United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (H-7508W) | EPA-738-F-92-007 August 1992

EPA R.E.D. FACTS

Zinc Salts

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for zinc salts.

Use Profile

Zinc salts include three pesticide active ingredients: zinc chloride, zinc oxide, and zinc sulfate monohydrate (or zinc sulfate). Zinc salts are used as herbicides to control the growth of moss on structures, walkways, patios and lawns in rainy areas, primarily in the Northwestern U.S. Zinc oxide also is an industrial preservative, incorporated into carpet fibers to inhibit bacterial and fungal spoilage, and a bacteriostat, applied as a pressure treatment to preserve cut lumber. Other, more significant, non-pesticidal uses of zinc salts in the U.S. include use in fertilizers, animal feed, dry cell batteries, and as galvanizers.

Zinc is an element necessary to all forms of life. It is a normal part of metabolism in all living organisms. Zinc is widely distributed in plants, animals and soils, and is normally present in food.

Regulatory History

Pesticide products containing zinc salts were first registered in the U.S. in 1973. At present, 10 such products are registered. Nine of these products contain zinc salts as their only active ingredient; one also contains another active ingredient.

Human Health Assessment

Not all the toxicity data usually required for pesticide reregistration were necessary to assess the human health risks of the zinc salts because much of this information was available in scientific literature available to the general public.

Toxicity

Zinc chloride is corrosive to the eyes and skin. It has been placed in Toxicity Category I (indicating the highest degree of toxicity) for these effects. Zinc sulfate also has been placed in Toxicity Category I because it can cause severe eye irritation. Zinc oxide is of relatively low acute toxicity.

There was no evidence of toxicity in a subchronic feeding study in which humans were fed zinc sulfate each day for up to three months.

Regarding effects on metabolism, zinc is an essential element in human nutrition and is part of the nutrition of all plants and animals. It is an essential component of several enzymes involved in human metabolism, and is present in every cell. In laboratory feeding studies, most of the zinc eaten by test animals was excreted. Ingesting large amounts of zinc salts does cause changes in metabolism; however, people usually are not exposed to such large amounts of zinc through the diet.

Concerning chronic toxicity, when laboratory rats and dogs were fed large doses of zinc sulfate, changes in blood composition were observed. Similarly, pregnant rats fed high doses of zinc oxide had increased stillbirths, and effects on the growth of their young were observed. Some mutagenicity studies using zinc oxide and zinc chloride showed positive results.

Dietary Exposure

Zinc salts as pesticides have no food uses. The Food and Drug Administration lists zinc salts as "generally recognized as safe" for use in food as dietary supplements and as nutrients.

Occupational and Residential Exposure

Although there is the potential for significant eye, inhalation and dermal exposure among mixers, loaders and applicators of zinc salt products, EPA finds no reason to expect that reasonable use of these pesticides will constitute any hazard beyond ordinary exposure to zinc salts. The Agency believes that the use of these pesticides does not represent an unreasonable hazard to these workers. Zinc salt labels must continue to reflect any eye or skin hazards, and must continue to recommend appropriate protective equipment including protective eyewear, long-sleeved shirts and long-legged pants, rubber gloves, and boots.

Human Risk Assessment

EPA has no reason to expect that appropriate use of pesticide products containing zinc salts will constitute any hazard beyond that presented by ordinary exposure to zinc from non-pesticidal sources. Although some positive mutagenicity studies have been reported, there is no indication that such effects result in normal living organisms from everyday exposure. The Agency has no significant exposure concerns other than those addressed by existing label precautions for eye and skin protection of mixers, loaders and applicators.

Environmental Assessment

Environmental Fate

Any toxicity associated with zinc can be attributed to the presence of "free" zinc, and not to total zinc concentration. When zinc salt pesticides are used outdoors, the zinc in these products binds to and is immobilized in soil. Use of these products, therefore, does not significantly increase the amount of "free" zinc in the environment.

Ecological Effects

Zinc is relatively non-toxic to bird populations and is used as a feed additive for animals. Considering the limited, outdoor use patterns of the zinc salts, and considering that relatively small amounts are used, it is unlikely that toxic amounts of zinc will be available to birds or other non-target animal and insect populations. Although some studies show that zinc may be highly toxic to aquatic organisms, other studies do not. The assessment of the risk posed to aquatic organisms resulting from the industrial preservative (carpet fiber) use is under the purview of the Agency's Office of Water. Therefore, EPA finds that the zinc salts products as registered pose no unreasonable risk to the environment.

Environmental Assessment

EPA has concluded that adding zinc to the environment through use of currently registered pesticides that contain zinc salts will not result in a significant increase in "free" zinc. Further, little exposure to non-target species is expected, due to the small-scale outdoor use of these products. EPA finds that the registered zinc salt pesticides pose no unreasonable risk to the environment.

Additional Data Required

EPA is requiring additional generic studies on physical chemistry as confirmatory data. In addition, product-specific studies on product chemistry and acute toxicology must be submitted prior to reregistration.

Product Labeling Changes Required

The labels of the zinc salt products must comply with EPA's current pesticide labeling requirements. In addition, the industrial preservative product must bear the following ecotoxicity statement:

> "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of U.S. EPA."

Regulatory Conclusion

- The registered pesticidal uses of zinc salts are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.

- Registered products containing one of the zinc salts as the sole active ingredient will be reregistered once EPA receives and accepts confirmatory generic data, product-specific data and amended labeling.

- The registered product containing one of the zinc salts as well as another active ingredient will be reregistered once EPA receives and accepts confirmatory generic data, product-specific data and amended labeling, and once EPA completes an eligibility decision on the other active ingredient.

For More Information

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

In the future, the zinc salts RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about zinc salts or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual zinc salts products, please contact the Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-7830.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 24 hours a day, seven days a week, or fax your inquiry to 806-743-3094.

United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(H-7508W)

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EPA

Reregistration Eligibility Document (RED)

Zinc Salts

ZINC SALTS REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Jim Saulmon	Biological Analysis Branch
Eric Maurer	Economic Analysis Branch

Environmental Fate and Effects Division

Katherine Valente	Ecological Effects Branch
Sylvia Termes	Environmental Fate and Groundwater Branch
Jean Holmes	Science Analysis and Coordination Staff

Health Effects Division

Linda Kutney	Chemical Coordination Branch
Pat McLaughlin	Toxicology Branch II
Jim Yowell	Occupational and Residential Exposure Branch

Registration Division

Sami Malak	Registration Support Branch
Olga Odiott	Registration Support branch
Mary Matzer	Herbicide Fungicide Branch
Joanne Miller	Herbicide Fungicide Branch

Special Review and Reregistration Division

Bruce Sidwell	Accelerated Reregistration Branch
Mark Wilhite	Accelerated Reregistration Branch

Policy and Special Projects Staff

Jean Frane	Analyst

Office of General Counsel

Jim Curtin	Attorney

Office of Compliance Monitoring

Beverly Updike

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
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 or feed, e.g., mg/l 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.
Ldlo	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System.

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
ppm	Parts Per Million
TD	Toxic Dose. The dose at which a substance produces a toxic effect
TC	Toxic Concentration. The dose at which a substance produces a toxic effect

EXECUTIVE SUMMARY

The active ingredients covered in this document include zinc chloride, zinc oxide and zinc sulfate monohydrate (hereafter referred to as zinc sulfate). Products containing these active ingredients are used as herbicides, fungicides and bacteriostats for the control of moss, mildew and fungi on structures and adjacent outdoor areas, in carpet, and in pressure treated lumber. This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of products containing these active ingredients for the above mentioned use sites only.

Formulations for zinc oxide include an end use industrial preservative for incorporation into nylon carpet fibers to inhibit bacterial and fungal spoilage, a powder for control of moss growth on walkways, patios and ornamental lawn use; a metal strip attached to roofs where it releases soluble oxide which inhibits moss growth; and an ingredient for pressure treatment of lumber. Zinc chloride is formulated as a solution or soluble concentrate for application to walkways and patios for control of moss. Zinc sulfate is formulated as a soluble concentrate also for control of moss on and around buildings.

The U.S. EPA (hereafter referred to as "the Agency") has determined that the uses of these three active ingredients as they are currently registered will not cause unreasonable risk to humans or the environment. Therefore the zinc salts are eligible for reregistration. The Agency is requiring additional studies on physical chemistry as confirmatory data and for purposes of labeling to complete the generic data base.

Before reregistering the products containing these zinc salts, the Agency is requiring that product specific data and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicology testing. After reviewing these data and any revised labels and finding them acceptable, the Agency will reregister a product based on whether or not that product meets the requirements in Section 3(c)(5) of FIFRA.

I. INTRODUCTION

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

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Document:

- **Common Name:** Butter of zinc

  Chemical Name: Zinc chloride

  CAS Registry Number: 7646-85-7

  Office of Pesticide Programs Chemical Code: 087801

  Empirical Formula: $ZnCl_2$

- **Common Name:** Flowers of zinc; philosopher's wool; zincite (mineral); zinc white

  Chemical Name: Zinc oxide

  CAS Registry Number: 1314-13-2

  Office of Pesticide Programs Chemical Code: 088502

  Empirical Formula: ZnO

- **Common Name:** Dried zinc sulfate

  Chemical Name: Zinc sulfate monohydrate

  CAS Registry Number: 7446-19-7

  Office of Pesticide Programs Chemical Code: 527200

  Empirical Formula: $ZnSO_4\ H_2O$

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of zinc chloride, zinc oxide and zinc sulfate is in Appendix A.

