Mnfg. Process**	ALL	43024001
61-2B	**Formation of Impurities**	ALL	43024001
62-1	**Preliminary Analysis**	ALL	Data Gap
62-2	**Certification of Limits**	ALL	43024001
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	41692102, 43024002
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Not Applicable
63-6	**Boiling Point**	ALL	Not Applicable

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
63-7	**Density**	ALL	41692102, 43024002
63-8	**Solubility**	ALL	Not Applicable
63-9	**Vapor Pressure**	ALL	Not Applicable
63-10	**Dissociation Constant**	ALL	Not Applicable
63-11	**Octanol/Water Partition**	ALL	Not Applicable
63-12	**pH**	ALL	Not Applicable
63-13	**Stability**	ALL	Not Applicable
63-14	**Oxidizing/Reducing Action**	ALL	41692102, 43024002
63-15	**Flamability**	ALL	Not Applicable
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage Stability**	ALL	41692102, 43024002
63-18	**Viscosity**	ALL	Not Applicable
63-19	**Miscibility**	ALL	Not Applicable
63-20	**Corrosion Characteristics**	ALL	Data Gap
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,K, L,M	Waived
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,K, L,M	Waived
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,K, L,M	05007354, 41377001

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,K, L,M	Waived
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,K, L,M	Waived
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,K, L,M	Waived
81-8	**Acute Neurotoxicity - Rat**	A,B,C,K, L,M	44139001, Data Gap
82-4	**90-Day Inhalation - Rat**	A,B,C,K, L,M	41413101
82-7	**90-Day Neurotoxicity - Rat**	A,B,C,K, L,M	44210401, Data Gap
83-3A	**Developmental Toxicity - Rat**	A,B,C,K, L,M	41377002
83-4	**2-Generation Reproduction - Rat**	A,B,C,K, L,M	Waived
83-5	**Combined chronic/oncogenicity - rats**	A,B,C,K, L,M	44415101, Data Gap
84-2A	**Gene Mutation (Ames Test)**	A,B,C,K, L,M	41434301
84-2B	**Structural Chromosomal Aberration**	A,B,C,K, L,M	41434302
84-4	**Other Genotoxic Effects**	A,B,C,K, L,M	42788101

ENVIRONMENTAL FATE

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
161-1	**Hydrolysis**	A,B,C,K, L,M	00153943
163-3	**Volatility (Lab)**	A,B,C,K, L,M	00153943
RESIDUE CHEMISTRY			
171-3	**Directions for Use**	A,B,C,K, L,M	
171-4A	**Nature of Residue - Plants**	A,B,C,K, L,M	00005813, 00155684, 05007621, 05008303, 05008840, 05012115, 05013027, 05015384, 05018681, 05020467
171-4C	**Residue Analytical Method - Plants**	A,B,C,K, L,M	05007190, 05007724, 05007845
171-4E	**Storage Stability**	A,B,C,K, L,M	Waived
171-4J	**Meat, Milk, Poultry and Eggs**	A,B,C,K, L,M	Waived

Data Supporting Guideline Requirements for the Reregistration of Aluminum and Magnesium Phosphide

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
171-4K	**Crop Field Trials**	A,B,C,K, L,M	00005671, 00005685, 00005686, 00005719, 00005750, 00005767, 00005781, 00005783, 00005905, 00005935, 00006724, 05007190, 05007830, 05007845, 05012293, 05013276, 05013439, 05014054, 05015520, 05016260, 05016893, 05019407, 05020467, 05020562, 05022032
171-4L	**Processed Food/Feed**	A,B,C,K, L,M	00005750, 00005768, 00005774, 00005775, 00005776, 00005777, 00005786, 00005905, 00005935, 00020578, 00022007, 00022008, 00022015, 00022017, 00022026, 00022913, 05007190, 05012293, 05022032
171-4M	**Multiresidue Methods**	A,B,C,K, L,M	Waived

