BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Sodium Ferric Ethylenediaminetetraacetate
(PC Code 139114)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

(Last updated November 20, 2008)

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

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I. EXECUTIVE SUMMARY:

Sodium Ferric ethylenediaminetetraacetate (Sodium Ferric EDTA) is a new active ingredient that is used to make slug and snail control products. Currently, the only end use product is a pelleted bait intended for use as a molluscicide in agricultural, nursery, greenhouse, and home and garden applications. When Sodium Ferric EDTA is ingested by slugs or snails, the iron in the compound interacts with the hemocyanin common to the blood of crustaceans, and eventually causes death.

Adequate mammalian toxicology data on the technical grade active ingredient (TGAI) are available to support registration of products containing Sodium Ferric EDTA. Acceptable acute guideline studies were submitted, and waivers requested for mutagenicity, developmental toxicity, and subchronic study requirements were granted by the Biopesticides and Pollution Prevention Division (BPPD) based on submissions from the scientific literature. Adequate non-target data were submitted to support the registration of this technical grade active ingredient. Due to the selectivity of Sodium Ferric EDTA for copper-based blood systems, effects on non-target insects are not expected.

The Agency considered human exposure to Sodium Ferric EDTA in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children. No significant exposure via drinking water is expected when Sodium Ferric EDTA is used according to the product label directions. The product is not to be applied directly to water or to areas where surface water is present The active ingredient is toxic to aquatic invertebrates such as daphnids, but exposure should not occur when the product is applied according to label directions.

Based on the information discussed above, the Agency has determined that registered use of Sodium Ferric EDTA as an active ingredient will have **No Adverse Effects (NAE)** on threatened and/or endangered species. Exposure to endangered or threatened terrestrial snails and crustaceans (isopods) is not expected since the currently listed endangered or threatened species pursuant to the Endangered Species Act of 1973, 16 U.S.C. 1531, et seq., are not found in locations where the product is intended for use; i.e., home gardens, turf, and agricultural lands.

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It was determined that the data/information submitted adequately satisfy current guideline requirements (refer to 40 CFR Subpart U § 158.2000).

II. ACTIVE INGREDIENT OVERVIEW

Common Name: Ferric (III) EDTA Complex

Chemical Names: Ferric Sodium Ethylenediaminetetraacetate

Trade & Other Names: Slug & Snail Killer

CAS Registry Number: 15708-41-5

OPP Chemical Code: 139114

Type of Pesticide: Biochemical pesticide (Insecticide).

Application rates and methods vary depending on the product. For specific information regarding the product*(s)* refer to Appendix B.

III. REGULATORY BACKGROUND

On December 17, 2004, the Agency received an application filed by Woodstream Corporation, 69 Locust Street, Litiz, PA 17543 (submitted by Technology Sciences Group, Inc., 1150 18th Street, N.W., Suite 1000, Washington, DC 20036 to register the product Safer Brand Slug & Snail Killer containing the new biochemical active ingredient Sodium Ferric ethylenediaminetetraacetate (Sodium Ferric EDTA) at 5.87%. A notice of receipt of this application was published in the Federal Register June 22, 2005 (70 FR 36153).

A. Classification

On May 16, 2001, the Biochemical Classification Committee determined that the active ingredient Iron (formulated as an Fe-Na EDTA complex) qualified to be reviewed in BPPD. The active ingredient was classified as "Not a biochemical, but eligible for a reduced data set". The classification is based on the abundance of Iron in nature, its low toxicity, its use as a nurtiritional supplement, and it low water solubility.

B. Food Clearances/Tolerances

Currently, this active ingredient is not registered for use on food or feed commodities because applications must be away from food plants.. A tolerance or exemption from the requirement of a tolerance is not relevant.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

Sodium Ferric EDTA is the active ingredient in products to control slugs and snails. The end use product is a granular (pellet) formulation.

The descriptions of the product formulation and production process as well as the formation of impurities were examined by BPPD and found to be acceptable in meeting current guideline standards. A preliminary analysis to determine the Sodium Ferric EDTA content in the end use product was not submitted, but results from analyses of 36 batches of the TGAI by the manufacturer were provided and determined to be acceptable by BPPD. The analytical method is high performance liquid chromatography (HPLC) with ultraviolet visible spectrophotometry (UV-VIS).

All product chemistry data requirements for registration of Sodium Ferric EDTA (TGAI) have been **satisfied.**

B. Human Health Assessment

1. Toxicology

Adequate mammalian toxicology data are available to support registration of products containing the new active ingredient Sodium Ferric EDTA. Acceptable acute guideline studies were submitted, and waivers requested for the mutagenicity, developmental toxicity, and subchronic study requirements were granted by BPPD based on submissions from the scientific literature.