For zinc chloride:

Type of Pesticide: Herbicide and preservative

Use Sites: Terrestrial non-food, Outdoor residential

Target Pests: Moss, fungi

Formulation Types Registered: Soluble concentrate - 6.2% zinc chloride
Ready to use liquid -26% zinc chloride

Method and Rates of Application: Equipment - Hose-end sprayer; non-aerosol pump; tank type sprayer, sprinkler can.

Method and Rate - Apply (sprinkle or spray) 3 gallons per 100 sq.ft.

Timing - When needed.

For zinc oxide:

Type of Pesticide: Fungicide, herbicide, bacteriostat

Use Sites: Terrestrial non-food, outdoor residential, indoor non-food

Target Pests: Moss, fungi, bacteria

Formulation Types Registered: Wettable powder- 20.76% zinc oxide;
Metal strip- 99.1% zinc
Powder- 99% zinc oxide (formulation intermediate)
Powder-99.4% zinc oxide (industrial preservative)

Method and Rates of Application: Equipment - sprinkler can (for wettable powder); galvanized nails (for metal strip)

Method and Rate - Dissolve 1 lb. in 5 gallons of water. For metal strip, apply along all roof peaks using galvanized or aluminum nails.

Timing - When needed.

For zinc sulfate:

Type of Pesticide: Herbicide

Use Sites: Terrestrial non-food, Residential outdoor

Target Pest: Moss

Formulation Types Registered: Wettable powder- 99% zinc sulfate monohydrate

Method and Rates of Application: Equipment - Apply by hand or use sprinkling can or pump-type sprayer.

Method and Rate - Apply as a powder along the ridge of the roof; dissolve in 5-10 gallons of water to cover 600 sq. ft. for gravel or paved surfaces.

Timing - When needed.

C. Regulatory History

Pesticidal products containing zinc salts were first registered in the United States in 1973. The uses include moss control in areas where moss growth is profuse due to high precipitation rates, primarily in the Northwestern U.S. Zinc oxide is also incorporated into carpet fibers as a bacteriostatic and fungistatic agent and as an ingredient in a solution for pressure treatment of wood.

The major use of zinc salts in the United States is non-pesticidal, as a fertilizer micronutrient. Other uses include as an electrolyte in dry cell batteries, as an animal feed additive, as a galvanizer and as an emulsion-breaker.

III. SCIENCE ASSESSMENT OF ZINC SALTS

The Agency has conducted a thorough review of the scientific data base for zinc salts for the purposes of determining the reregistration eligibility of these pesticides. These finding are summarized below. The complete references cited in the text are in the Bibliography (Appendix C).

A. Physical Chemistry Assessment

Zinc chloride is a clear, very deliquescent salt. It has a boiling point of 260°C and at room temperature it is completely soluble in water. The vapor pressure is 1.5 mmHg and the pH is 5.4. Outstanding generic physical chemistry data requirements are listed in Section V.

Zinc oxide is an odorless white or yellowish-white powder. It has a melting point of 2010°C and its density is 0.481 gm/cm^3. It is relatively insoluble in water, has a pH of 7.37 and is stable.

Zinc sulfate monohydrate is an odorless white solid. It has a melting point of 600°C and a density of 1.121 gm/cm^3. It is soluble in water up to 35% and is stable. Additional physical chemistry data requirements are listed in Section V

Zinc metal is an odorless bluish-white lustrous solid. It has a melting point of 419°C and a density of 7.169 gm/cm^3. It is insoluble and has a low stability in the natural environment, easily forming the solid phases ZnO, $Zn(OH)_2$ and Zn_2O_3 and soluble zinc ions.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology - Data Base

The toxicological data base on zinc oxide, zinc chloride, and zinc sulfate is adequate and will support reregistration eligibility.

a. Acute Toxicity

Zinc oxide:

ACUTE TOXICITY VALUES

TEST	RESULT (mg/kg)	TOXICITY CATEGORY
Oral LD50--rat	>5000	IV
Dermal LD50--rabbit	>5000	III
Eye effects--rabbit	mild irritant	III
Skin effects--rabbit	non-irritant	IV

The TDlo was reported as 6846 mg/kg in an oral test in rats (1). An oral LD50 in mice was reported as >7950 mg/kg (2). One report states that 500 mg applied for 24 hours produced mild irritation on skin or eyes of rabbits. A TClo reported for human inhalation was 600 mg/m^3 of zinc oxide (1).

Zinc chloride:

ACUTE TOXICITY VALUES

TEST	RESULT (mg/kg)	TOXICITY CATEGORY
Oral LD50--rat	350	II
Inhalation LClo--human	4800 mg/m^3/30min	III
Eye effects	Corrosive	I
Skin effects	Corrosive	I

Acute oral tests found the LD50 was 350 mg/kg in rats and in mice, and 200 mg/kg in guinea pigs (1). The human TClo for inhalation has been reported as 4800 mg/m^3/30 minutes (1).

Zinc sulfate:

ACUTE TOXICITY VALUES

TEST	RESULT (mg/kg)	TOXICITY CATEGORY
Oral LD50--rat	>2949	III
Eye effects--rabbit	severe irritation	I
Skin effects	very slight irritation	IV

Acute oral tests found the LDlo was 333 mg/kg in rats and 2000 mg/kg in rabbits; the LD50 was >2949 mg/kg in rats and 1891 mg/kg in mice (1, 2). Another acute oral study found the LD50 was 1374 mg/kg in rats (3). The oral TDlo for humans is reported to be 45 mg/kg/7 days (continuous), 106 mg/kg, and 180 mg/kg/6 weeks (intermittent) (1, 2). A dermal irritation study in rabbits with 99% zinc sulfate found very slight irritation. In one study, severe irritation was found when 0.09g of 99% zinc sulfate was applied to rabbit eyes. In another study,

the application of 420 ug zinc sulfate to the rabbit eye found moderate irritation (1).

b. Subchronic Toxicity

There was no evidence of toxicity in humans fed 10 mg/kg/day of zinc sulfate for up to 3 months (3).

c. Metabolism

Zinc is an essential element in human nutrition and is involved in the nutrition of all plants and animals. It is an integral component of several metalloenzymes in various metabolic systems and is present in every cell (3). In test animals, 8-10 percent of ingested zinc was absorbed in the intestine and the rest excreted in the feces (3).

Ingestion of large amounts of zinc salts induces a variety of metabolic changes, with inhibition of some enzymes, effects on excretion, and a reduction in size and hemoglobin content of red blood cells (microcytic hypochromic anemia) (3).

It has been calculated that the consumption of zinc salts added to food may be 0.50 mg of elemental zinc per person per day and the intake of zinc occurring naturally in food may be 5 to 22 mg per day (3).

d. Chronic Toxicity, Carcinogenicity

In some long-term studies, extending for one year and over three generations of rats, zinc chloride, oxide, and sulfate showed no effects at levels up to 0.25 percent of the diet (3). In other studies, zinc sulfate caused hematological changes in rats and dogs fed about 100 ppm in the diet (3).

No evidence of carcinogenicity was found in feeding zinc oxide (at 34.4 mg zinc per day) to rats for 29 weeks. Carcinogenicity has been reported in mice given zinc chloride in drinking water, but the reports were not complete and controls were not used consistently. In another report, mice given up to 5,000 ppm of zinc as zinc sulfate in drinking water showed no evidence of carcinogenicity and no differences between treated and control groups (3).

e. Reproductive and Developmental Toxicity

When 6846 mg/kg of zinc oxide was given to pregnant rats on days 1-22 of pregnancy, there were increased stillbirths and effects on growth of the young (2).

When rats were given 333 mg/kg zinc sulfate orally on days 1-18 of pregnancy, there was post-implantation mortality (2). Teratologic studies with oral zinc sulfate in three species of animals were negative for effects on pregnancy, maternal or fetal survival, or abnormalities. In these studies mice were given up to 30 mg/kg/day for days 6-15 of gestation, rats were given up to 42.5 mg/kg/day for days 6-15 of gestation, and hamsters were given up to 88 mg/kg/day for days 6-10 of gestation (3).

f. Mutagenicity

Positive results with zinc oxide have been reported in some studies. DNA damage in *Escherichia coli* occurred at 3000 ppm, and unscheduled DNA synthesis occurred in guinea pigs after exposure to 5300 ug/m^3/3 hours/6 days in an inhalation study (1, 2).

Positive results with zinc chloride also have been reported in several studies. Mutagenic effects were seen at 90 mmol/L in a microsomal mutagenicity assay with *Salmonella typhimurium*. Unscheduled DNA synthesis in human lymphocytes occurred at 180 umol/L and at 360 umol/L. DNA inhibition was seen in human lymphocytes. In cytogenetic analyses, effects were seen in mice treated orally with 18 g/kg for 30 days and in human lymphocytes treated with 300 umol/L. Effects also were seen in a host-mediated assay with mice and *Salmonella typhimurium* at 6 mg/kg and at 180 umol/L in an oncogenic transformation assay using hamster embryos (1).

Positive results have been seen with zinc sulfate in some studies, including a *Drosophila melanogaster* sex chromosome assay with an oral 5mmol/L dose and a mutation assay with *Saccharomyces cerevisiae* at 100 mmol/L. DNA inhibition was seen in human HeLa cells at 1 umol/L/4 hours and oncogenic transformation occurred at 200 umol/L with hamster embryo (1, 2).

2. Dietary Exposure

There are no pesticidal food uses for zinc. Zinc is widely distributed in plants, animals and food, and is a normal part of metabolism in all living organisms.

The Food and Drug Administration lists these zinc salts as generally recognized as safe for use in food as dietary supplements and as nutrients: zinc oxide in 21 CFR 182.5991 and 182.8991, zinc chloride in 21 CFR 182.5985 and 182.8995, and zinc sulfate in 21 CFR 182.5997 and 182.8997.