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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MRID	CITATION
00005671	Wagner, R.M. (1962) Determination of Phosphine Residues in Commercial Wheat Flour: Project #: 20-0222-33. (Unpublished study received Jan 17, 1962 under 5857-1; prepared by Hazleton Nuclear Science Corp., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:022502-A)
00005685	Bruce, R.B. (1958) Bake-out Studies--Phostoxin Treated Grain; Residue Analysis--Phostoxin Treated Grain--Kansas; Supplement to Report Dated Apr 30, 1958. (Unpublished study received Sep 25, 1958 under 5857-1; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:025959-C)
00005686	Sullivan, J.B. (1969) Fumigation of and Determination of Phosphine Residues in Flue-Cured Tobacco Samples: Final Report. (Unpublished study received Feb 4, 1969 under 5857-2; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc.; CDL:007792-B)
00005719	Leesch, J.G. (1974) Fumigations of Farmers Stock Peanuts with Phosphine Derived from Aluminum phosphide: Progress Report No. 1. (Unpublished study including letter dated Apr 18, 1974 from J.G. Leesch to J.O. Hibbard, received May 10, 1974 under 2548-59; prepared by U.S. Agricultural Research Service, Southern Region, Stored-Product Insects Research and Development Laboratory, Chemical Control Research Unit, submitted by Research Products Co., Salina, Kans.; CDL:009822-F)
00005750	Rosebrook, D. (1972) Evaluation of Phosphine Preparation Detia Gas EX-B, Final Report: MRI Project No. 3502-C. Includes four methods dated Jan 20, 1972. (Unpublished study received May 2, 1972 under 2548-59; prepared by Midwest Research Institute, submitted by Research Products Co., Salina, Kans.; CDL:006384-A)
00005767	Bruce, R.B. (1959) Residue Study--Milo: Supplement to Reports Dated April 30, 1958, September 19, 1958, September 22, 1958, and October 17, 1958. (Unpublished study received May 12, 1959 under 5857-1; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:022505-B)
00005768	Bruce, R.B. (1958) Phosphine Residues in Wheat Oil; Recovery of Phosphine: Supplement to Reports Dated April 30, 1958 and September 19, 1958. (Unpublished study including letter dated Oct 15, 1958 from H. Rauscher to U.S. Food and Drug Administration and Pesticide Regulations Section, received Oct 20, 1958 under 5857-1; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:022506-A)
00005774	Sullivan, J.B. (1966) Phosphine Residues from Phostoxin-Fumigated Food Samples. (Unpublished study including letter dated Sep 12, 1973 from J.B. Sullivan to E.A.R. Liscombe, received May 6, 1974 under 5857-4; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-A)

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MRID	CITATION
00005775	Sullivan, J.B. (1966) Phosphine Residues from Phostoxin Treated Feed and Food Samples. (Unpublished study received May 6, 1974 under 5857-4; prepared by Hazelton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-B)
00005776	Sullivan, J.B. (1966) Phosphine Residues from Phostoxin Treated Cereals. (Unpublished study received May 6, 1974 under 5857-4; prepared by Hazleton Laboratories, Inc. for Kellogg Co., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-C)
00005777	Hild, K.; Mayr, G. (1964) Recovery Test: [Aluminum phosphide]. Includes three methods dated Sep 8, 1964 entitled: Analytical Determination of ALP (in Form of PH43^) with a Modified White and Bushey Method, Analytical Method for the Determination of Vitamin A, and Analytical Method for the Determination of Vita min B2 (Riboflavin). (Unpublished study received May 6, 1974 under 5857-4; prepared by Deutsche Gesellschaft fuer Schaedlingsbekaempfung m.b.H., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009859-E)
00005781	Sullivan, J.B. (1972) Analyses of Fumigated Deglet Noor Dates for Phosphine Residues. (Unpublished study received May 6, 1974 under 5857-4; prepared by Hazleton Laboratories, Inc. for U.S. Dept. of Agriculture, submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-K)
00005783	Sullivan, J.B. (1973) Final Report: Determination of Phosphine Residues in Unprocessed Adriatic Figs and Inshell Almonds. (Unpublished study including letters dated Nov 9 and 21, 1972 from H.D. Nelson to J.B. Sullivan, received May 6, 1974 under 5857-4; prepared by Hazleton Laboratories, Inc., for U.S. Agricultural Research Service; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-M)
00005786	Sullivan, J.B. (1969) Final Report: Determination of Phosphine Residues in Egg Yolk Samples: Project No. 129-156. (Unpublished study including letter dated Dec 7, 1972 from L. Shipman to E.A. Lipscomb [sic], received May 6, 1974 under 5857-4; prepared by Hazleton Laboratories, Inc. for General Foods Corp., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:009879-S)
00005813	Fluck, E. (1973) The Fate of Phosphine in the Atmosphere. (Unpublished study received Apr 27, 1976 under 5857-5; prepared by Univ. Stuttgart, Institut fuer Anorganische Chemie; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:234588-C)
00005905	Bruce, R.B. (1958) Phosphine Residues on Grain. (Unpublished study received Oct 20, 1961 under 5857-1; prepared by Hazleton Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:120707-A)
00005935	Dieterich, W.H.; Mayr, G.; Hild, K.; Sullivan, J.B.; Murphy, J. (1967) Hydrogen phosphide as a fumigant for foods, feeds and processed food products. Pages 135-149,InResidue Reviews: Volume 19. New York: Springer-Verlag. (Also In unpublished submission received Sep 25, 1969 under 0F0890; submitted by Hawaii, Dept. of Agriculture, Honolulu, Hawaii; CDL:093187-V)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as 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 03-31-99).