Sodium Ferric EDTA is a common chelating agent that immobilizes metal ions until they are in an environment where they are available for uptake. Chelating agents are commonly applied to agricultural commodities. EDTA is typically used as a chelating agent for trace elements, including iron.

Iron is an essential element for nutrition and is used in nutritional supplements. Elemental iron is listed as Generally Regarded as Safe (GRAS) by FDA (21 CFR 184.1375). Acute iron toxicity in humans typically results from accidental ingestion of medicinal iron or ingestion of adult iron supplements by children. Chronic toxicity in humans is generally limited to individuals with inherited metabolic disorders that affect iron balance, such as human leukocyte antigen-linked hereditary haemochromatosis.

A public literature review of toxicological and exposure data (Heimbach et al., 2000) concluded that sodium Ferric EDTA possesses very low toxicity. Heimbach et al. (2000) determined the upper bound estimated daily intake of EDTA from sodium Ferric EDTA to be 1.15 mg/kg body wt/day, which is less than half the acceptable daily intake of 2.5 mg/kg body wt/day determined by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974).

Sodium Ferric EDTA dissociates in the gastrointestinal tract to form iron and an EDTA salt, which are absorbed independently. The toxicologic effects of EDTA salts should be similar regardless of the salt form. Since EDTA-metal complexes freely exchange in the digestive tract, assessment of EDTA-metal complexes containing metals other than iron is relevant to the assessment of sodium Ferric EDTA.

All toxicology data requirements for Sodium Ferric EDTA have been **satisfied.**

a. Acute Toxicity

Acute toxicity studies submitted in support of the EP are summarized in Table 3 below. Sodium Ferric EDTA is classified in Toxicity Category IV for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, and primary dermal irritation; Toxicity Category I for primary eye irritation; and is not a dermal sensitizer. Based on the review and analysis of the information,

guideline studies, and submitted literature discussed in detail in this section of the BRAD, no additional toxicity data are required to support the nonfood use of this of this active ingredient.

TABLE 1. Acute toxicity and primary irritation data for Sodium Ferric EDTA

Study/ OPPTS Guideline No.	Results	Toxicity category	MRID No.
Acute Oral Toxicity 870.1100	LD_{50} >5000 mg/kg in male rats. LD_{50} = 5719 mg/kg in female rats.	IV	45848103
Acute Dermal Toxicity 870.1200	LD_{50} >5000 mg/kg in rats	IV	45848104
Acute Inhalation Toxicity 870.1300	LC_{50} >2.05 mg/L in rats	IV	45848105
Primary Eye Irritation 870.2400	Maximum average score (Draize method) was 11.7 @ 24 hours	I	45848106
Primary Dermal Irritation 870.2500	Very slight erythema. Irritation index = 0.3	IV	45848107
Skin Sensitization 870.2600	Not a sensitizer	Not a sensitizer	45848108
Hypersensitivity Incidents	No data	No data	No data

b. Subchronic Toxicity

Waivers requested for the subchronic [90-day feeding (OPPTS 870.3100), 90-day dermal (OPPTS 870.3250), and 90-day inhalation (OPPTS 870.3465)] and immunotoxicity study requirements were granted by BPPD, based on the rationales below.

No references for feeding studies using Sodium Ferric EDTA were located in the published literature. Rats fed low mineral diets with or without added calcium disodium EDTA for four months had reduced weight gain, but their general condition was comparable to that of controls (Yang, 1964). Rats fed 1%, 5%, or 10% disodium salt of EDTA for 90 days had significantly lower food consumption and weight gain than controls (Wynn, et al.1970). Hematology was comparable among all groups, except that prothrombin time was increased in the 10% group. The only significant necropsy finding was pale livers in the 10% group.

Mice fed 3750 or 7500 ppm trisodium EDTA for 103 weeks had no treatment-related clinical signs, and gross and microscopic pathology were unremarkable (National Cancer Institute, 1977). A companion study conducted by NCI using rats produced the same results (National Cancer Institute, 1977). In a 12-month feeding study using dogs, Oser et al. (1963) found no significant changes in hematology or urinalysis parameters, and no abnormal gross or microscopic findings in groups receiving up to 250 mg/kg body weight/day of calcium disodium EDTA.

The end use product containing Sodium Ferric EDTA is a pellet that does not produce any dust and is applied directly to the ground. Therefore, it is unlikely that there will be any dermal exposure when the product is applied according to the label use directions. Furthermore, Sodium Ferric EDTA was demonstrated to be practically non-toxic (Toxicity Category IV) to rats in an acute dermal toxicity guideline study (MRID 45848104).