3. Occupational and Residential Exposure

The toxicological data base on these zinc salts is adequate and will support reregistration. Therefore, no new exposure data are necessary. Based on the application methods (specified and implied) and the formulation types, the potential for significant eye, inhalation and dermal exposure to concentrated solutions or dusts exists for mixers, loaders, and applicators. Accordingly, the zinc salt labels must consistently reflect any potential eye and skin hazard (Danger, Warning or Caution Signal Words) and recommend appropriate protective equipment (protective eyeware [goggles or face shield], long sleeved shirts and long-legged pants, waterproof gloves, shoes and socks). However, there is no reason to expect reasonable pesticide usage to constitute any hazard beyond ordinary non-pesticidal exposure to zinc salts if label directions are followed, and the Agency believes that the uses of these products do not represent an unreasonable hazard to workers.

4. Risk Assessment

The toxicological data on these zinc salts in public literature are adequate for assessing risk to humans. Accordingly, additional studies are not required for the reregistration of present uses of these salts. Although some positive mutagenicity studies have been reported, there is no indication of mutagenic effects in normal living organisms from everyday exposure. Living organisms have long been exposed to the components of these zinc salts without such exposure being attributed to

mutagenicity. Zinc is widely distributed in plants, animals and soils and is normally present in food. Zinc is a normal part of metabolism in all living organisms. These zinc salts are also added ingredients in foods.

There is no reason to expect appropriate pesticide usage to constitute any hazard beyond ordinary exposure from non-pesticidal sources. There are no significant exposure concerns other than those addressed by appropriate label precautions for eye and dermal protection for the mixers, loaders, and applicators. Refer to section V for product labeling requirements.

C. Environmental Assessment

1. Environmental Fate

The Agency is relying on data available in the scientific literature to assess the environmental fate and transport of zinc salts as used in pesticidal compounds. No data were submitted by registrants.

a. Environmental Fate and Transport

Zinc chloride and zinc sulfate are very soluble in water; zinc oxide is relatively insoluble. The dissolution of zinc compounds in water results in the formation of various species of zinc ions which, in the absence of complexing or chelating agents, is dependent on pH. Zinc oxide is less soluble than zinc chloride or zinc sulfate, but dissolves in more acidic media to form $ZnOH^+$ and $[Zn(H_2O)_6]^{2+}$. In a more basic pH, zinc oxide dissolves to form $[Zn(OH)_3]^-$ and $[Zn(OH)_4]^{2-}$. In natural waters (both freshwater and seawater), identification of which species of zinc ion is present is difficult due to the presence of organic and inorganic natural complexing agents.

Based on calculations using equilibrium constants and in the absence of organic complexing agents, $[Zn(H_2O)_6)]^{2+}$, $ZnOH^+$ and $Zn(OH)_2$ are the predominant species in freshwater. Zn-chloro complexes may also be present in seawater.

The availability of zinc to plants and other organisms in soil decreases with increased soil pH. Several components of soil (clay minerals, mineral oxides and hydroxides, carbonates and organic matter) can absorb zinc (predominantly as $ZnOH^+$). Zinc therefore can be considered as relatively immobile in most

b. Environmental Fate Assessment

Zinc is necessary to all forms of life and any toxicity associated with zinc can be attributed to the presence of "free" zinc and not to total zinc concentration. The Agency has concluded that the addition of zinc to the environment in the form of zinc salts used as pesticides will not result in a significant increase in "free" zinc. This conclusion is based on indications that "free" zinc is immobilized by various organic and inorganic substances and by formation of insoluble phases, thereby making it less bioavailable. Therefore, the terrestrial use of the pesticidal products containing the zinc salts covered in this document is not likely to result in the movement of "free" zinc in soils, and there are no additional environmental fate data required for the reregistration of the zinc salts.

2. Ecological Effects

Ecological effects data have been submitted for zinc oxide only. Published information also was used by the Agency to assess the risk posed by the use of pesticides containing zinc to non-target organisms.

a. Ecological Hazard

1. Ecological Effects Data

Avian toxicity studies were submitted by registrants. Since most of the applied zinc salts will transform (or become immobile in soil) to zinc oxide/hydroxide, and since the use of these products is on a relatively low volume basis, the avian studies for zinc oxide are sufficient for the other active ingredients. An acute oral toxicity study in bobwhite quail provided an LD_{50} of 606 mg/kg. In an acute dietary study in bobwhite quail, the LC_{50} was greater than 5000 ppm. These studies provide sufficient information to classify the acute toxicity of zinc salts as slightly to practically non-toxic to birds. Published studies show that coturnix quail fed a diet containing 1.5% zinc oxide had reproductive effects (4). Mallards fed a diet of 3,000-12,000 ppm zinc showed decreased feed consumption and body weight (5) and laying hens showed decreased egg production, shell strength and hatchability on a diet containing 20,000 ppm zinc (6).

b. Environmental Fate Assessment

Zinc is necessary to all forms of life and any toxicity associated with zinc can be attributed to the presence of "free" zinc and not to total zinc concentration. The Agency has concluded that the addition of zinc to the environment in the form of zinc salts used as pesticides will not result in a significant increase in "free" zinc. This conclusion is based on indications that "free" zinc is immobilized by various organic and inorganic substances and by formation of insoluble phases, thereby making it less bioavailable ( ). Therefore, the terrestrial use of the pesticidal products containing the zinc salts covered in this document is not likely to result in the movement of "free" zinc in soils, and there are no additional environmental fate data required for the reregistration of the zinc salts.

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Avian toxicity studies were submitted by registrants. Since most of the applied zinc salts will transform (or become immobile in soil) to zinc oxide/hydroxide, and since the use of these products is on a relatively low volume basis, the avian studies for zinc oxide are sufficient for the other active ingredients. An acute oral toxicity study in bobwhite quail provided an LD_{50} of 606 mg/kg. In an acute dietary study in bobwhite quail, the LC_{50} was greater than 5000 ppm. These studies provide sufficient information to classify the acute toxicity of zinc salts as slightly to practically non-toxic to birds. Published studies show that coturnix quail fed a diet containing 1.5% zinc oxide had reproductive effects (4). Mallards fed a diet of 3,000-12,000 ppm zinc showed decreased feed consumption and body weight (5) and laying hens showed decreased egg production, shell strength and hatchability on a diet containing 20,000 ppm zinc (6).

Studies submitted to the Agency, as well as published

literature, were used to assess the toxicity of these zinc salts to non-target organisms in aquatic or estuarine ecosystems; however, the results were highly variable. The LC_{50} for bluegill sunfish was greater than 320 ppm but was 1.1 ppm in rainbow trout in studies submitted to the Agency, while the 96 hr LC_{50} reported in the literature ranged from 1.2-17.9 ppm for freshwater fish (7,8). Acute toxicity in *Daphnia magna* was greater than 1000 ppm (i.e. practically non-toxic) in a study submitted to the Agency. Data from the literature were variable, indicating that zinc may be highly toxic to freshwater invertebrates (9). However, in two published studies, the 96 hr LC_{50} values ranged from 0.25-18.4 ppm in freshwater invertebrates (7,8). In conclusion, although the data showed extreme variability of results, at least two of the studies indicated that zinc oxide may be highly toxic to both freshwater fish and freshwater invertebrates.

b. Ecological Effects Risk Assessment

Zinc is relatively non-toxic to avian populations and is used as a feed additive for animals. Given the use patterns and frequency of application of pesticidal products containing these zinc salts, it is unlikely that zinc would be available in toxic amounts to avian or other non-target animal and insect populations in terrestrial environments as a result of their use. Although zinc may be toxic to aquatic organisms in some environments, based on the environmental fate assessment, aquatic exposure resulting from the use of these products is expected to be negligible. Therefore, the Agency has determined that these products, as they are currently registered, pose no unreasonable risk to the environment.

The textile industrial preservative use of zinc oxide results in indirect discharge of effluent containing zinc into natural waters. An assessment of the risk posed to aquatic organisms resulting from this route of exposure is under the purview of the Agency's Office of Water and will not be covered in this document. Although the aquatic toxicity studies showed variability in results, they are adequate to determine the appropriate label statements for this industrial preservative. The required label precaution statement is included in section V.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR ZINC SALTS

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has completed its review of data from the open literature and generic data submitted by registrants, and has determined that the data are sufficient to support reregistration of products containing zinc salts. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of zinc salts, and lists the submitted studies that the Agency found acceptable.

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

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that current products containing zinc salts are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing zinc salts, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

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

Eligibility Decision

The Agency has sufficient information on the human health effects of zinc salts and on its potential for causing effects in fish and wildlife and the environment when used to control moss and fungus growth in outdoor residential areas, on structures, in pressure-treated lumber and incorporated into fibers used in carpet. The Agency concludes that products containing zinc salts for these uses are eligible for reregistration. Only certain generic physical chemistry data studies on zinc salts still are needed as confirmatory information. The Agency has determined that zinc salt containing products, labeled and used as specified in this Reregistration Eligibility

Document, will not pose unreasonable risks or adverse effects to humans or the environment.

Eligible and Ineligible Uses

The Agency has determined that all registered uses are eligible for reregistration at this time.

B. Regulatory Position

Tolerances and Action Levels

There are no registered food uses or tolerances for products containing zinc salts as an active ingredient.

V. ACTIONS REQUIRED BY REGISTRANTS

This section is designed to assist the registrant by providing data requirements and responses necessary for the reregistration of manufacturing-use and end-use products.

A. Additional Generic Data Requirements

The generic data base supporting the reregistration of zinc salt-containing products has been reviewed and determined to be substantially complete. Although some of the generic product chemistry data requirements are acceptable, additional data are required as confirmatory. These are part of the generic Data Call-In. These generic data requirements are listed in Appendix F.

