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Environmental Protection
Agency

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

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Reregistration Eligibility Document (RED)

Iron Salts

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United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (H-7508W)
EPA-738-F-93-002 February 1993

EPA R.E.D. FACTS

Iron 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 iron salts.

Use Profile

The iron salts consist of three pesticide active ingredients that are eligible for reregistration: Iron (III) sulfate, Iron (II) sulfate monohydrate, and Iron (II) sulfate heptahydrate.

Iron salts are registered for use as herbicides to control moss on lawns, turf, ornamental herbaceous plants, woody shrubs and vines. Registered products are formulated as soluble concentrates and granulars. They are applied by sprinkler can, hose-end sprayer, spreader, or by hand.

The major use of iron salts in the United States is non-pesticidal, as a fertilizer micronutrient. Iron salts also are used as an electrolyte in dry cell batteries, as an animal feed additive, as a galvanizer and as an emulsion-breaker. They have further uses in water purification and sewage treatment, and in textile dying and calico printing.

Regulatory History

Iron salts first were registered as pesticides in 1962. In addition to the current outdoor moss control uses, iron salts were registered previously for use inside households, and in and around commercial, institutional and industrial premises.

At present, a total of 13 products are registered containing iron salts as sole or one of several active ingredients; one product contains Iron (III)

sulfate, nine contain Iron (II) sulfate monohydrate, and three contain Iron (II) sulfate heptahydrate.

A fourth active ingredient, Iron II ammonium sulfate, is not being supported for reregistration and so is not covered in this RED.

Human Health Assessment

Toxicity

Iron salts are present normally in the environment. Iron is the fourth most abundant element and the second most abundant metal in the earth's crystal rocks. Iron occurs in a wide variety of minerals, and is present in foods naturally and through added ingredients.

The iron salts are of low acute toxicity through oral, dermal and inhalation routes of exposure. They have been placed in Toxicity Category III for these effects. Although a mutagenicity study using microorganisms showed positive results, it is unlikely that such effects would result in humans or other mammals at the levels of exposure expected from the use of iron salts as pesticides. Other toxicity studies normally required for reregistration were not necessary to evaluate the risks of the iron salts.

Dietary Exposure

Dietary exposure is not expected to result from use of the iron salts as pesticides. No food or feed-related uses are registered, and no tolerances (maximum residue limits) or exemptions from the requirement of a tolerance are established. Further, the iron salts are generally recognized as safe (GRAS) by the Food and Drug Administration for use as a flavoring agent and nutrient supplement in foods (please see 40 CFR 180.2(a)).

Occupational and Residential Exposure

The potential for mixer, loader and applicator exposure exists when liquid or granular iron salts products are applied to lawns, turf and other outdoor sites using spreaders, sprinkler cans or by hand. However, these inorganic salts are of little concern from a toxicity perspective. Any exposure of mixers, loaders or applicators is considered inconsequential.

Human Risk Assessment

The risks to people from dietary, occupational and residential exposure to iron salts pesticides are considered negligible. It is general knowledge that these compounds are of low toxicity. They are intentionally added to foods as flavoring agents and nutrient supplements, and they have an inherent function in the metabolic systems of humans and domestic animals.

Environmental Assessment

Environmental Fate

The environmental fate and transport of iron salts is dominated by three processes: the conversion of Iron (II) to Iron (III), the formation of

insoluble oxides and hydroxides that also are well known components of soils, and the distinct surface chemistry of the iron salts that causes their adsorption with other soil components, forming larger soil particles.

Use of the iron salts produces iron oxides and hydroxides that are no different from those normally found in soils, and which give them their brown and red colors. Although certain bacteria can reduce Iron (III) to the more mobile Iron (II), this is rapidly immobilized.

Therefore, the use of iron salts as herbicides to control moss is not expected to contribute significantly to the chemistry and fate of the compounds existing naturally in the environment. No unreasonable effects are expected from the use of these pesticide products as directed.

Ecological Effects

In dietary acute toxicity studies, iron salts are practically nontoxic to bird species and are nontoxic or slightly toxic to rats. Iron (II) sulfate heptahydrate, the most toxic form of the iron salts compounds, is moderately toxic to aquatic invertebrates and slightly toxic to fish.

No adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9. Runoff to aquatic systems is unlikely since the parent compounds convert very rapidly to less soluble forms in the environment. Furthermore, the oxidized iron compounds bind tightly to soil under turf.

No adverse effects to endangered species are anticipated from the us of iron salts.

Additional Data Required

EPA is requiring additional physical chemistry studies as confirmatory data and to complete the generic data base for iron salts. Product-specific product chemistry studies and revised labeling also are required for reregistration. These additional studies are being required through Data Call-Ins issued in conjunction with the iron salts RED.

Product Labeling Changes Required

The labels of all registered iron salts products must comply with EPA's current pesticide labeling requirements. In addition, to protect surface waters, end-use product labels must bear the following Environmental Hazards statement:

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Regulatory Conclusion

- The three pesticide active ingredients discussed in the iron salts RED will not result in unreasonable adverse effects to human health or th environment, and all registered products containing these active ingredien

are eligible for reregistration. These products will be reregistered once the required generic and product-specific data and revised labeling are received and accepted by EPA.

- Registered products containing iron salts as well as other active ingredients will be reregistered once the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for iron 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 Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the iron 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 iron 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 iron salts products, please contact Joanne Miller, Product Manager, 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, between 8:00 am and 6:00 pm Central Time, Monday through Friday.

REREGISTRATION ELIGIBILITY DOCUMENT

IRON SALTS

LIST D

CASE 4058

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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Attachment D - List of all Registrant(s) sent this DCI
Attachment E - Cost Share/Data Compensation Forms

APPENDIX G - Product Specific Data Call-In

Attachment A - Chemical Status Sheet
Attachment B - Product Specific DCI Response Forms (Form A) plus Instructions
Attachment C - Requirements Status and Registrants' Response Forms (Form B) plus Instructions
Attachment D - EPA Grouping of End Use Products for meeting Acute Toxicology Data Requirements.
Attachment E - EPA Acceptance Criteria
Attachment F - List of all Registrant(s) sent this DCI
Attachment G - Cost Share/Data Compensation Forms

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.
Ld_{lo}	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.