Since the end use product is a pellet that does not produce any dust and is applied directly to the ground, it is unlikely that there will be any inhalation exposure when the product is applied according to the label use directions. Furthermore, Sodium Ferric EDTA was demonstrated to

be practically non-toxic (Toxicity Category IV) to rats in an acute inhalation toxicity guideline study (MRID 45848105).

No literature was located suggesting that Sodium Ferric EDTA impacts the immune system. FDA has approved calcium disodium EDTA and disodium EDTA as food additives, and these materials are added to a wide range of processed foods at levels of 200 to 500 ppm. Based on the use of EDTA and iron supplements as food ingredients, there do not appear to be any concerns regarding immune response safety issues.

c. Developmental Toxicity and Mutagenicity

Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium Ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature.

In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations *in vitro*. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) "the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level."

The teratogenic potential of disodium EDTA has been investigated (Swenerton and Hurley, 1971; Gasset and Akaboshi, 1977; Kimmel, 1977) with variable results. The differences in toxicity and teratogenicity shown in the scientific literature probably relate to several factors, such as absorption differences, stress associated with the administration of treatments, different species and strain susceptibility, and interaction with metals (Kimmel, 1977). Since it has been shown that EDTA may chelate zinc (Swenterton and Hurley, 1971), the exchange of iron for zinc is the predominant reaction of concern during pregnancy because of the potential effect of disodium EDTA on zinc balance, and the high sensitivity of the developing embryo to zinc deficiency (Hurley and Swenerton, 1966; Swenerton and Hurley, 1971; Kimmel, 1975; and Kimmel and Sloan, 1975). Effects of EDTA on zinc balance depend on the EDTA:zinc ratio, and the dietary dose range of 2.5 mg EDTA/kg bw/day recommended by the FAO/WHO Expert Committed on Food Additives (JECFA, 1974) would not be expected to have detrimental effects on zinc balance. Overall, many of the results found in the scientific literature, including Schardein et al. (1981), indicated little or no teratogenic effect of disodium EDTA in rats and rabbits. Based on the submitted data, the active ingredient is not likely to be teratogenic.

d. Chronic exposure and oncogenicity assessment

Repeated dose studies are conditionally required if the potential for adverse chronic effects are indicated based on: 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies; 2) the pesticide use pattern; or 3) the frequency and the level of

repeated human exposure that is expected. Oncogenicity studies are required only if Tier I studies show that the active ingredient or any of its metabolites, degradation products, or impurities produce any morphologic effects in any organ that could potentially lead to neoplastic changes. None of the results of the submitted studies triggered the need for chronic exposure or oncogenicity testing. There are no reliable data documenting carcinogenicity of Sodium Ferric EDTA.

e. Effects on the Endocrine System

The US Environmental Protection Agency (Agency) is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by Food Quality Protection Act, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid-hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for Sodium Ferric EDTA and none is expected since it does not share any structural similarity to any known endocrine disruptor.

2. Dose Response Assessment

No toxicological endpoints were identified; therefore, a dose response assessment was not required.

3. Drinking Water Exposure and Risk Characterization

No significant exposure via drinking water is expected when Sodium Ferric EDTA is used according to the product label directions. The product is not to be applied directly to water or to areas where surface water is present, and if used as labeled, is not likely to accumulate in drinking water. In the unlikely event that exposure via drinking water did occur, the health risk would be expected to be minimal, based on the low acute oral and dermal toxicity of Sodium Ferric EDTA.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Occupational exposure to Sodium Ferric EDTA is mitigated as long as the end-use product is used according to label directions. Occupational exposures are not included under the FFDCA in the assessment of aggregate exposures for the purpose of establishing tolerances and exemptions from tolerance. The signal word on the end use product label is "Caution" and

precautionary statements include "Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling." Since the product is applied directly to soil as a pelleted bait, there is no potential for exposure via spray drift.

b. Residential, School and Day Care Exposure and Risk Characterization

Significant human exposure to Sodium Ferric EDTA is unlikely in residential, school and day care areas when the end use product is used according to the label directions. The end use product is a pelleted bait intended to be applied directly to soil. A public literature review of toxicological and exposure data (Heimbach et al., 2000) concluded that sodium Ferric EDTA may be generally regarded as safe. Should accidental exposure occur, the health risk is expected to be minimal, based on the low acute oral, dermal, and inhalation toxicity of Sodium Ferric EDTA.

5. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm to the US population will result from aggregate exposure to residues of Sodium Ferric EDTA. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of Sodium Ferric EDTA and the current use of EDTA and iron supplements as food ingredients by the general public without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Therefore, the Agency has not used a margin of exposure (safety) approach to assess the safety of Sodium Ferric EDTA.