B. Product specific data requirements

1. Additional Product-Specific Data Requirements

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

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment E) and if not, commit to conduct new studies. If the 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.

C. Labeling Requirements for Manufacturing and End-Use Products

End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. Labels must consistently reflect any potential eye and skin hazard (Danger, Warning or Caution Signal Words) and recommend appropriate protective equipment (protective eyeware [goggles or face shield], long sleeved shirts and long-legged pants, waterproof gloves, shoes and socks). Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

Manufacturing use (Includes Industrial Preservatives)

In addition to the above requirements for end-use products, labels and labeling of all manufacturing use products must contain the following statement:

"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of U.S. EPA."

APPENDIX A

Table of Zinc Salts Use Patterns Subject to Reregistration

Zinc oxide

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appl	Max. # Appl @ Max Rate	Min Interval Between Appl @ Max Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED USES										
TEXTILES/TEXTILE FIBERS/CORDAGE (nylon carpet fiber) USE GROUP: INDOOR NON-FOOD										
Industrial preservative treatment; not on label; during manufacture.	FNI/S	na	500 ppm AI by wt.	not specified	not spec	not spec	not spec			
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES USE GROUP(S): OUTDOOR RESIDENTIAL										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not specified	not spec	not spec	not spec			
Strip treatment, by hand, when needed	Impr	na	not specified	not specified	not spec	not spec	not spec			
Sprinkle, watering can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not specified	not spec	not spec	not spec			
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES USE GROUP(S): TERRESTRIAL NON-FOOD CROP										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
Sprinkle, watering can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
NON-AGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS USE GROUP(S): TERRESTRIAL NON-FOOD CROP										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
Sprinkle, watering can, when needed	WP/D	na	.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
PATHS/PATIOS USE GROUP(S): TERRESTRIAL NON-FOOD + OUTDOOR RESIDENTIAL										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			

Zinc oxide

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls	Max # Appls @ Max. Rate	Min Interval Between Appls. @ Max Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations also see Abbreviations
Sprinkle, watering can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	no spec			
PAVED AREAS (PRIVATE ROADS/SIDEWALKS) USE GROUP(S): TERRESTRIAL NON-FOOD + OUTDOOR RESIDENTIAL										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
Sprinkle, watering can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
ORNAMENTAL LAWNS AND TURF USE GROUP(S): OUTDOOR RESIDENTIAL										
Dust, shaker can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			
Sprinkle, watering can, when needed	WP/D	na	0.4152 lb AI/1K sq.ft.	not spec	not spec	not spec	not spec			

Abbreviations used

Header: form = formulation; max. # app. = maximum number of applications;
Form: FNI/S = Form Not Identified/Solid WP/D = Wettable Powder/Dust; Impr = Impregnated Material;
Rate: na = not applicable
Limitations: Do not discharge effluent containing this pesticide into sewage without notifying the sewage treatment plant authority.
(524-354) Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction.)

Zinc chloride

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Appls	Max # Appls @ Max Rate	Min Interval Between Appls @ Max Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED USES										
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES USE GROUP(S): OUTDOOR RESIDENTIAL										
spray, hose-end sprayer, when needed	SC/L	na	dose cannot be calculated	not specified	not spec	not spec	not spec			
spray, non-aerosol pump, when needed	SC/L	na	not specified	not specified	not specified	not spec	not spec			

Zinc chloride

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rates	Maximum Application Rate	Max. # Apps	Max. # Apps @ Max. Rate	Min. Interval Between Apps @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations also see Abbreviations
								Allowed	Disallowed	
spray, tank-type sprayer, when needed	SC/L	na	dose cannot be calculated	not specified	not specified	not spec	not spec			
sprinkle, sprinkler can, when needed	SC/L	na	dose cannot be calculated	not specified	not specified	not spec	not spec			
NON-AGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS USE GROUP(S): TERRESTRIAL NON-FOOD CROP										
spray, non-aerosol pump, when needed	L/RTU	na	not specified	not spec	not spec	not spec	not spec			
PATHS/PATIOS USE GROUP(S): OUTDOOR RESIDENTIAL										
spray, hose-end sprayer, when needed	SC/L	na	dose cannot be calculated	not specified	not spec	not spec	not spec			
spray, non-aerosol pump, when needed	L/RTU	na	dose cannot be calculated	not specified	not spec	not spec	not spec			
spray, tank-type sprayer, when needed	SC/L	na	dose cannot be calculated	not spec	not spec	not spec	not spec			
PAVED AREAS (PRIVATE ROAD/SIDEWALKS) USE GROUP(S): OUTDOOR RESIDENTIAL										
spray, hose-end sprayer, when needed	SC/L	na	dose cannot be calculated	not spec	not spec	not spec	not spec			
spray, non-aerosol pump, when needed	L/RTU	na	dose cannot be calculated	not spec	not spec	not spec	not spec			
spray, tank-type sprayer, when needed	SC/L	na	dose cannot be calculated	not spec	not spec	not spec	not spec			
sprinkle, sprinkler-can, when needed	SC/L	na	dose cannot be calculated	not spec	not spec	not spec	not spec			

Abbreviations used

Header: form = formulation; not spec = not specified

Form: SC/L = Soluble Concentrate/Liquid; L/RTU = Liquid/Ready to Use;

Rate: na = not applicable;

Zinc sulfate monohydrate

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Appls	Max # Appls @ Max Rate	Min Interval Between Appls @ Max Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES USE GROUP(S): OUTDOOR RESIDENTIAL										
Spray, hydraulic sprayer, when needed	WP/D	na	1.8 lb /1K sq.ft	not spec	not spec	not spec	not spec			
Spray, sprinkler can, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
spray, tank-type sprayer, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Sprinkle, package applicator, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
PATHS/PATIOS (PRIVATE ROADS/SIDEWALKS) USE GROUP(S): TERRESTRIAL NON-FOOD + OUTDOOR RESIDENTIAL										
Spray, hydraulic sprayer, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
spray, sprinkler can, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Spray, tank-type sprayer, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Sprinkle, package applicator, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
PAVED AREAS (PRIVATE ROADS/SIDEWALKS) USE GROUP(S): OUTDOOR RESIDENTIAL										
Spray, sprinkler can, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Spray, tank-type, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Sprinkle, package applicator, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			
Spray, hydraulic sprayer, when needed	WP/D	na	same	not spec	not spec	not spec	not spec			

Abbreviations used

Header: not spec = not specified;

Form: WP/D = Wettable Powder/Dust;

Rate: Zinc standardized dose = 1.8 lb/1K sq.ft represents the available metallic zinc, however, it is neither active ingredient nor product; na = not applicable;

APPENDIX B

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the zinc salts covered by this Reregistration Eligibility document. It contains generic data requirements that apply to zinc salts in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B
Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement		Use Pattern	Citation
		ZINC CHLORIDE	
§158.120 Product Chemistry			
61-1	Chemical Identity	All	41758802
61-2	Beginning Materials and Manufacturing Process	All	41758802
61-2	Formulation of Impurities	All	41758802
62-2	Certification of Limits	All	DATA GAP
62-3	Analytical Methods	All	DATA GAP
63-2	Color	All	41758802
63-3	Physical State	All	41758802
63-4	Odor	All	41758802
63-6	Boiling Point	All	41758802
63-7	Density	All	42261001
63-8	Solubility	All	41758801
63-10	Dissociation Constant	All	41758801
63-12	pH	All	DATA GAP

APPENDIX B
Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement	Use Pattern	Citation
§158.130 Environmental Fate		
All environmental fate data requirements have been waived.		
§158.135 Toxicology		
All data toxicity data requirements have been waived.		
§158.145 Ecological Effects		
All ecological effects data requirements have been waived.		
ZINC OXIDE[1]		
§158.120 Product Chemistry		
61-1 Chemical Identity	All	41777901, 41672401 41673701, 42126501
61-2 Beginning Materials and Manufacturing Process	All	41777901, 41672401 41673701, 42126501

[1]Although there are no data gaps listed for zinc oxide, there are some confirmatory data requirements for individual registrants. These are addressed in the generic data call in as appropriate.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement		Use Pattern	Citation
61-2	Formulation of Impurities	All	41777901, 41672401 41673701, 42126501
62-3	Analytical Methods	All	41777902, 42126502
63-2	Color	All	41777903, 41672401 41673701, 42126503
63-3	Physical State	All	41777903, 41672401, 41673701, 42126503
63-4	Odor	All	41777903, 41672401 41673701, 42126503
63-5	Melting Point	All	41777903, 41672401 41673701, 42126503
63-7	Density	All	41777903,41672401 41673701, 42126503
63-8	Solubility	All	41777903, 41672401 41673701, 42126503
63-10	Dissociation Constant	All	41777903
63-12	pH	All	41777903, 42126503

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement		Use Pattern	Citation
§158.130 Environmental Fate			
All environmental fate data requirements have been waived. Refer to section III.C.1.			
§158.135 Toxicology			
81-1	Acute oral toxicity	All	147624
81-2	Acute dermal toxicity	All	147625
81-3	Acute inhalation	All	WAIVED
81-4	Primary eye irritation	All	147627
81-5	Primary dermal irritation	All	147626
81-6	Dermal sensitization	All	WAIVED
84-2	Structural Chromosomal Aberration	All	WAIVED
84-4	Other Genotoxic Effects	All	WAIVED
§158.145 Ecological Effects			
71-1	Acute Avian Oral Toxicity - Quail/Duck	All	155226
71-2	Avian Dietary Toxicity - Quail/Duck	All	155225
72-1	Freshwater Fish Toxicity - Bluegill/Trout	All	155224, 155228

APPENDIX B
Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement		Use Pattern	Citation
72-2	Freshwater Invertebrate Toxicity	All	155227
	ZINC SULFATE MONOHYDRATE		
§158.120 Product Chemistry			
61-1	Chemical Identity	All	42233802
61-2	Beginning Materials and Manufacturing Process	All	41758802
61-2	Formulation of Impurities	All	41758802
62-1	Preliminary Analysis	All	DATA GAP
62-2	Certification of Limits	All	DATA GAP
62-3	Analytical Methods	All	DATA GAP
63-2	Color	All	41758802
63-3	Physical State	All	41758802
63-4	Odor	All	41758802
63-6	Boiling Point	All	41758802
63-7	Density	All	42261001

APPENDIX B
Data Supporting Guideline Requirements for the Reregistration of Zinc Salts

Requirement		Use Pattern	Citation
63-8	Solubility	All	41758801
63-10	Dissociation Constant	All	41758801
63-12	pH	All	42261001

§158.130 Environmental Fate

All environmental fate data requirements have been waived.