I. EXECUTIVE SUMMARY

The active ingredients covered in this document include iron (III) sulfate, iron (II) sulfate monohydrate and iron (II) sulfate heptahydrate in the chemical case iron salts. Products containing these active ingredients are used as herbicides for the control of moss on ornamental herbaceous plants, lawns, turf, wood shrubs and vines. This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of products containing these active ingredients for the above mentioned use sites only.

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, products containing the iron 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 iron 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 toxicity testing. After reviewing these data and any revised labels and finding them acceptable, the Agency will reregister a product based on whether or not that product meets the requirements in Section 3(c)(5) of FIFRA.

II. 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 iron (III) sulfate, iron (II) sulfate monohydrate, and iron (II) sulfate heptahydrate. The document consists of six sections. Section I is the introduction. Section II describes these iron 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 iron salts. Section V discusses the reregistration requirements for iron 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 requested from the Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

III. CASE OVERVIEW

A. Chemical Overview

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

1. **Chemical Name:** Iron (III) sulfate

   - **CAS Registry Number:** 10028-22-5
   - **Office of Pesticide Programs Chemical Code:** 34902
   - **Empirical Formula:** $Fe_2(SO_4)_3$

2. **Chemical Name:** Iron (II) sulfate monohydrate

   - **CAS Registry Number:** 17375-41-6
   - **Office of Pesticide Programs Chemical Code:** 50507
   - **Empirical Formula:** $FeSO_4H_2O$

3. **Chemical Name:** Iron (II) sulfate heptahydrate

   - **CAS Registry Number:** 7782-63-0
   - **Office of Pesticide Programs Chemical Code:** 50502
   - **Empirical Formula:** $FeSO_47H_2O$

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 iron (III) sulfate, iron (II) sulfate monohydrate and iron (II) sulfate heptahydrate is in Appendix A.

1. **For Iron (III) sulfate:**

Type of Pesticide: Herbicide

Use Sites: Ornamental lawns and turf--terrestrial non-food, outdoor residential

Target Pest: Mosses

Formulation Types Registered:
Soluble concentrate/liquid

Method and Rates of Application: Equipment - Sprinkler can and hose-end sprayer.

Method and Rate - Soluble concentrate/liquid (1 qt./500 sq.ft.)

Timing - When needed.

2. **For Iron (II) sulfate monohydrate:**

Type of Pesticide: Herbicide

Use Sites: Ornamental herbaceous plants, ornamental lawns and turf, ornamental woody shrubs and vines--terrestrial non-food, outdoor residential.

Target Pests: Mosses

Formulation Types Registered:
Granular

Method and Rates of Application:

Equipment - By hand and spreader

Method and Rate - Ground; broadcast; sprinkle; spot treatment

Ornamental Hervaceous Plants
35 lb iron/A.
Ornamental Lawns
35 lb iron/A.
Ornamental Woody Srubs and Vines
35 lb iron/A.

Timing - When needed; Fall; Winter; Spring; Early Spring.

3. For Iron (II) sulfate heptahydrate:

Type of Pesticide: Herbicide

Use Sites: Ornamental lawns and turf--terrestrial non-food, Outdoor Residential

Target Pests: Mosses

Formulation Types Registered:
Soluble concentrate/liquid, Soluble concentrate/solid, Granular

Method and Rates of Application:

Equipment
Spreader; sprinkler can; by hand; sprayer

Method and Rate Spray
Ornamental lawns and turf
57 lb iron/A.
Timing
When needed.

C. Regulatory History

Pesticidal products containing iron salts were first registered in the United States in 1962. In addition to active products which are currently approved for use on ornamental herbaceous plants, ornamental perennial, ornamental lawns, ornamental woody shrubs and ornamental turfs, iron salts were previously registered for household or domestic dwellings (indoor) and commercial institutional and industrial areas/premises. The current uses include moss control in areas where moss growth is profuse due to high precipitation rates, primarily in the Northwest. Currently there are 14 registered products with these ingredients; 1 with iron (III) sulfate, 9 with iron (II) sulfate monohydrate, and 3 with iron (II) sulfate heptahydrate.

The major use of iron 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, as an emulsion-breaker, as a coagulant, in water purification and sewage treatment, and as mordant in textile dyeing and calico printing.

Iron II ammonium sulfate is currently not being supported and is not covered in this Reregistration Eligibility Document.

IV. SCIENCE ASSESSMENT OF IRON SALTS

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

A. Physical Chemistry Assessment

Iron (III) sulfate is a grayish-white powder, or rhombic or rhombohedral crystals. The commercial product usually contains about 20% water and is yellowish in color. It is slowly soluble in water, rapidly soluble in the presence of a trace of iron (III) sulfate, sparingly soluble in alcohol, practically insoluble in acetone and ethyl acetate.

Iron (II) sulfate monohydrate is white to a yellow crystal powder. It is soluble in water and forms a monohydrate at 65°C.

Iron (II) sulfate heptahydrate may appear as blue green crystals or granules and is usually odorless. It is efflorescent in dry air and oxidizes in moist air forming a brown coating of basic iron (III) sulfate. The tetrahydrate is formed at 56.6°C. iron (II) sulfate heptahydrate is soluble in water and practically insoluble in alcohol.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on iron (III) sulfate, iron (II) sulfate monohydrate, and iron (II) sulfate heptahydrate is adequate and will support reregistration eligibility.

a. Acute and Subchronic Toxicity

ACUTE TOXICITY VALUES

TEST Iron III Sulfate	RESULT	TOXICITY CATEGORY
Oral LD_{50}--rat	1487 - 2102 mg/kg	III
Inhalation LC_{50}--rat	> 1.10 mg/L	III
Dermal LD_{50}--rabbit	> 2000 mg/kg	III
Eye Irritation	corrosive	I
Dermal Irritation	corrosive	IV
Dermal Sensitization	negative	-

Iron (III) sulfate, in an acute oral study in rats, had an LD_{50} of 1487 mg/kg in females and 2102 mg/kg in males. An acute dermal toxicity test in rabbits with Iron (III) sulfate found an LD_{50} greater than 2000 mg/kg. An acute inhalation toxicity study in rats using iron (III) sulfate determined the LC_{50} to be greater than 1.10 mg/L.