6. Cumulative Effects

When used as proposed, residues of Sodium Ferric EDTA will not reach levels that are of toxicological concern. Because of its low toxicity, cumulative effects with other substances that share a common mechanism of toxicity are not expected.

7. Risk Characterization

The Agency considered human exposure to Sodium Ferric EDTA in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of Sodium Ferric EDTA when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

Ecological effects data requirements for Sodium Ferric EDTA were fulfilled by data submitted for acute avian toxicity and by submissions from the scientific literature to support waiver requests pertaining to toxicity and effects on non-target organisms.

An avian acute oral toxicity study (OPPTS 850.2100) was conducted in which groups of ten young adult northern bobwhite quail were administered a single oral dose of 0, 275, 454, 749, 1235, or 2038 mg Sodium Ferric EDTA/kg of body weight and observed for 14 days (MRID 45848109). Three of ten birds in the 2038 mg/kg group died by day 3 after displaying impaired balance, low body carriage, and hypoactivity. No mortality or adverse clinical signs occurred in any of the other test groups. Mean feed consumption was significantly lower in groups receiving ≥454 mg/kg test material for days 0-3, but was comparable to that of controls afterward. Mean body weight of the 2038 mg/kg group was significantly lower on days 3 and 7, but was comparable to that of controls on day 14. The no observed effect level (NOEL) for mortality was 1235 mg/kg, and the lowest lethal dose (LLD) was ≥1235 mg/kg. The LD_{50} was >2038 mg/kg, which is practically non-toxic to birds on an acute basis.

Waivers requested for the remaining non-target organism study requirements [avian dietary toxicity (OPPTS 850.2200), fish acute toxicity (OPPTS 850.1075), aquatic invertebrate toxicity (OPPTS 850.1010), non-target plant testing (OPPTS 850.4100), and non-target insect toxicity (OPPTS 850.4340)] were granted by BPPD, based on the rationales described below.

FDA has approved the use of up to 240 ppm disodium EDTA as an additive in finished animal feed (21 CFR § 573.360). Scott and Zeigler (1963) reported that the addition of 300 ppm EDTA to prepared diet containing 5 ppm added zinc markedly improved chick growth, which was nearly comparable to growth of chicks fed diet containing 60 ppm zinc without added EDTA.

The iron in Sodium Ferric EDTA interacts with the hemocyanin in the bloodstream of mollusks and crustaceans. The blood of vertebrate animals contains hemoglobin, which is iron-based, rather than the copper-based hemocyanin. There have been no reported effects of sodium Ferric EDTA on vertebrates having iron-based blood systems. Since both birds and fish are vertebrate animals, field application of Sodium Ferric EDTA at label rates should present little or no risk from ingestion of the end use product pellets. Additionally, exposure of fish should not occur when label directions are followed, as the end use product is applied directly to soil, and is not intended for use in aquatic environments.

Freshwater invertebrate testing is not required; as stated above, the iron in Sodium Ferric EDTA would be toxic to *Daphnia*, since they are crustaceans. Exposure of daphnids and other crustaceans is not likely to occur when label directions are followed, as the end use product is applied directly to soil, and is not intended for use in aquatic environments.

EDTA is used in specialty fertilizers to chelate inorganic sources of iron and other elements. In soil, EDTA is eventually degraded through microbial activity, and the cations released as a result act as inorganic ions. Tomato plants grown for 130 days in hydroponic solution containing ^{14}C-labelled EDTA contained ^{14}C-labelled amino acids in addition to the ^{14}C-EDTA, indicating EDTA was slowly decomposed by the plants (Matsuda, 1968). In another study using tomato plants grown in solution containing labeled iron chelate (^{59}Fe-^{14}C-EDTA), Hill-Cottingham and Lloyd-Jones (1961) reported that nearly all the iron, and only about 60% of the EDTA, was recovered after 24 days, indicating that the EDTA was decomposed by the plants. No phytotoxic effects were reported in this study.

Due to the selectivity of Sodium Ferric EDTA for copper-based blood systems, effects on non-target insects are not expected. The registrant's testing of the effect of Sodium Ferric EDTA

pellets on insects showed that Melyrid beetles (*Dicranolaius bellulus*) ladybird beetles (*Harmonia conformis*), and carabid beetles (*Notonomus gravis*) were not affected. Sodium Ferric EDTA was found to be toxic to sowbugs (*Oniscus asellus*), pillbugs (*Armadillidium vulgare*), and common woodlice (*Porcellio laevis*); however, these are land-living crustaceans in which the oxygen carrier is hemocyanin.