§158.135 Toxicology

All data toxicity data requirements have been waived.

§158.145 Ecological Effects

All ecological effects data requirements have been waived.

APPENDIX C

ZINC SALTS BIBLIOGRAPHY

Citations Considered to be Part of the Data Base
Supporting the Reregistration of Zinc Salts

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.

APPENDIX C
ZINC SALTS BIBLIOGRAPHY

MRID	CITATION
00155224	McAllister, W.; Bowman, J.; Cohle, P. (1985) Acute Toxicity of Zinc Oxide to Bluegill Sunfish (*Lepomis macrochirus*):Static Acute Toxicity Report No. AB-85-134 prepared by Analytical Bio-chemistry Laboratories Inc.
00155225	Beavers, J.; (1985) Zinc Oxide: A Dietary LC_{50} Study with the Bobwhite: Final Report Project No. 139-224. Unpublished study prepared by Wildlife International Ltd.
00155226	Beavers, J. (1985) Zinc Oxide: An Acute Oral Toxicity Study with the Bobwhite: Final report Project No. 139-224. Unpublished study prepared by Wildlife International Ltd.
00155227	Forbis, A.; Georgie, L.; Burgess, D. (1985) Acute Toxicity of Zinc Oxide to *Daphnia magna*: Static Acute Toxicity Report No. 33229. Unpublished Monsanto Study No. AB-85-136 prepared by Analytical Bio-Chemistry Laboratories, Inc.
00155228	McAllister, W.; Bowman, J.; Cohle, P. (1985) Acute Toxicity of Zinc oxide to Rainbow Trout (*Salmo gairdneri*): Static Acute Toxicity Report No. 33228. Unpublished Monsanto Study no. AB-85-135 prepared by Analytical Bio-Chemistry Laboratories Inc.
41672401	Waltz, D. (1990) Product Chemistry of Zinc Oxide. Unpublished study prepared by David Waltz Imports.
41758801	Klettke, M.; (1991) Product Chemistry: Zinc Chloride. Unpublished study prepared by Chas. H. Lily Corp.
41758802	Klettke, M.; (1991) Product Chemistry: Zinc Chloride. Unpublished study prepared by Chas. H. Lily Corp.
41777901	Geiselman, S. (1991) Phase 3 Submission of Zinc Oxide: Product Identity and Composition. Unpublished study prepared by Monsanto Corp.
41777902	Geiselman, S. (1991) Phase 3 Submission of Zinc Oxide: Analysis and Certification of Product Ingredients. Unpublished study prepared by Monsanto Corp.
41777903	Geiselman, S. (1991) Phase 3 Submssion of Zinc Oxide: Physical and Chemical Characteristics. Unpublished study prepared by Monsanto Corp.

APPENDIX C
ZINC SALTS BIBLIOGRAPHY

MRID	CITATION
42126501	Palmer, E. (1991) Product Chemistry Studies for Zinc Oxide. Unpublished study prepared by American Chemet Corp.
42126502	Palmer, E. (1991) Product Chemistry Studies for Zinc Oxide. Unpublished study prepared by American Chemet Corp.
42126503	Palmer, E. (1991) Product Chemistry Studies for Zinc Oxide. Unpublished study prepared by American Chemet Corp.
42233803	Glaza, S. (1988) Primary Eye irritation Study of Zinc Sulfate Monohydrate in Rabbits. Lab project No. HLA 80200644. Unpublished study prepared by Hazelton Labs. America, Inc.
42233804	Glaza, S. (1988) Primary Dermal Irritation Study of Zinc Sulfate Monohydrate in Rabbits. Lab Project No. HLA 80200645. Unpublished study prepared by Hazelton Labs. America, Inc.
42252501	Mischkot, J. (1991) Physical and Chemical properties of Zinc Sulfate Monohydrate. Unpublished study prepared by Retta Mfg., Inc.

The following are sources from the open literature cited in this document:

(1) Sax, N.; Lewis, R. (1989) Dangerous Properties of Industrial Materials, 7th Edition. Van Nostrand Reinhold, New York.

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(5) Gasaway, W.; Buss S. (1972) Zinc Toxicity in the Mallard Duck. Journal of Wildlife Management 36(4):1107-1117.

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(8) Hudson, R.; Tucker, R. ; Haegele, M. (1984) Handbook of Toxicity of Pesticides to Wildlife, 2nd ed. United Satates Fish and Wildlife Service, Resource Publication No. 153, Washington, DC.

(9) United States Atomic Energy, (1973) Toxicity of Power Plant Chemicals to Aquatic Life. Compiled by C. Becker and T. Thatcher, Battelle Inc. Richland, WA.

APPENDIX D

List of Available Related Documents

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

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

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

PR NOTICE 91-2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

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

V. COMPLIANCE SCHEDULE

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

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentration" on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX F

Generic Data Call-In

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

DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Sir or Madam:

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

1. how you will comply with the requirements set forth in this Notice and its Attachments A through E; or

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and five 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:

Attachment A - Data Call-In Chemical Status Sheet
Attachment B - Data Call-In Response Form
Attachment C - Requirements Status And Registrant's Response Form
Attachment D - List Of All Registrants Sent This Data Call-In Notice
Attachment E - Cost Share And Data Compensation Forms

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. This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient. 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 data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice 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 are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the 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, Attachment B and the Requirements Status and Registrant's Response Form, Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment A.

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

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

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending

registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 557-2126.

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

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

a. The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

b. Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

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

4. Satisfying the Data Requirements of this Notice There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

Option 1. Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates

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

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

Option 3. Offer to Share in the Cost of Data Development -- If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you 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 E. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section

3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

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

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

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

computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purpos 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

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

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

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

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

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

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

d(i). A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

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

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

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

alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

2. Request for Waiver of Data -- Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice,

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most

circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrants Response Form
D - List of Registrants Receiving This Notice
E - Cost Share and Data Compensation Forms

ATTACHMENT A

CHEMICAL STATUS SHEET

ZINC SALTS: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing zinc chloride or zinc sulfate.

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Mark Wilhite at (703) 308-8586.

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

Mark Wilhite, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: ZINC SALTS

ATTACHMENT B

GENERIC DATA CALL-IN RESPONSE FORMS (Form A)
PLUS INSTRUCTIONS

SPECIFIC INSTRUCTIONS FOR
THE DATA CALL-IN RESPONSE FORM

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

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

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on

the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is a end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the

person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 058509
DAVID A. WALTZ IMPORTS
D/B/A MENZIES SHEET METAL
13903 S.E. 14TH ST
VANCOUVER WA 98684

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
58509-1					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 055500
WESPAC ENTERPRISES INC
2415 S 200TH ST BOX 46337
SEATTLE WA, 98146

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
55500-1					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 050019
JAMES W. NIELSEN
BOX 6669
BROOKINGS OR, 97415

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
50019-1					

8. Certification

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

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 003098
BAXTER J H & COMPANY
1700 S EL CAMINO REAL
SAN MATEO CA, 94402

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3098-18					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 000802
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR, 97218

2. Case # and Name
4099 Zinc salts
Chemical # and Name 087801
Zinc chloride

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
802-508 802-553					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 000802
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR, 97218

2. Case # and Name
4099 Zinc salts
Chemical # and Name 527200
Zinc Sulfate Monohydrate

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
802-591					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

GENERIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

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

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP __%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date of your receipt of the Data Call-In Notice.

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

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the

requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

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

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that

has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

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

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

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 003098
BAXTER J H & COMPANY
1700 S EL CAMINO REAL
SAN MATEO CA 94402

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	BAXTER J H & COMPANY
03098 / Address	SAN MATEO, CA
Chemical Number / Name	
088502	Zinc oxide
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	C

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		
	Comments: This guideline appears as a data gap for another registrant. It does not apply to you.		
61-1	Chemical Identity	42126501	Pending
61-2(a)	Begin. mat. & mnfg. proc		
	Comments: See comments for guideline 61-1.		
61-2(a)	Begin. mat. & mnfg. proc	42126501	Pending
61-2(b)	Discussion of Impurities		
	Comments: See comments for guideline 61-1.		
61-2(b)	Discussion of Impurities	42126501	Pending
62-1	Preliminary Analysis		
	Comments: You must provide analysis of five production samples showing upper, lower and nominal concentrations, in accordance with PR-Notice 91-2, and the upper limits of all impurities. A confidential statement of formula must also be submitted.		
62-1	Preliminary Analysis	42126502	Pending
62-2	Certification of limits		Data Gap
62-2	Certification of limits	42126502	Pending
62-3	Analytical Method		Data Gap
	Comments: The anlytical method required must be validated and sample chromatograms must be submitted.		