Iron (II) sulfate heptahydrate, in an acute oral study in rats, showed an LD_{lo} of 1389 mg/kg and an acute oral study in rabbits showed an LD_{lo} of 2778 mg/kg(4). The LD_{50} determined for this compound in mice was 1520 mg/kg(4). A sensitization study using guinea pigs with iron (II) sulfate monohydrate and iron (III) sulfate found no indication of contact sensitization by this compound.

b. **Mutagenicity**

A mutation study in E. coli reported positive results at 30 umol/L(4). With due regard for the continuing exposure that human beings have had to the iron and sulfate components of these chemicals over many generations, it is considered unlikely that this reported result in microorganisms has any bearing on probable effects in humans or other mammals at the levels expected from use of these compounds as pesticides.

c. **Metabolism**

Iron sulfates are normal constituents of the diet and are metabolized and utilized by the body.

d. **Other Toxicological Consideration**

The toxicological data on iron sulfates within the Agency and in the literature are adequate for assessing risk to humans. Not all of the toxicity data usually required for pesticide registration or reregistration are necessary for the present uses of iron sulfates. There are some unusual factors in this case which indicate that specific studies to fulfill the usual data requirements are not necessary to regulate these substances as pesticides. Iron sulfates are normally present in the environment. They may be present in foods naturally and as added ingredients. There is no reason to expect that pesticide usage in accordance with the product label or labeling accompanying the product will constitute any hazard beyond that from ordinary exposure.

2. **Exposure Assessment**

a. **Dietary**

Dietary exposure to iron (III) sulfate, iron (II) sulfate heptahydrate, and iron (II) sulfate monohydrate is not expected to occur from pesticidal use. There are no active products involving pesticidal uses on food or animal feed. Therefore, there are no tolerances or exemptions from the requirements of tolerances established for iron salts. Since there are no toxicological endpoints of concern and no food uses, no risk assessment was performed for dietary exposure. Iron (II) sulfate is generally recognized as safe as noted in 40 CFR 180.2(a). The Food and Drug Administration has affirmed that iron (III) sulfate and iron (II) sulfate (hepta and monohydrate) are generally recognized as safe (GRAS) for use in food as flavoring agents and nutrient supplements, respectively, with no limitations other than

current good manufacturing practice.

b. Occupational and Residential

As stated in Appendix A, iron (III) sulfate and iron (II) sulfate hepta- and monohydrate are applied to turf and ornamental lawns using drop and broadcast spreaders, sprinkler cans, and by hand. These inorganic salts are formulated as a granular and soluble concentrate (liquid and solid). They are used as a herbicide to control moss on residential lawns and ornamental turf. The potential for mixer/loader/applicator exposure exists; however, these inorganic salts are of little concern from a toxicity perspective. Any mixer/loader/applicator exposure to these inorganic salts is considered inconsequential and no additional exposure data are required for reregistration eligibility.

3. Risk Assessment

The human risks from both dietary and occupational exposures are considered to be negligible. The general knowledge of iron (III) sulfate and iron (II) sulfate hepta- and monohydrate indicate low toxicities associated with these compounds. They are used by humans as food flavoring agents and food nutrient supplements, and have inherent function in the metabolic pathways of humans and domestic animals. No additional hazard or exposure data are required for reregistration eligibility.

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 iron salts as used in pesticidal compounds. No environmental fate data were submitted by registrants.

a. Environmental Chemistry and Fate

Iron is the fourth most abundant element and the second most abundant metal in the Earth's crystal rocks. Iron occurs in a wide variety of minerals among them the oxides hematite (α-Fe_2O_3) and magnetite (Fe_3O_4), the "hydrated oxide oxide limonite" ($\sim$ "$2Fe_2O_3 \cdot 3H_2O$"), the oxyhydroxide geothite and its polymorph lepidocrocite (α-FeOOH and γ-FeOOH, respectively), ferrihydrite ("$5Fe_2O_3 \cdot 9H_2O$"), in carbonates such as siderite ($FeCO_3$), in sulfides

(pyrite and marcasite, FeS_2; chalcopyrite, $CuFeS_2$, etc.), phosphates (for example vivianite) and incomplex silicates.(1,2) Weathering (that is, "the group of processes such as the chemical action of air, rainwater, plants and bacterial, and the mechanical action of changes of temperature whereby rocks on exposure to weather change in character, decay and finally crumble into soil")(3) has considerably influenced the distribution of iron in the earth. The oxides and hydroxide minerals of iron are strong pigments and are responsible, for the most part, for the brown and red colors of soils. The presence of hematite and goethite in soils (usually associated with gibsite and kaolinite) is indicative of an advanced stage of weathering.(4)

The oxidation of ferrous iron to ferric iron (from here on referred to as Fe(II) and Fe(III), respectively) is a very important aspect of the chemistry of iron salts in the environment. The oxidation is dependent on the pH and the redox potential of the medium (water; soil) and the nature of the ligands that may be complexed to Fe(II). But in general, Fe(II) is more prevalent only in very acid media of very low oxygen content, rather than in more basic media of normal-to-high oxygen content, the latter being the most commonly encountered condition. The speciation and subsequent fate and transport of Fe(II) and Fe(III) in the environment is, therefore, determined by the pH and redox potential of the media and by the nature of the ligands to which they complex. (1,2,5,6)