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 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

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

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

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 160.3(a)(6)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). 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 (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), 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.

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements

Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) 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(Insert A). 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 -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the

original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed 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 (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

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

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " '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(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of

submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

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

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 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 should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

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

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

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 (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

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

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(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

    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 CANCELED PRODUCTS

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

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

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

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

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE 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 (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for 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 Data Call-In Response Form (Insert A) need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

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

ALUMINUM AND MAGNESIUM 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 Aluminum and Magnesium 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 Aluminum and Magnesium 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 Compensation Forms in replying to this Aluminum and Magnesium 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 Aluminum and Magnesium Phosphide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Aluminum and Magnesium 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 Aluminum and Magnesium 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 Bonnie Adler at (703) 308-8523.

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

Bonnie Adler
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: **Aluminum and Magnesium Phosphide**

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

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled 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 FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also

submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating 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. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

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EPA'S BATCHING OF **Aluminum/Magnesium Phosphide** PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

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

to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

The following products contain Aluminum Phosphide as the active ingredient.

Twenty four products contain aluminum phosphide as the active ingredient. They are separated into five batches, based on the percentages and compositions of the active and the inert ingredients, there are no acute toxicity data provided by the registrants. Two products were considered to be not similar and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately. Each product, however, may rely on acute data performed with the technical, or request waivers based on the highly toxic nature of these materials.

Table 1.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	30574-1	60	solid
	30574-4	60	solid
	30574-9	60	solid
	30574-10	60	solid
	30574-11	60	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	59209-1	60	solid
	59209-2	60	solid
	59209-3	60	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	43743-1	57	solid
	43743-2	57	solid
	43743-3	57	solid
	30574-5	57	solid
	30574-6	57	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	30574-7	57	solid
	30574-8	57	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	5857-1	55	solid
	5857-2	55	solid
	5857-6	55	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	40285-1	55	solid
	40285-3	55	solid
	40285-13	55	solid
	40285-14	55	solid

Table 2 (No Batch).

EPA Reg. No.	% Active Ingredient	Formulation Type
59209-8	57	solid
40285-16	57	solid

The following products contain Magnesium Phosphide as the active ingredient.

Four products contain magnesium phosphide as the active ingredient. Two of them are grouped into one batch,in accordance with the percentages and compositions of the active and the inert ingredients, and type of formulation. The other two products were considered to be not similar and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately. Each product, however, may rely on acute data performed with the technical.

Table 3.

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
6	59209-4	66	solid
	59209-6	66	solid

Table 4 (No Batch).

EPA Reg. No.	% Active Ingredient	Formulation Type
40285-12	66	solid
40285-8	56	solid

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Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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

Dear Registrant:

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

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

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:
   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

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

Date of receipt
EPA identifying number
the Product Manager assignment

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

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

Documents Associated with this RED

Electronic File format: Portable Document Format (.PDF) requires Adobe® Acrobat or compatible reader. Electronic copies of this RED are available on our website at www.epa.gov/REDs, or contact Mark Hartman at (703) 308-0734.