Chemical/Case Number	Company Number / Name
38502 / 4099	003098 BAXTER J H & COMPANY

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
62-3	Analytical Method	42126502	Pending
63-2	Color		
	Comments: See comments for guideline 61-1.		
63-2	Color	42126503	Pending
63-3	Physical State		
	Comments: See comments for guideline 61-1.		
63-3	Physical State	42126503	Pending
-4	Odor		
	Comments: See comments for guideline 61-1.		
63-4	Odor	42126503	Pending
63-5	Melting Point		
	Comments: See comments for guideline 61-1.		
63-6	Boiling Point		
	Comments: See comments for guideline 61-1.		
63-6	Boiling Point	42126503	Pending
63-7	Density		Data Gap

Chemical/Case Number	Company Number / Name
088502 / 4099	003098 BAXTER J H & COMPANY

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: You did not identify the unit expressed for bulk density in your submission.		
63-7	Density	42126503	Pending
63-8	Solubility		
	Comments: See comments for guideline 61-1.		
63-8	Solubility	42126503	Pending
63-9	Vapor Pressure		
	Comments: See comments for guideline 61-1.		
63-13	Stability		
	Comments: See comments for guideline 61-1.		
160-5	Chemical identity	41777901	Pending
171-2	Chemical identity	41777901	Pending

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 050019
JAMES W. NIELSEN
BOX 6669
BROOKINGS OR 97415

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

ompany Number / Name	JAMES W. NIELSEN
J50019 / Address	BROOKINGS, OR
Chemical Number / Name	
088502	Zinc oxide
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	K

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		Data Gap
61-2(a)	Begin. mat. & mnfg. proc		Data Gap
61-2(b)	Discussion of Impurities		Data Gap
62-1	Preliminary Analysis		Data Gap
62-2	Certification of limits		Data Gap
62-3	Analytical Method		Data Gap
3-2	Color		

Comments: See comments for guideline 61-1.

63-3	Physical State		Data Gap
63-4	Odor		Data Gap
63-5	Melting Point		Data Gap
63-6	Boiling Point		Data Gap
63-7	Density		Data Gap
63-8	Solubility		Data Gap
63-9	Vapor Pressure		Data Gap
63-13	Stability		Data Gap

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 055500
WESPAC ENTERPRISES INC
2415 S 200TH ST BOX 46337
SEATTLE WA 98146

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	WESPAC ENTERPRISES INC.
55500 / Address	SEATTLE, WA
Chemical Number / Name	
088502	Zinc oxide
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	K

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		Data Gap
61-2(a)	Begin. mat. & mnfg. proc		Data Gap
61-2(b)	Discussion of Impurities		Data Gap
62-1	Preliminary Analysis		Data Gap
62-2	Certification of limits		Data Gap
62-3	Analytical Method		Data Gap
63-2	Color		Data Gap
63-3	Physical State		Data Gap
63-4	Odor		Data Gap
63-5	Melting Point		Data Gap
63-6	Boiling Point		Data Gap
63-7	Density		Data Gap
63-8	Solubility		Data Gap
63-9	Vapor Pressure		Data Gap
63-13	Stability		Data Gap

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 058509
DAVID A. WALTZ IMPORTS
D/B/A MENZIES SHEET METAL
13903 S.E. 14TH ST
VANCOUVER WA 98684

2. Case # and Name
4099 Zinc salts
Chemical # and Name 088502
Zinc oxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	DAVID A. WALTZ IMPORTS
58509 / Address	VANCOUVER, WA
Chemical Number / Name	
088502 Zinc oxide	
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	K

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		
	Comments: This guideline appears as a data gap for another registrant. It does not apply to you.		
61-1	Chemical Identity	41672401	Pending
61-2(a)	Begin. mat. & mnfg. proc		
	Comments: See comments for guideline 61-1.		
61-2(a)	Begin. mat. & mnfg. proc	41672401	Pending
61-2(b)	Discussion of Impurities		
	Comments: See comments for guideline 61-1.		
61-2(b)	Discussion of Impurities	41672401	Pending
62-1	Preliminary Analysis		Data Gap
62-2	Certification of limits		Data Gap
62-2	Certification of limits	41672401	Pending
62-3	Analytical Method		Data Gap
62-3	Analytical Method	41672401	Pending
63-2	Color		
	Comments: See comments for guideline 61-1.		
63-2	Color	41672401	Pending

Chemical/Case Number	Company Number / Name
88502 / 4099	058509 DAVID A. WALTZ IMPORTS

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
63-3	Physical State		
	Comments: See comments for guideline 61-1.		
63-3	Physical State	41672401	Pending
63-4	Odor		
	Comments: See comments for guideline 61-1.		
63-4	Odor	41672401	Pending
63-5	Melting Point		
	Comments: See comments for guideline 61-1.		
63-5	Melting Point	41672401	Pending
63-6	Boiling Point		
	Comments: See comments for guideline 61-1.		
63-6	Boiling Point	41672401	Pending
63-7	Density	41672401	Pending
63-8	Solubility		
	Comments: See comments for guideline 61-1.		
63-8	Solubility	41672401	Pending
63-9	Vapor Pressure		

Chemical/Case Number	Company Number / Name
88502 / 4099	058509 DAVID A. WALTZ IMPORTS

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: See comments for guideline 61-1.		
63-9	Vapor Pressure	41672401	Pending
63-10	Dissociation Constant	41672401	Pending
63-13	Stability		
	Comments: See comments for guideline 61-1.		
63-13	Stability	41672401	Pending

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address 000802
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR 97218

2. Case # and Name
4099 Zinc salts
Chemical # and Name 087801
Zinc chloride

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-12	pH					all	TGAI	12 mos.	

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	CHAS H. LILLY CO.
00802 / Address	PORTLAND, OR
Chemical Number / Name	
087801	Zinc chloride
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	CK

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity	41758802	Pending
61-2(a)	Begin. mat. & mnfg. proc	41758802	Pending
61-2(b)	Discussion of Impurities	41758802	Pending
62-1	Preliminary Analysis	42261001	Pending
62-2	Certification of limits		Data Gap
62-2	Certification of limits	41758802	Pending
62-3	Analytical Method		Data Gap

Comments: The material you submitted for this guideline does not address the requirement. The analytical procedure you described does not apply to zinc chloride.

62-3	Analytical Method	41758802	Pending
63-2	Color	41758802	Pending
63-3	Physical State	41758802	Pending
63-4	Odor	41758801	Pending
63-5	Melting Point	41758802	Pending
63-6	Boiling Point	41758802	Pending
63-7	Density	41758802	Pending
63-8	Solubility	41758802	Pending
63-9	Vapor Pressure	41758802	Pending
63-10	Dissociation Constant	41758802	Pending
63-12	pH		Data Gap

Chemical/Case Number	Company Number / Name
87801 / 4099	000802 CHAS H. LILLY CO.

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments:	You reported two widely different values for pH in two physical chemistry data submissions. You must provide the correct value and explain the discrepancy.	
63-12	pH	41758801	Pending
63-13	Stability	41758801	Pending

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

1. Company name and Address 000802
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR 97218

2. Case # and Name
4099 Zinc salts
Chemical # and Name 527200
Zinc Sulfate Monohydrate

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-10	Dissociation Constant					all	TGAI	12 mos.	
63-12	pH					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	CHAS H. LILLY CO.
00802 / Address	Portland, OR
Chemical Number / Name	
527200	Zinc sulfate monohydrate
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	CK

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		Data Gap
61-2(a)	Begin. mat. & mnfg. proc		Data Gap
61-2(b)	Discussion of Impurities		Data Gap
62-1	Preliminary Analysis		Data Gap
62-2	Certification of limits		Data Gap
62-3	Analytical Method		Data Gap
63-2	Color		Data Gap
63-3	Physical State		Data Gap
63-4	Odor		Data Gap
63-5	Melting Point		Data Gap
63-6	Boiling Point		Data Gap
63-7	Density		Data Gap
63-8	Solubility		Data Gap
63-9	Vapor Pressure		Data Gap
63-10	Dissociation Constant		Data Gap
63-12	pH		Data Gap
63-13	Stability		Data Gap

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
Retta Mfg., Inc.
Box 2306
Eugene, OR 97402

2. Case # and Name
4099 Zinc salts
Chemical # and Name 527200
Zinc Sulfate Monohydrate

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	Discussion of Impurities					all	TGAI	12 mos.	
62-1	Preliminary Analysis					all	TGAI	12 mos.	
62-2	Certification of limits					all	TGAI	12 mos.	
62-3	Analytical Method					all	TGAI	12 mos.	
63-2	Color					all	TGAI	12 mos.	
63-3	Physical State					all	TGAI	12 mos.	
63-4	Odor					all	TGAI	12 mos.	
63-5	Melting Point					all	TGAI	12 mos.	
63-6	Boiling Point					all	TGAI	12 mos.	
63-7	Density					all	TGAI	12 mos.	
63-8	Solubility					all	TGAI	12 mos.	
63-9	Vapor Pressure					all	TGAI	12 mos.	
63-10	Dissociation Constant					all	TGAI	12 mos.	
63-12	pH					all	TGAI	12 mos.	
63-13	Stability					all	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Company Number / Name	RETTA MFG., INC.
010699 / Address	EUGENE, OR
Chemical Number / Name	
527200	Zinc sulfate monohydrate
Case Number / EPA Manager	Use Pattern
4099 Mark Wilhite	K

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity		
	Comments: This guideline appears as a data gap for another registrant. It does not apply to you.		
61-1	Chemical Identity	42233801	Pending
61-2(a)	Begin. mat. & mnfg. proc		
	Comments: See comments for guideline 61-1.		
61-2(a)	Begin. mat. & mnfg. proc	42233801	Pending
61-2(b)	Discussion of Impurities		
	Comments: See comments for guideline 61-1.		
61-2(b)	Discussion of Impurities	42233801	Pending
62-1	Preliminary Analysis		Data Gap
	Comments: In the sample analysis you submitted, you did not account for the monohydrate. You must either calculate the amount of all fractions or submit a new method.		
62-2	Certification of limits		Data Gap
	Comments: You must submit the upper, lower and nominal concentrations of zinc sulfate monohydrate as well as the upper and lower limit of each impurity of toxicological concern.		
62-2	Certification of limits	42233802	Pending
62-3	Analytical Method		Data Gap

Chemical/Case Number	Company Number / Name
27200 / 4099	010699 RETTA MFG., INC.