Under normal environmental conditions (pH 5 to 9; aerobic environments), the highly soluble Fe(II) salts will be rapidly oxidized to Fe(III), but this oxidation is accompanied by the formation of less soluble oxide and hydroxide.(7) The precipitation of Fe(III) oxides/oxyhydroxides from oxidation of Fe(II) salts or from Fe(III) salts occurs in a stepwise manner, which involves (a) formation of low-molecular weight species of poor crystalline ordering; (b) formation of red cationic polymers; (c) aging of the polymers, with eventual conversion to better defined oxide phases; (d) precipitation of oxide/oxyhydroxide phases of well defined crystallographic characteristics.(5) The rate of formation and the onset of the polymeric species are known to be strongly influenced by the nature of the counter anion of the salts.(5) In the case of salts of the divalent sulfate counter anion, precipitation occurs at lower pHs than with salts of monovalent counter anions (for example, nitrate, chloride). Like in laboratory experiments, the use of Fe(II) and Fe(II) sulfates in a terrestrial environment leads to the formation of insoluble oxide/oxyhydroxide species.(7)

The oxide/oxyhydroxide species that form from the use of Fe

(II) or Fe(III) sulfates are the same oxide/oxyhydroxide species (principally ferrihydrite, goethite, lepidocrocite, and hematite) that are present in soils as a result of weathering.(4,7) Thermodynamic and kinetic factors influence the predominance of certain species over other.(7) Soil temperature, soil moisture and soil pH are significant environmental factors that control the distribution of these species.(8) For example, it has been observed that goethite is commonly the sole iron oxide in cool and temperate zones, but in the majority of tropical or subtropical regions hematite is the predominant oxide, although it is rarely free of goethite.(8) The lepidocrocite-goethite association in soils is less understood. The predominance of lepidocrocite in a soil has been attributed to the prevalence of conditions favoring reduction of Fe(III) to Fe(II) followed by movement of Fe(II) to better aerated sites, where oxidation to Fe(III) and precipitation of lepidocrocite occurs.(9) Ferrihydrite may be considered as a young iron oxide of low order of crystallinity. Subsequent transformation of ferrihydrite into other oxides of iron is dominated by the environmental conditions.(10)

One of the most important properties of iron oxides/ oxydroxides (naturally occurring or formed by precipitation from iron salts) is their very active surface chemistry.(11) The surfaces of iron oxides and hydroxides acquire a pH-dependent charge, which controls the adsorption of a wide range of chemical species. Anions (such as molybdate, sulfate, arsenate, silicate, phosphate, and organic anions) as well as metal cations are known to chemisorb onto iron oxides and oxyhydroxide surfaces.(6,11,12,13) In the environment, iron oxides/oxyhydroxides are known to serve as a sink for metals such as copper, lead, zinc, cadmium, cobalt, nickel and manganese.(11) Adsorption of phosphate by iron oxides/ oxyhydroxides is an important process in soils; together with aluminum, calcium, magnesium, potassium, and manganese (II), they control the solubility of phosphates in soils.(14) Soils rich in iron oxide/oxyhydroxides (for example, oxisols) are known to fix large amounts of phosphate fertilizers.(15) Humic substances and other organic materials are known to adsorb onto oxide/ oxyhydroxide particulates. The surface properties of oxides/ oxyhydroxides determine the degree of aggregation/cementation of soil and mineral particulates, where the iron oxides/hydroxides are believed to behave as binding agents for the particulates.(16,17)

Some microorganisms (mainly anaerobic bacteria) are known to reduce Fe(III) oxide/oxyhydroxides to Fe(II),(18) with the subsequent re-mobilization of iron as more soluble Fe(II) species. This occurs predominantly in oxygen deficient soils, such as poorly drained soils. However, Fe(II) can be immobilized again by precipitation (for example, as siderite, vivianite or a sulfide) or by re-oxidation.

Although acid mine drainage could potentially stabilize Fe(II) species, the effect of bacterially mediated oxidation by organisms such as Thiobacillus ferrooxidans results in formation of insoluble Fe(III) oxides/oxyhydroxides.(19) Free, mobile Fe(II) or Fe(III) cations are not expected to persist under normal environmental conditions when the Fe(II) and (III) sulfates are used as herbicides to control moss in outdoor residential sites or as foliar spray fertilizers to correct iron chlorosis. The chemical species that are produced from the reactions of Fe(II) and Fe(III) sulfates under environmental conditions are not expected to differ from those iron minerals commonly encountered in soils. No unreasonable environmental effects are expected from the use of these salts as directed.

b. Environmental Fate Assessment

In summary, the fate and transport of Fe(II) and Fe(III) salts in the environment is dominated by three major processes: (1) the pH-redox potential dependent oxidation of Fe(II) to Fe(III); (2) the formation of insoluble oxides and hydroxides that are also well known components of soils; and (3) the distinct surface chemistry of the oxides and hydroxides of iron that control the adsorption of anions, cations and organic material or the adsorption of iron species onto the surfaces of mineral and organic components of soils, contributing to the aggregation of soil particles into larger units.

In terrestrial environments, the use of Fe(II) and Fe(III) sulfates is expected to produce iron oxides and hydroxides that are no different from the iron oxides and hydroxides found in soils and which are responsible for their brown and red colors. Although certain bacteria can reduce Fe(III) to the more mobile Fe(II), reoxidation and re-precipitation to Fe(III) oxides and hydroxides will rapidly immobilize any free Fe(II) that may form.

Therefore, the use of iron salts as herbicides to control moss in residential outdoor ornamentals (herbaceous and woody plants; lawns and turf) or as fertilizers to correct chlorosis in plants is not expected to contribute significantly to the chemistry and fate of the compounds existing naturally in the environment.

2. Ecological Effects

Ecological effects data presented here are derived from the six basic tests typically required by the Agency for assessing ecological hazard.

a. **Ecological Effects Data**

(1) **Non-Target Terrestrial**

Iron (II) sulfate heptahydrate and iron (II) sulfate monohydrate are classified as practically non-toxic to the bobwhite quail on an acute oral basis. The LD_{50} was 2250 mg/kg for iron (II) sulfate heptahydrate and for sulfate monohydrate the LD_{50} is >2150 mg/kg. On a dietary basis, both active ingredients are classified as practically non-toxic for the bobwhite quail and the mallard duck. The LC_{50} for iron (II) sulfate heptahydrate was >5620 ppm for both the bobwhite quail and the mallard duck. For iron (II) sulfate monohydrate, the LC_{50} was >5000 ppm for both the bobwhite quail and the mallard duck.