All non-target toxicology data requirements for Sodium Ferric EDTA have been **satisfied.**

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because Sodium Ferric EDTA was practically non-toxic in the avian acute oral study, and the remaining Tier I studies were waived.

3. Ecological Exposure and Risk Characterization

Based on the studies and rationales for the data waivers discussed above, exposure and risk from the proposed use of Sodium Ferric EDTA are expected to be minimal for non-target organisms (with the exception of pillbugs and sowbugs). The mode of action for Sodium Ferric EDTA targets copper-based (hemocyanin) blood systems, which are found in mollusks and crustaceans. The active ingredient is toxic to aquatic invertebrates such as daphnids, but exposure should not occur when the product is applied according to label directions.

4. Endangered Species Assessment

Based on the information discussed above, the Agency has determined that registered use of Sodium Ferric EDTA as an active ingredient will have **No Adverse Effects (NAE)** on threatened and/or endangered species. Exposure to endangered or threatened terrestrial snails and crustaceans (isopods) is not expected since the currently listed endangered or threatened species pursuant to the Endangered Species Act of 1973, 16 U.S.C. 1531, et seq., are not found in locations where the product is intended for use; i.e., home gardens, turf, and agricultural lands. The habitats of currently listed threatened or endangered mollusks or crustacean species range from isolated caves and streams to wood or forests. When the product is used according to label use directions, there are no concerns for any non-target organisms.

D. PRODUCT PERFORMANCE DATA (EFFICACY)

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. Customarily, the Agency requires efficacy data to be submitted for review only in connection with the registration of products directly pertaining to the mitigation of disease bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles, etc. For a list of organisms considered by the Agency as “public health pests”, please refer to Pesticide Registration Notice 2002-1 (http://www.epa.gov/PR_Notices/pr2002-1.pdf).

No efficacy data were required to be submitted with this pesticide application because the active ingredient will not be used to control any disease bearing human health organisms and certain designated quarantine pests as discussed above.

V. Risk Management Decision

A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing *active ingredient*. Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, Sodium Ferric EDTA is eligible for registration for the labeled uses.

B. Regulatory Decision

The data submitted fulfill the requirements of registration for use of Sodium Ferric EDTA to control slugs and snails. Refer to Appendix B for product-specific information.

1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that unconditional registration of Sodium Ferric EDTA is appropriate.

C. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to Sodium Ferric EDTA, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the initial registration of *active ingredient* and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. Reporting of Adverse Effects

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. Appendix A. Data Requirements (40 CFR Part 158-Subpart U)

*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements for *Active Ingredient* (40 CFR § 158.2030)

OPPTS Guideline No.	Study	Results *(below are example results)*
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	45848101 46758501 47315701 47302903
830.1700	Analysis of samples	45848101 47434001 46954601
830.1750	Certification of limits	45848101
830.1800	Analytical method	45848102

Table 2. Human Toxicology Data Requirements for Sodium Ferric EDTA (40 CFR § 158.2050)

Study/OPPTS Guideline No.	Results	Toxicity Category/Description
Acute oral toxicity (rat) (870.1100)	LD_{50} >5000 mg/kg in male rats. LD_{50} = 5719 mg/kg in female rats.	IV
Acute dermal toxicity (rat) (870.1200)	LD_{50} >5000 mg/kg in rats	IV
Acute inhalation toxicity (rat) (870.1300)	LC_{50} >2.05 mg/L in rats	IV
Primary eye irritation (rabbit) (870.2400)	Maximum average score (Draize method) was 11.7 @ 24 hours	I
Primary dermal irritation (rabbit) (870.2500)	Very slight erythema. Irritation index = 0.3	IV
Dermal sensitization (guinea pig) (870.2600)	Not a sensitizer	Not a sensitizer
Hypersensitivity incidents (885.3400)	No data	

Table 3. Nontarget Organism, Fate and Expression Data Requirements for Sodium Ferric EDTA (40 CFR § 158.2060)	
Study/OPPTS Guideline No.	**Results**
Avian acute oral toxicity (850.2100)	LD_{50} >2038 mg/kg (practically non-toxic)
Avian Dietary Toxicity (850.2200)	Waived
Fish Acute Toxicity – Freshwater and Marine (850.1075)	Waived
Aquatic Invertebrate Acute Toxicity (850.1010)	Waived
Nontarget Plant Studies (850.4100)	Waived
Nontarget Insect Studies (880.4350)	Waived

VIII. Appendix B.

For product specific information, please refer to http://www.epa.gov/pesticides/pestlabels

IX. Appendix C.

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