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: In the analysis you submitted the water content was not accounted for. You must revise this data submission using another analysis or submit a new method.		
62-3	Analytical Method	42233802	Pending
63-2	Color		
	Comments: See comments for guideline 61-1.		
63-2	Color	42252501	Pending
63-3	Physical State		
	Comments: See comments for guideline 61-1.		
63-3	Physical State	42252501	Pending
63-4	Odor		
	Comments: See comments for guideline 61-1.		
63-4	Odor	42252501	Pending
63-5	Melting Point		
	Comments: See comments for guideline 61-1.		
63-5	Melting Point	42252501	Pending
63-6	Boiling Point		

Chemical/Case Number	Company Number / Name
27200 / 4099	010699 RETTA MFG., INC.

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: See comments for guideline 61-1.		
63-6	Boiling Point	42252501	Pending
63-7	Density		
	Comments: See comments for guideline 61-1.		
63-7	Density	42252501	Pending
63-8	Solubility		
	Comments: See comments for guideline 61-1.		
63-8	Solubility	42252501	Pending
63-9	Vapor Pressure		
	Comments: See comments for guideline 61-1.		
63-9	Vapor Pressure	42252501	Pending
63-10	Dissociation Constant		
	Comments: See comments for guideline 61-1.		
63-10	Dissociation Constant	42252501	Pending
63-13	Stability		
	Comments: See comments for guideline 61-1.		

Chemical/Case Number	Company Number / Name
527200 / 4099	010699 RETTA MFG., INC.

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
63-13	Stability	42252501	Pending
81-4	Primary eye irration-rabbit	42233803	Pending
81-5	Primary dermal irritation	42233804	Pending

ATTACHMENT D

LIST OF ALL REGISTRANT(S) SENT THIS DCI

List of All Registrants Sent This Data Call-In Notice

Case # and Name
4099 Zinc salts
Chemical # and Name
088502 Zinc oxide

Company Number	Company Name	Additional Name	Address	City & State	Zip
003098	BAXTER J H & COMPANY		1700 S EL CAMINO REAL	SAN MATEO CA	94402
050019	JAMES W. NIELSEN		BOX 6669	BROOKINGS OR	97415
055500	WESPAC ENTERPRISES INC		2415 S 200TH ST BOX 46337	SEATTLE WA	98146
058509	DAVID A. WALTZ IMPORTS	D/B/A MENZIES SHEET METAL	13903 S.E. 14TH ST	VANCOUVER WA	98684

List of All Registrants Sent This Data Call-In Notice

Case # and Name
4099 Zinc salts
Chemical # and Name
087801 Zinc chloride

Company Number	Company Name	Additional Name	Address	City & State	Zip
000802	CHAS H. LILLY CO.		7737 N.E. KILLINGSWORTH	PORTLAND OR	97218

List of All Registrants Sent ..s Data Call-In Notice

Case # and Name
4099 Zinc salts
Chemical # and Name
527200 Zinc sulfate monohydrate

Company Number	Company Name	Additional Name	Address	City & State	Zip
000802	CHAS H. LILLY CO.		7737 N.E. KILLINGSWORTH	PORTLAND OR	97218
10699	Retta Mfg.,Inc.		Box 2306	Eugene, OR	97402

ATTACHMENT E

COST SHARE/DATA COMPENSATION FORMS

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are:

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

APPENDIX G

Product Specific Data Call-In

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

DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Sir or Madam:

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

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

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting

your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 6. Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable

toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

b. Fulfill the commitment to develop and submit the data as required by this Notice; or

c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for

issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols (if applicable), including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with

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

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

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

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

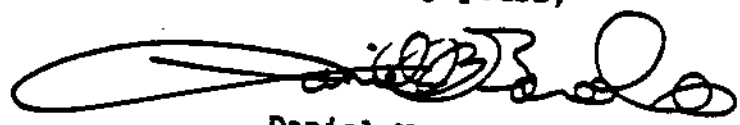
SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,



Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

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

ATTACHMENT A

ZINC SALTS: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of zinc salts, please contact Mark Wilhite at (703) 308-8086.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Joanne Miller (703) 305-7830.

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

Joanne Miller, Product Manager Team 23
Herbicide/Fungicide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: ZINC SALTS

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A)
PLUS INSTRUCTIONS

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

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

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 (MP) or 7b (EP) on this form, provide the EPA registration numbers of your source(s) and complete and submit the "Generic Data Exemption" form; 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 (MP) 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 (EP) 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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Product Specific Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of product specific data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RETTA MFG., INC. BOX 2306, EUGENE OR 97402	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
10699-1		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
DAVID A. WALTZ IMPORTS D/B/A MENZIES SHEET METAL 13903 S.E. 14TH ST VANCOUVER WA 98684	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
58509-1		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CANADIAN ROOFING PRODUCTS 5555 SALISH RD BLAINE WA 98250	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
58494-1		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
WESPAC ENTERPRISES INC 2415 S 200TH ST BOX 46337 SEATTLE WA 98146	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
55500-1		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
BAXTER J H & COMPANY 1700 S EL CAMINO REAL SAN MATEO CA 94402	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3098-18		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
802-591		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
802-553		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
802-508		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
MONSANTO CO. 700 14TH STREET, N.W. SUITE 1100 WASHINGTON DC 20005	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
524-354		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
JAMES W. NIELSEN BOX 6669 BROOKINGS OR 97415	4099 Zinc salts	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
50019-1		N.A.	N.A.		

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS
AND
PR NOTICE 86-5

SPECIFIC INSTRUCTIONS FOR COMPLETING
THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Product Specific Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of product specific data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
JAMES W. NIELSEN BOX 6669 BROOKINGS OR 97415	4099 Zinc salts EPA Reg. No. 50019-1	PRODUCT SPECIFIC ID# 50019-RD-2379

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
JAMES W. NIELSEN BOX 6669 BROOKINGS OR 97415	4099 Zinc salts EPA Reg. No. 50019-1	PRODUCT SPECIFIC ID# 50019-RD-2379

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of u.e will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
MONSANTO CO.
700 14TH STREET, N.W. SUITE 1100
WASHINGTON DC 20005

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 524-354

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 524-RD-2377

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
MONSANTO CO.
700 14TH STREET, N.W. SUITE 1100
WASHINGTON DC 20005

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 524-354

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 524-RD-2377

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts EPA Reg. No. 802-508	PRODUCT SPECIFIC ID# 802-RD-2341

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

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1. Company name and Address
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR 97218

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 802-508

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 802-RD-2341

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

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Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
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United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts EPA Reg. No. 802-553	PRODUCT SPECIFIC ID# 802-RD-2342

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CHAS H. LILLY CO. 7737 N.E. KILLINGSWORTH PORTLAND OR 97218	4099 Zinc salts EPA Reg. No. 802-553	PRODUCT SPECIFIC ID# 802-RD-2342

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR 97218

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 802-591

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 802-RD-2375

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
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1. Company name and Address
CHAS H. LILLY CO.
7737 N.E. KILLINGSWORTH
PORTLAND OR 97218

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 802-591

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 802-RD-2375

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
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5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
BAXTER J H & COMPANY
1700 S EL CAMINO REAL
SAN MATEO CA 94402

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 3098-18

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 3098-RD-2378

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

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

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1700 S EL CAMINO REAL
SAN MATEO CA 94402

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 3098-18

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 3098-RD-2378

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
WESPAC ENTERPRISES INC 2415 S 200TH ST BOX 46337 SEATTLE WA 98146	4099 Zinc salts EPA Reg. No. 55500-1	PRODUCT SPECIFIC ID# 55500-RD-2380

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

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

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1. Company name and Address	2. Case # and Name	3. Date and Type of OCI
WESPAC ENTERPRISES INC 2415 S 200TH ST BOX 46337 SEATTLE WA 98146	4099 Zinc salts EPA Reg. No. 55500-1	PRODUCT SPECIFIC ID# 55500-RD-2380

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
CANADIAN ROOFING PRODUCTS
5555 SALISH RD
BLAINE WA 98250

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 58494-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 58494-RD-2381

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials,(1,2) production & formulation proc					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
CANADIAN ROOFING PRODUCTS 5555 SALISH RD BLAINE WA 98250	4099 Zinc salts EPA Reg. No. 58494-1	PRODUCT SPECIFIC ID# 58494-RD-2381

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
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5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address
DAVID A. WALTZ IMPORTS
D/B/A MENZIES SHEET METAL
13903 S.E. 14TH ST
VANCOUVER WA 98684

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 58509-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 58509-RD-2382

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8,mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

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1. Company name and Address
DAVID A. WALTZ IMPORTS
D/B/A MENZIES SHEET METAL
13903 S.E. 14TH ST
VANCOUVER WA 98684

2. Case # and Name
4099 Zinc salts

EPA Reg. No. 58509-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 58509-RD-2382

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is requi.ed for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RETTA MFG., INC. BOX 2306 EUGENE OR 97402	4099 Zinc salts EPA Reg. No. 10699-1	PRODUCT SPECIFIC ID# 10699-RD-2376

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

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

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Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4099 Zinc salts

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

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

JUL 29 1986

PR NOTICE 86-5

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS
AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX -

****

A. Organization of Submittal Package

A 'submittal package' consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.
- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (ie., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study,

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

C. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed 'example' cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required.	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies. (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1 Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; DO NOT INCLUDE CBI ON THE TITLE PAGE. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the Statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c). (See Attachment 3) These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(d)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked 'Confidential Attachment.' An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5 Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (see Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the 'Supplemental Statement of Data Confidentiality Claims'.
- Remove the 'Confidential Attachment'.
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact William C. Grosse, Chief, Information Services Branch, Program Management and Support Division, (703-557-2613).