Iron (II) sulfate heptahydrate was classified as practically non-toxic to rats on an acute oral basis. The LD_{50} was >5 g/kg. Iron (III) sulfate was classified as non-toxic to male rats on an acute oral basis. The LD_{50} was 2,102 mg/kg. The LD_{50} for female rats was 1,487 mg/kg which classifies iron (III) sulfate as slightly toxic on an acute oral basis.

(2) **Non-Target Aquatic**

Iron (II) sulfate heptahydrate is the most toxic form of the iron salts compounds. The EC_{50} of 7.1 ppm for Daphnia pulex and LC_{50} of 20.8 ppm for rainbow trout classify iron salts as moderately toxic to aquatic invertebrates and slightly toxic to fish.

b. **Ecological Effects Risk Assessment**

(1) **Non-Endangered Species**

No adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the most abundant elements and will be immobilized at the environmentally important pH range of 5-9. There is very little likelihood for runoff to aquatic systems since the parent compounds convert very rapidly to less soluble forms in the environment. Furthermore these oxidized iron compounds bind tightly to soil under turf.

(2) Endangered Species

No adverse effects to terrestrial or aquatic endangered species are anticipated from the use of iron salts.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR IRON 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 iron salts. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of iron 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 iron 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 iron salts as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section VI 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 iron 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 iron 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 iron salts. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

VI. ELIGIBILITY DECISION

The Agency has sufficient information on the human health effects of iron salts and on its potential for causing effects in fish and wildlife and the environment when used to control moss growth in outdoor residential areas. The Agency concludes that products

containing iron salts for these uses are eligible for reregistration. Only certain generic physical chemistry data studies on iron salts are needed as confirmatory information. The Agency has determined that iron 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.

A. Eligible and Ineligible Uses

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

VII. ACTIONS REQUIRED BY REGISTRANTS

A. Additional Generic Data Requirements

The generic data base supporting the reregistration of iron 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. The required confirmatory data is based on the fact that not all companies complied with all product chemistry guideline requirements. These are part of the generic Data Call-In requirements in Appendix F.

B. Product specific data requirements

1. Additional Product-Specific Data Requirements

Based on the reviews of the generic data for iron salts, the products containing iron 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-Use and End-Use Products

All labels or labeling of end-use products and Manufacturing-Use Products must contain the following label statements:

1. Manufacturing-Use Products

In addition to the above requirements under 40 CFR §156.10 and the Pesticide Reregistration Handbook, for end-use products, labels and labeling of all manufacturing-use products must contain the following Environmental Hazards statement:

"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."

2. 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. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

IV. APPENDICES

APPENDIX A - Case 4058, [Iron Salts] Chemical 050502 [Ferrous sulfate heptahydrate]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
Ornamental Lawns and Turf Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Sprinkle, When needed, Sprinkle can	SC/S	na	52.272 lb Iron per acre	not spec	not spec	not spec	not spec			
Spray, When needed, Sprayer	SC/S	na	52.272 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, When needed, Spreader	G	na	13.9392 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, When needed, Spreader	SC/S	na	41.8176 lb Iron per acre	not spec	not spec	not spec	not spec			
Sprinkle, When needed, Sprinkler can	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Broadcast, When needed, By hand	SC/S	na	41.8176 lb Iron per acre	not spec	not spec	not spec	not spec			

Abbreviations used

Header: max = maximum; min = minimum; apps = applications; not spec = not specified; na = not applicable

Form : G = granular; SC/L = soluble concentrate/liquid; SC/S = soluble concentrate/solid

APPENDIX A - Case 4058, [Iron Salts] Chemical 034902 [Ferric sulfate]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
Ornamental Lawns and Turf Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Spray, When needed, Hose-end Sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			
Spray, When needed, Sprinkler can	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			

Abbreviations used

Header;max = maximum; min = minimum; apps = applications; not spec = not specified; na = not applicable

Form : SC/L = soluble concentrate/liquid

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 iron salts covered by this Reregistration Eligibility document. It contains generic data requirements that apply to iron 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.

IRON III SULFATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	41764501, 41764502
61-2(a)	Beginning Materials and Manufacturing Process	All	41764501, 41764502
61-2(b)	Formulation of Impurities	All	41764501, 41764502
62-1	Preliminary Analysis	All	41764501, 41764502
62-2	Certification of Limits	All	41764501, 41764502
62-3	Analytical Methods	All	41764501, 41764502
63-2	Color	All	DATA GAP
63-3	Physical State	All	DATA GAP
63-4	Odor	All	DATA GAP
63-5	Melting Point	All	DATA GAP
63-6	Boiling Point	All	DATA GAP
63-7	Density	All	DATA GAP
63-8	Solubility	All	DATA GAP
63-10	Dissociation Constant	All	DATA GAP
63-12	pH	All	DATA GAP
63-13	Storage Stability	All	DATA GAP

IRON III SULFATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.130 Environmental Fate			
All environmental fate data requirements have been waived.			
§158.135 Toxicology			
81-1	Acute oral tox. rat	All	42170701
81-2	Acute dermal tox. rabbit	All	42171702
81-3	Acute inhal. tox rat	All	42171703
81-4	Primary eye irritation-rabbit	All	41758701
81-5	Primary dermal irritation	All	41758702
81-6	Dermal sensitization/guinea pig	All	41758703
§158.145 Ecological Effects			
71-1(a)	Acute Avian Oral Toxicity -Quail/Duck	All	WAIVED
71-2(a)	Avian Dietary Toxicity -Quail/Duck	All	WAIVED
71-2(b)	Acute avian diet. duck	All	WAIVED
72-1(a)	Freshwater Fish Toxicity -Bluegill	All	WAIVED
72-1(c)	Fish toxicity rainbow trout	All	WAIVED
72-2(a)	Freshwater Invertebrate Toxicity	All	WAIVED