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

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

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

December 18, 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of aluminum phosphide Incident Reports
(DP Barcode D231933, PC Code 066501)

TO: William J. Hazel, Section Head
Special Review Section
Risk Characterization and Analysis Branch (7509C)
and
Jack Housenger, Branch Chief
Special Review Branch
Special Review and Reregistration Branch (7508W)

FROM: Jerome Blondell, Ph.D., Health Statistician
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Monica Spann, Environmental Protection Specialist
Special Review and Registration Division (7508W)

THRU: Dick Griffith, Acting Section Head
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Ed Zager, Acting Branch Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

BACKGROUND

The following data bases have been searched for the poisoning incident data on the active ingredient aluminum phosphide (Case Number: 066501):

1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

2) Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from 70 centers at hospitals or universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

3) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in hospital are provided.

4) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories humans, animals, calls, incidents and others.

ALUMINUM PHOSPHIDE REVIEW

I. IDS

Of six cases reported to the Incident Data System, only three involved accidental exposure to aluminum phosphide alone. Two other cases involved exposures to several pesticides and one other case was a suicide reported from Mexico. The three accidental cases are summarized below.

On May 22, 1994, the Washington Post reported the death of a thirty-nine year old woman stationed in Cairo by the U.S. Department of State. In mid-December, she had submitted a pest extermination work order to the U.S. Embassy to have moths removed from she and her husband's government-owned apartment. Moths were found in a closet in the middle bedroom. According to the Naval Medical Research Unit Report, sixty German-made pesticide tablets of phostoxin were used by a pest-control operator for the extermination. After the extermination, the research team reported that the fumigated bedroom was sealed with tape, but the apartment's air ducts were not sealed. The team determined that the gas circulated through the heating system. After arriving home, the woman and her husband noticed an odor that persisted for a few days. The morning of December 24, her husband became ill, and at midnight she also became sick. About 9:00 a.m. the next morning, Lewis arrived at an infirmary experiencing severe difficulty in breathing, and died at 1:00 p.m.

A letter submitted from a Union representing railway workers stated that members were exposed to phostoxin while heating and cutting underframes of railcars. This practice is alledged to result in health problems, but number of workers affected and symptoms were not reported.

A pesticide incident occurred on November 9, 1994, in Ark City, Kansas, that resulted in the death of a two year old child and the hospitalization of an additional six family members. Apparently, phostoxin was acquired illegally by a roofer working on the building where it was allegedly "improperly stored" and misused by a member of the family to control rats in their own residence.

II. Poison Control Center Data

Aluminum phosphide was not one of 28 chemicals for which Poison Control Center data were requested.

III. California Data - 1982 through 1994

Detailed descriptions of 166 cases submitted to the California Pesticide Illness Surveillance Program (1982-1994) were reviewed. In 162 of these cases, aluminum phosphide was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Aluminum phosphide ranked 15th as a cause of systemic poisoning in California and 7th as a cause of hospitalization. Twenty-one individuals were hospitalized between 1982 and 1994. Among agricultural workers, aluminum phosphide is the 7th most frequent cause of systemic poisoning. Table 1 presents the types of illnesses reported by year. Table 2 gives the total number of workers that took time off work as a result of their illness and how many were hospitalized and for how long.

Table 1: Cases Due to Aluminum Phosphide Exposure in California Reported by Type of Illness and Year, 1982-1994

Year	Illness Type				
	Systemic	Eye	Skin	Respir.	Total
1982	5	1	-	-	6
1983	14	1	1	-	16
1984	3	-	1	-	4
1985	13	-	1	-	14
1986	6	-	-	-	6
1987	19	1	-	-	20
1988	18	25	-	-	43

1989	6	-	-	1	7
1990	12	-	1	1	14
1991	7	1	-	1	9
1992	4	-	-	-	4
1993	8	1	-	4	13
1994	4	-	-	2	6
Total	119	30	4	9	162

Table 2: Number of Persons Disabled (taking time off work) or Hospitalized for Indicated Number of Days after Aluminum Phosphide Expsosure in California, 1982-1994.