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1.

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

†Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

†Smith Chemical Corp. will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

.
.
.

Vol n. Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

** Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2.

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3.

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4.

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5.

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1 (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
28	25	"	"
100	19	"	"

Example 2 (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

(Reproduce the deleted paragraph(s) here)

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20	8-17	Description of the quality control process	§10(d)(1)(C)

Example 3 (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
33-41	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter _____

Sponsor _____

Study Director _____

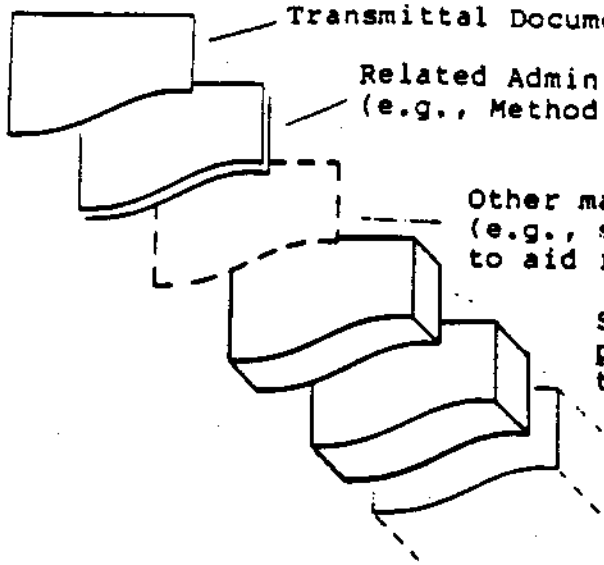
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

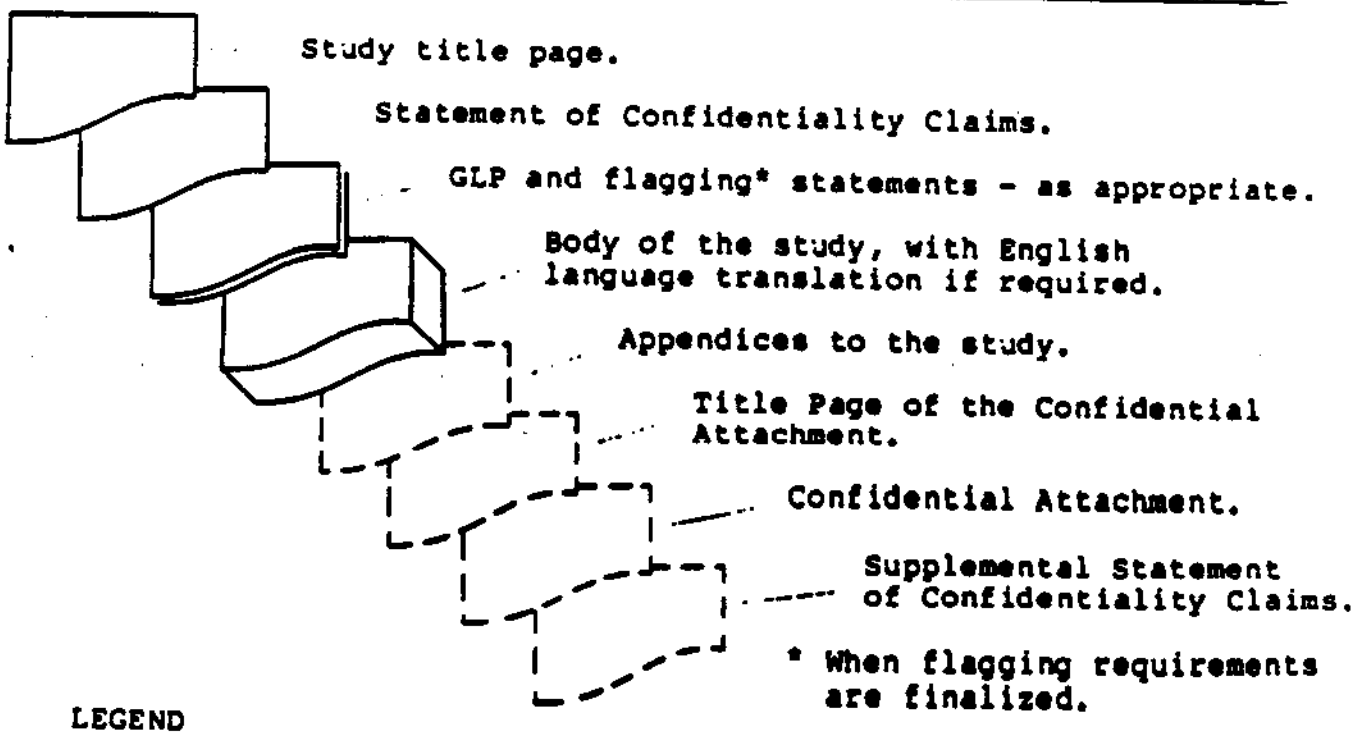
Submitter _____

ATTACHMENT 7.

FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND

EPA

TS-767
United States
Environmental Protection
Agency
Washington, DC 20460

Official Business
Penalty for Private Use
$300

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING
DATA REQUREMENTS FOR REREGISTRATION

EPA'S BATCHING TO FULFILL ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION OF PRODUCTS CONTAINING THE FOLLOWING ZINC SALTS: ZINC OXIDE, ZINC CHLORIDE AND ZINC SULFATE

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredients zinc oxide, zinc chloride and zinc sulfate, 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.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

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.

Some products were excluded from the batching process. Products which were not included in the following batches were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of products which were not batched are responsible for meeting the acute toxicity data requirements for each product.

Table I.

Batch	EPA Reg. No.	% Zinc oxide	Formulation type
1	524-354	99.4	powder
	3098-18	99.0	powder
	55500-1	99.9	strips
	58494-1	99.0	strips
	58509-1	99.0	strips

Table II.

Batch	EPA Reg. No.	% Zinc sulfate	Formulation type
2	802-591	99.0	granular
	10699-1	99.0	dust

The following table show products that were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not batched. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table III.

EPA Reg. No.	* % Zinc oxide or zinc chloride	Formulation type
802-508	29.6 Zinc chloride	liquid
802-553	6.2 Zinc chloride	liquid
50019-1	20.76 Zinc oxide 2.35 Copper	powder

* expressed as metallic equivalent

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

8. (continued)

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

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

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

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

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

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

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

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color
- ___ Verbal description of coloration (or lack of it)
- ___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
- ___ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
- ___ Based on visual inspection at about 20-25° C

63-4 Odor
- ___ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
- ___ Observed at room temperature

63-5 Melting Point
- ___ Reported in C°
- ___ Any observed decomposition reported

63-6 Boiling Point
- ___ Reported in C°
- ___ Pressure under which B.P. measured reported
- ___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
- ___ Measured at about 20-25° C
- ___ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

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

63-12 pH

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

63-13 Stability

___ Sensitivity to metal ions and metal determined
___ Stability at normal and elevated temperatures
___ Sensitivity to sunlight determined

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

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

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

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc)

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

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

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

GUIDANCE FOR SUMMARIZING STUDIES

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

dose your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc)
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ One of the following methods is utilized;
- _____ Freund's complete adjuvant test
- _____ Guinea pig maximization test
- _____ Split adjuvant technique
- _____ Buehler test
- _____ Open epicutaneous test
- _____ Mauer optimization test
- _____ Footpad technique in guinea pig

4.____ Complete description of test
5.*___ Reference for test.
6.____ Test followed essentially as described in reference document.
7.____ Positive control included (may provide historical data conducted within the last 6 months)

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

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

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

81-7 Acute Neurotoxicity in the Hen

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

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

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 4099 Zinc salts

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
000524	MONSANTO CO.		700 14TH STREET, N.W. SUITE 1100	WASHINGTON DC	20005
000802	CHAS H. LILLY CO.		7737 N.E. KILLINGSWORTH	PORTLAND OR	97218
003098	BAXTER J H & COMPANY		1700 S EL CAMINO REAL	SAN MATEO CA	94402
050019	JAMES W. NIELSEN		BOX 6669	BROOKINGS OR	97415
055500	WESPAC ENTERPRISES INC		2415 S 200TH ST BOX 46337	SEATTLE WA	98146
058494	CANADIAN ROOFING PRODUCTS		5555 SALISH RD	BLAINE WA	98250
058509	DAVID A. WALTZ IMPORTS	D/B/A MENZIES SHEET METAL	13903 S.E. 14TH ST	VANCOUVER WA	98684

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

US Environmental Protection Agency
Washington, DC 20460

EPA

Product Specific Data Report

Registration Standard for:

EPA Registration Number

Form Approved
OMB #2070-0057
Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above (Check below)	I am complying with Data Requirements by - Citing MRID No.	I am complying with Data Requirements by - Submitting Data (Attached) (Check below)	(For EPA Use Only) Accession numbers assigned
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit / rat / g.pig				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

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

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.