IRON II SULFATE MONOHYDRATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	142309
61-2(a)	Beginning Materials and Manufacturing Process	All	142309
61-2(b)	Formulation of Impurities	All	142309
62-1	Preliminary Analysis	All	142309
62-2	Certification of Limits	All	142309
62-3	Analytical Methods	All	142309
63-2	Color	All	142309
63-3	Physical State	All	142309
63-4	Odor	All	142309
63-5	Melting Point	All	142309
63-6	Boiling Point	All	142309
63-7	Density	All	142309
63-8	Solubility	All	142309
63-10	Dissociation Constant	All	142309
63-12	pH	All	142309
63-13	Storage Stability	All	142309

APPENDIX A - Case 4058, [Iron Salts] Chemical 050507 [Ferrous 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		Use Limitations
								Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
Ornamental Herbaceous Plants Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Broadcast, Fall, Spreader	G	na	34.848 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, Fall, By hand	G	na	34.848 lb Iron per acre	not spec	not spec	not spec	not spec			
Sprinkle, When needed, Not on Label	G	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Ornamental Lawns and Turf Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Broadcast, Early Spring, Not on Label	G	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Broadcast, Early Spring, Spreader	G	na	27.8784 lb Iron per acre	not spec	not spec	not spec	not spec			
Spot treatment, Fall, Not on Label	G	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Broadcast, Spring, Spreader	G	na	19.1936 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, When needed, Spreader	G	na	36.3 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, Winter, Spreader	G	na	10.0052 lb Iron per acre	not spec	not spec	not spec	not spec			
Spot treatment, Early Spring, Not on Label	G	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Broadcast, Fall, By hand	G	na	34.848 lb Iron per acre	not spec	not spec	not spec	not spec			
Broadcast, Fall, Not on Label	G	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			

IRON II SULFATE MONOHYDRATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	142309
61-2(a)	Beginning Materials and Manufacturing Process	All	142309
61-2(b)	Formulation of Impurities	All	142309
62-1	Preliminary Analysis	All	142309
62-2	Certification of Limits	All	142309
62-3	Analytical Methods	All	142309
63-2	Color	All	142309
63-3	Physical State	All	142309
63-4	Odor	All	142309
63-5	Melting Point	All	142309
63-6	Boiling Point	All	142309
63-7	Density	All	142309
63-8	Solubility	All	142309
63-10	Dissociation Constant	All	142309
63-12	pH	All	142309
63-13	Storage Stability	All	142309

IRON II SULFATE MONOHYDRATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.130 Environmental Fate			
All environmental fate data requirements have been waived.			
§158.135 Toxicology			
81-1	Acute oral tox. rat	All	WAIVED
81-2	Acute dermal tox. rabbit	All	WAIVED
81-3	Acute inhal. tox rat	All	WAIVED
81-4	Primary eye irration-rabbit	All	WAIVED
81-5	Primary dermal irritation	All	WAIVED
81-6	Dermal sensitization/Guinea pigs	All	41763701
§158.145 Ecological Effects			
71-1(a)	Acute Avian Oral Toxicity -Quail/Duck	All	40091902
71-2(a)	Avian Dietary Toxicity -Quail/Duck	All	40091903
71-2(b)	Acute avian diet. duck	All	40091904
72-1(a)	Freshwater Fish Toxicity -Bluegill	All	40091905
72-1(c)	Fish toxicity rainbow trout	All	40091906
72-2(a)	Freshwater Invertebrate Toxicity	All	40091907

IRON II HEPTAHYDRATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	[1]
61-2(a)	Beginning Materials and Manufacturing Process	All	[1]
61-2(b)	Formulation of Impurities	All	[1]
62-1	Preliminary Analysis	All	[1]
62-2	Certification of Limits	All	[1]
62-3	Analytical Methods	All	[1]
63-2	Color	All	[1]
63-3	Physical State	All	[1]
63-4	Odor	All	[1]
63-5	Melting Point	All	[1]
63-6	Boiling Point	All	[1]
63-7	Density	All	[1]
63-8	Solubility	All	[1]
63-10	Dissociation Constant	All	[1]
63-12	pH	All	[1]
63-13	Storage Stability	All	[1]

[1] Public literature and information was provided to the Agency as part of the reregistration process. The public literature is identified the bibliography.

IRON II HEPTAHYDRATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.130 Environmental Fate			
All environmental fate data requirements have been waived.			
§158.135 Toxicology			
81-1	Acute oral tox. rat	All	WAIVED
81-2	Acute dermal tox. rabbit	All	WAIVED
81-3	Acute Inhalation-Rat	All	137725
81-4	Primary eye irration-rabbit	All	137726
81-5	Primary dermal irritation	All	137726
81-6	Dermal sensitization/Guinea pigs	All	WAIVED
§158.145 Ecological Effects			
71-1(a)	Acute avian oral quail/duck	All	40142201
71-2(a)	Acute avian diet. quail	All	40142202
71-2(b)	Acute avian diet. duck	All	40142203
72-1(a)	Fish toxicity bluegill	All	40142204
72-1(c)	Fish toxicity rainbow trout	All	40142205
72-2(a)	Invertebrate toxicity	All	

APPENDIX C
IRON SALTS BIBLIOGRAPHY

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

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00137725	Klettke, M. Primary Eye Irritation Study, Ferrous Sulfate, Project T.1008, Harris Laboratories, Inc. 1990.
00137726	Klettke, M., Primary Skin Irritation Study, Project T.1009, Harris Laboratories, Inc. 1990.
40091902	Fletcher, D. (1986) Acute Oral Toxicity Study with Ferrous Sulfate Monohydrate in Bobwhite Quail: Laboratory Project ID: BLAL No. 85 QD 61. Unpublished study prepared by Bio-Life Associates, Ltd. 27 p.