	Number of Persons Disabled	Number of Persons Hospitalized
One day	28	10
Two days	16	11
3-5 days	7	-
6-10 days	6	-
more than 10 days	5	-
unknown	33	2

A total of 119 persons had systemic illnesses or 73% out of 162 persons. The majority of 30 eye-related cases resulted from two incidents which occurred in 1988 when workers returned to buildings that had been fumigated over the weekend. A variety of worker activities were associated with exposure to aluminum phosphide as illustrated in Table 3 below.

Table 3: Illnesses by Activity Categories for Aluminum Phosphide Exposure in California, 1982-1994

Activity Category	Illness Category				
	Systemic	Eye	Skin	Respir-atory	Total
Field fumigation	19	-	-	1	20
Tarp fumigation	19	1	2	-	22
Chamber fumigation	12	1	1	-	14
Other applicator	-	1	-	-	1
Coincidental	22	25	-	-	47
Drift Exposure	4	1	-	1	6
Packing/Processing	10	-	-	-	10
Emergency response	11	-	-	1	12
Other	22	1	1	6	30
Total	119	30	4	9	162

According to the above activity categories, coincidental systemic and coincidental eye categories were associated with the majority of the exposures. Coincidental cases typically occur when bystanders are accidently exposed. Out of a total of twenty-two systemic coincidental exposures, sixteen workers became ill after their almond sorting building was fumigated the previous day. Symptoms included headache, nausea, vomiting, chills, abdominal cramps, weakness, dizziness, and difficulty breathing. Out of the twenty-five coincidental eye exposures, fourteen workers experienced eye irritation after their storage building was fumigated the previous weekend. Symptoms included red and watery eyes, and nasal secretions. The other eleven workers out of the twenty-five coincidental eye exposures had re-occurring eye irritations while working in an almond/pistachio processing plant.

Detailed review of the types of activities associated with incidents suggests a number of patterns that may be amenable to mitigation through improved label warnings. Improper handling or disposal of aluminum phosphide tablets has resulted in fires and explosions leading to eight incidents involving 19 people. Workers responsible for opening fumigated structures or removing

tarps have been involved in 15 incidents. And application to kill gophers or squirrels have resulted in 13 incidents of poisoning.

REPORTS OF HUMAN POISONINGS FROM THE LITERATURE

A case was reported when aluminum phosphide tablets were mistakenly placed in a home for rodent control (Augenstein et al. 1988). Six people became ill, including a six year old female that ingested one or more tablets and was admitted to the hospital. She was seriously ill and in profound shock thirty-six hours after exposure. She experienced multi-system failure sixteen hours after admission. The patient recovered and was discharged three weeks after admission.

Feldstein et al. (1991) reported on occupational exposure to phosphine among three federal grain inspectors while inspecting wheat on a railroad train in Portland, Oregon. Respiratory protection was not worn by the workers. After opening the seventh car, the workers noticed a very distinct odor. Almost immediately, the workers started to develop symptoms such as facial numbness and tingling, dizziness, nausea, and shortness of breath. In one case, a worker experienced a headache, nausea, shortness of breath, fatigue and intermittent diaphoresis. Three weeks later, the worker was still experiencing shortness of breath. Six weeks later, the worker no longer experienced any symptoms. In the second case, the worker no longer experienced symptoms after four days. In the third case, three months after the exposure, the worker complained of episodes of disorientation and daily occipital headaches.

The Texas Department of Health and California EPA reported two incidents on exposure to phosphine gas on September 18, 1993 and March 29, 1989. In one incident, four males, aged 12, 35, 39, and 52 years were found in a railroad car containing loose bulk lima beans by border patrol agents four hundred fifty miles east of El Paso, Texas. After inhalation exposure from the gas, the three men had symptoms of nausea, vomiting, headache, and abdominal discomfort. The fourth male was twelve years old and had died from asphyxiation. In the second incident, a twenty-three year old man was found dead in a rice-filled rail car in Maxwell, California after having entered the sealed car after fumigation. Earlier, aluminum phosphide pellets had been loaded onto the railroad car with warning signs posted on the car. In the editorial note by the Centers for Disease Control and Prevention, it was noted that both EPA and the Department of Transportation have guidelines which require warning signs on transport vehicles or freight containers that have been fumigated. Reexamination of these guidelines are recommended to assure that appropriately placed, highly visible warning signs printed in English and other languages that incorporate warning symbols are required.