MRID	CITATION
40091903	Fletcher, D. (1986) 8-Day Dietary LC50 Study with Ferrous Sulfate Monohydrate in Mallard Ducklings: Laboratory Project ID: BLAL No. 85 DC 63. Unpublished study prepared by Bio-Life Associates, Ltd. 28 p.
40091904	Fletcher, D. (1986) 8-Day Dietary LC_{50} Study with Ferrous Sulfate Monohydrate in Bobwhite Quail: Laboratory Project ID: BLAL No. 85 QC 61. Unpublished study prepared by Bio-Life Associates, Ltd. 28 p.
40091905	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulfate Monohydrate to Rainbow Trout: Laboratory Project ID: BW-86-11-2227: Study #11501.0886.6100.103. Unpublished study prepared by Springborn Bionomics, Inc. 19 p.
40091906	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulphate Monohydrate to Bluegill: Laboratory Project ID: BW-86-11-2228: Study #11501.0886.6100.100. Unpublished study prepared by Springborn Bionomics, Inc. 19 p.
40091907	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulfate Monohydrate to Daphnids (Daphnia magna): Laboratory Project ID: BW-86-112229: Study #11501.0886.6100.110. Unpublished study prepared by Springborn Bionomics, Inc. 18 p.
40142201	Grimes, J.; Jaber, M. (1986) Ferrous Sulfate Heptahydrate: An Acute Oral Toxicity Study with the Bobwhite: Laboratory Project ID: 223-103. Unpublished study prepared by Wildlife International Ltd. 18 p.
40142202	Grimes, J.; Jaber, M. (1986) Ferrous Sulfate Heptahydrate: A Dietary LC50 Study with the Bobwhite: Laboratory Project ID: 223101. Unpublished study prepared by Wildlife International Ltd. 17 p.
40142203	Grimes, J.; Jaber, M. (1986) Ferrous Sulfate Heptahydrate: A Dietary LC50 Study with the Mallard: Laboratory Project ID: 223102. Unpublished study prepared by Wildlife International Ltd.
40142204	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulfate Heptahydrate ...to Bluegill (Lepomis macrochirus): Bionomics Report #BW-86-12-2262: Bionomics Study #1297.0786.6101.100. Unpublished study prepared by Springborn Bionomics, Inc. 6 p.
40142205	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulfate Heptahydrate...to Rainbow Trout (Salmo gairdneri): Bionomics Report #BW-87-3-2317: Bionomics Study #1297.0786.6101.103. Unpublished study prepared by Springborn Bionomics, Inc. 7 p.

MRID	CITATION
40142206	Surprenant, D. (1986) Acute Toxicity of Ferrous Sulfate Heptahydrate...to Daphnids (Daphnia pulex): Bionomics Report #BW-87-32318: Bionomics Study #1297.0786.6101.110. Unpublished study prepared by Springborn Bionomics, Inc. 6 p.
41758701	Robbins, G., Pimary Eye Irritatancy Study in Rabbits, Ferric Sulfate, Ferri Floc: Lab Project No. D3082. Unpublished Study prepared by Cosmopolitan Safety Evaluation, 1990.
41758702	Robbins, G., Pimary Eye Irritatancy Study in Rabbits, Ferric Sulfate, Ferri Floc: Lab Project No. E3082. Unpublished Study prepared by Cosmopolitan Safety Evaluation, 1990.
41758703	Robbins, G., Guinea Pig Sensitization, Ferric Sulfate, Ferri Floc: Lab Project No. F3082. Unpublished Study prepared by Cosmopolitan Safety Evaluation, 1991.
41763701	Robbins, G. (1990) Guinea Pig Sensitization (Buhler): WGM-30 Brand: Lab Project Number: F3081. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 19 p.
41764501	Gohlke, A., Product Identity and Disclosure of Ingredients, Tennessee Chemical Company's Ferri-Floc, Ferric Sulfate Lab Project No 1991-1. Unpublished Study prepared by Tennessee Chemical Co., 1991.
41764501	Gohlke, A., Analysis and Certification of Ingredinents in Tennessee Chemical company's Ferri-Floc, Tennessee Chemical Company's Ferri-Floc, Ferric Sulfate Lab Project No 1991-2. Unpublished Study prepared by Tennessee Chemical Co., 1991.
42171701	Robbins, G. (1992) Acute Oral Toxicity in Rats: Ferric Sulfate, Ferri Floc: Lab Project Number: A3251. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 28 p.
42171702	Robbins, G. (1991) Acute Dermal Absorption in Rabbits: Ferric Sulfate, Ferri Floc: Lab Project Number: B3251. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 24 p.
42171703	Robbins, G. (1991) Acute Inhalation Study in Rats: Ferric Sulfate, Ferri Floc: Lab Project Number: C3251. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 34 p.

APPENDIX D
List of Available Related Documents

The following is a list of available documents related to iron 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 iron 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. Iron salts RED Fact Sheet

4. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

Appendix E, F, & G are separate docucments

APPENDIX E

Pesticide Reregistration Handbook and PR Notice 91-2

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower 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 153.640.

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

V. COMPLIANCE SCHEDULE

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

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

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

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or 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

Attachment A

Chemical Status Sheet

IRON SALTS: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 ieon 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 Iron 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 iron salts are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on iron salts 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 Yvonne Brown at (703) 308-8073.

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

Yvonne Brown, 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: IRON SALTS

Attachment B

Generic DCI Response Forms (Form A) plus Instructions

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for th purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. F 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.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office o Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503

INSTRUCTIONS

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

Item 2 — This item identifies the ease number, ease name, EPA chemical number and chemic 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. Pleas 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 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 — Cheek 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 y 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 registratio 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 th and-any other outstanding Data Call-In Notice), and incorporate that product into al 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 produc (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. Attac the Requirements Status and Registrant's Response Form that Indicates how you wil satisfy those requirements.

Item 7a — Check this item if this call-in if 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 Requireme 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 an 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.

Attachment C

Requirements Status and Registrants' Response Forms (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPON8E FORM

Generle Data

This form is designed to be used for registrants to respond to eall-in- for generie and produet-speeifie data as part of EPA's reregistration program under the Federal Insectieide Fungieide and Rodenticide Act. Although the form is the same for both produet speeifie and generie data, instructions for eompleting the forms differ slightly. Specifieally, options for satisfying produet specific data reguirements do not inelude (1) deletion of uses or (2) request for a low volume/minor use waivcr. These instructions are for completion of generic data reguirements

EPA has developed this form individually for each data call-in addressed to each registrant, and ha 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.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy 8ranch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Nanagement and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRICIONS

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 chemic 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 reguired to support t 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 an whether protocols and 1, 2, or 3-year progress reports are reguired to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-d 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 Reguirements 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.	Aguatic 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	Hanufacturing-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/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TCAI/TEP	Technical Grade Active Ingredient or Typical End-Use Produc
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
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 reguirement. Brief dcscriptions of each code follow. The Data Call-I Notice contains a fuller description of oach of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specifled in item 8 above. By indicating that I have chosen this option I certify that I will comply with all the reguirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice a that I will provide the protocol and progress reports reguired in item 5 above

2. (Agreement to Cost Share) I have entered into an agreement with one or mo registrants to develop data jointly. By indicating that I have chosen this optio 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 o or more registrants to develop data jointly. I am submitting a copy of the for "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 dat to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) th EPA has assigned to the data that I am citing as well as the MRID of the stu 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 no yet been revicwed by the Agency. I am providing the Agency's classfication 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 an I request a low-volume minor use waiver of the data reguirement. I am attaching a detailed justification to support this waiver request including, among other things, all information reguired to support the request. I understand that, unless modified by the Agency in writing, the data reguirement as stated in the Notice governs.

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

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

APPENDIX G

Product Specific Data Call-In

ATTACHMENT A
Chemical Status Sheet

IRON 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 iron 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 iron 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 Requirement Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeti Acute Toxicology Data Requirement (Attachment D), (5) the EPA Acceptance Criteria (Attachmen E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this iron 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 iron salts are containe in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on iron 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 iron salts products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of iron salts, please contact Yvon Brown at (703) 308-8073.

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: IRON SALTS

ATTACHMENT B

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

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

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice an 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 Existi Stocks provision of the Data Call-In Notice (Section IV-C).

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

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesti 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 (Waive 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 repo that your product has already been transferred to another company or that yo have already voluntarily cancelled this product. For these cases, please suppl all relevant details so that EPA can ensure that its records are correct.

APPENDIX C
IRON SALTS BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting the Reregistration of Iron 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.

ATTACHMENT C

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

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

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

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

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

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

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

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

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

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in th Data Call-In Notice.

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

3. I have made offers to share in the cost to develop data **(Offers to Cost Share).** I understand that this option is available **only** for acute toxicity or certain efficacy dat and **only** if EPA indicates in an attachment to this Data Call-In Notice that my

product is similar enough to another product to qualify for this option. I am **submitting evidence that I have made an offer to another** registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form** I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data: if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitte previously to the Agency by anyone **(Submitting an Existing Study).** I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated t choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and **upgradable (upgrading a Study).** I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency **(Citing an Existing Study).** If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy

data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession Number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite anoth registrant's data, I will submit a completed **"Certification with Respect To Data Compensation Requirements" form.**

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

Items 10-13 Self-explanatory.

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

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING DATA REQUREMENTS FOR REREGISTRATION

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING IRON SALTS FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient iron salts, the Agency considered batching end-use products. This process involves grouping simi products for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type o formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.).

Batching has been attempted using the readily available information described above, and frequently acute toxicity data on individual end-use 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 end-use product should the need arise.

After consideration of the available information described above, batching of end-use products containing iron salts was not possible. The accompanying table lists all the end-use products containing iron salts. These products were either considered not to be similar for purpos of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product. Registrants must generate all the required acute toxicological studies for each of their products. If a registrant chooses to rely upon previously submitted acute toxicity data, he/sh 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 the Agency to be similar for acute toxici and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registran must clearly identify the test material by it's EPA Registration Number.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will mee 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 acu toxicity tests. A registrant must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). Since the end-use products containing iron salts could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

End-Use Products Containing Irons Salts (none were batched).

EPA Reg. No.	% Active Ingredient	Formulation Type
538-223	15.2% ferrous sulfate monohydrate	granular
557-1838	40.0% ferrous sulfate heptahydrate	granular
802-504	4.78% ferrous sulfate heptahydrate 8.80% ferrous sulfate monohydrate	granular
802-509	35.0% ferric sulfate	soluble conc.
802-543	32.0% ferric sulfate monohydrate	granular
802-558	95.4% ferrous sulfate monohydrate	granular
3234-44	32.5% ferrous sulfate monohydrate	granular
7001-290	15.0% ferrous sulfate monohydrate	granular
7404-03	25.38% ferrous sulfate monohydrate	granular
7404-04	17.05% ferrous sulfate monohydrate	granular
7404-10	39.85% ferrous sulfate monohydrate	granular
34704-713	65.0% ferrous sulfate heptahydrate	soluble conc.
64864-13	17.0% ferrous sulfate monohydrate	granular
64864-14	6.6% ferrous sulfate heptahydrate	soluble conc.

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 e 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) Regi 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 assig 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, proper 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.
- ____ 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 wh may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically signific impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitri polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and sto 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 w explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically signific 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 exe 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.

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 compoun

____ 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 w reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallo

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulat 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 press 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 7735

____ 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

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

81-1 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.

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 prev 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 an * are supplemental and may not be required for every study.

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 μm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm$2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respira 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.

81-4 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 an * are supplemental and may not be required for every study.

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^2.
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 d (whichever is shorter).
11.*__ Individual daily observations.

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

81-6 Dermal Sensitization in the Guinea Pig

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.___ 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 an * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

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

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

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: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] 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

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

Please fill in blanks below.

Company Name	Company Number

Chemical Name	EPA Chemical Number

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)

EPA Form 8570-32

United States Environmental Protection Agency
Washington, DC 20460

EPA Formulator's Exemption Statement

(40 CFR 152.85)

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address	EPA File Symbol/Registration Number
	Product Name
	Date of Confidential Statement of Formula *(EPA Form 8570-4)*

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product *(during formulation or packaging)* of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name	Registration Number

Signature	Name and Title	Date