On July 7, 1991, EPA headquarters was notified by Region 8, Denver, Colorado, of a potential grain fumigant use problem in North Dakota. In August, 1989, a woman died that lived in close proximity to a grain fumigation operation. Her husband was treated at a medical facility in October, 1989 for possible organophosphate poisoning. The couple had complained about the fumigation operation since December, 1985. The two cases were based on: (1) a review of epidemiology, environmental, and health case material referred to headquarters from the Denver Regional Toxicologist; and (2) supplemental case files provided by State of North Dakota personnel. Both of these cases were considered possible pesticide poisoning incidents, based on information

presented in the files, and using standard rankings terminology for human poisoning incidents. In the first case, Mrs. O'Brien's death, the role of heat and chronic grain dust exposure are unclear and her death could have resulted from other factors. In the second case, possible poisoning, Mr. O'Brien reported symptoms of loss of peripheral motor control (uncontrollable shakiness of the hands and feet), diarrhea, headache, burning gums, lips and teeth, skin irritation, dry mouth and throat, and watering eyes during his hospitalization on October 7, 1989. These reported symptoms were worse when the aerator of the fumigation facility were operating about three hundred fifty feet from their home. October, 1989, had the highest monthly use of aluminum phosphide. Based on the available evidence OREB concludes that both of these incidents were possibly related to aluminum phosphide. The evidence does not support a finding of a probable or definite relationship between the exposure and the effects.

In the late 1950s 2 adults and a child died while living in a dwelling with a party wall to a granary being fumigated (World Health Organization 1988). It was estimated that phosphine levels in the bedroom reached 1.2 mg/m^3.

Hayes and Vaughn (1977) reported two deaths in 1973 and 1974 out of a total of 113 accidental pesticide deaths in those two years. In one case a father placed pellets behind a stove indoors and in the other, a 17 year old climbed into a fumigated boxcar and went to sleep on the grain.

Garry et al. (1993) reported the suspicious death of a pregnant rural woman who lived 30 yards from a large bunker-type grain storage facility. Reportedly, the facility was not tightly sealed in contrast to standard practice.

The American Association of Poison Control Centers reported one death in 1994 when a 4 year old girl could not be aroused in the morning (Litovitz et al. 1995). Other family members were symptomatic for headaches, nausea, and vomiting. Aluminum phosphide tablets were found in the crawl space under the home. Other details about this case are not available.

SUMMARY/CONCLUSIONS

From the review of the California data, it appears that a majority of cases involved illnesses to workers that entered a previously aluminum phosphide fumigated facility including buildings, fields, tarps and chambers. Aluminum phosphide is capable of causing illness after fumigation. A large proportion of cases have occurred when people have returned to fumigated structures to reopen and ventilate. Often exposure results from lack of proper protective equipment and inadequate ventilation before persons are allowed in or near the treated area. Instructions on proper disposal and storage of this product are critical to prevent explosions and fires that result in damage to health and property.

RECOMMENDATIONS

Aluminum phosphide is a highly toxic fumigant with the potential to cause serious poisoning and death if mishandled. Only certified and trained personal should be allowed to handle such a product. Currently all uses of aluminum phosphide are restricted. Consideration should be given to making this restriction, so that only certified individuals can handle this product. Then, individuals under the supervision of a certified applicator would not be permitted to use this product. Proper posting of fumigated sites may need to be reexamined to assure that warning are appropriately placed, highly visible, with symbols and language that will prevent exposures to bystanders.

Monitoring near treated sites should be considered for areas where residential dwellings are close by. This monitoring should be conducted independently, perhaps by ORD or NIOSH, under "real world" circumstances to determine potential risks. For workers who do reenter proper respiratory protection and protective eyewear should be mandatory. EPA's enforcement office should continue to make aluminum phosphide a high priority for routine inspections of misuse. Special review is not recommended for this pesticide, but it should be given high priority for reregistration so that these recommendations can be implemented soon.

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cc: Correspondence file
Aluminum phosphide file no. 066501
Bill Hazel (7509C)

RDI:ActSecHd:FDGriffith:11/10/96:ActBrSrSci:SHummel:12/12/96