



BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Iron HEDTA

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

This document is for informational purposes only and is representative of the Agency's justification in registering products containing this active ingredient. This is not a legal document. (Need OGC language)

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I. EXECUTIVE SUMMARY:

The active ingredient Iron HEDTA is a deep red, odorless liquid compound. It is intended for use in households (residential) and on lawns, commercial right of ways, golf courses, parks and playgrounds to control weeds, algae and moss using ground equipment.

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the data required to support the registration of this biochemical active ingredient, under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Product chemistry data requirements were satisfied by acceptable guideline studies. Adequate mammalian toxicology data/information was submitted to support registration of Iron HEDTA. Acceptable acute toxicity guideline studies were submitted, and data waivers were granted by the Agency to fulfill the remaining toxicity requirements based on the lack of toxicity of the active ingredient. Ecological effects data requirements for Iron HEDTA were fulfilled by acceptable guideline studies and additional data/information from the scientific literature sufficient to support data waivers for the remaining Tier I and Tier II requirements.

Based on the data available to the Agency, it has been determined that no unreasonable adverse effects to the U.S. population and the environment will result from the use of the active ingredient when label instructions are followed and good agricultural practices are employed. Laboratory studies indicate that the active ingredient is not toxic following oral, inhalation or dermal exposure. Iron HEDTA and other chelates like ferric EDTA have been extensively used as liquid fertilizers in soil and foliar applications for many years to address micronutrient deficiencies in plants. There are no reports of adverse effects following human exposure to Iron HEDTA. Moreover, the pesticidal usage of this biochemical will not have any harmful environmental effects. Studies indicate that Iron HEDTA will not cause adverse effects to mammals, birds, fish and aquatic invertebrates, other non-target insects, or plants.

Efficacy data submitted on the end use product were reviewed and showed support to the claims of product performance on the label.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: Ferric HEDTA

Chemical Names: Iron HEDTA

Trade & Other Names: FeHEDTA

CAS Registry Number: 17084-02-5

OPP Chemical Code: 034702

Type of Pesticide: Herbicide, algaecide and mossicide.

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

III. REGULATORY BACKGROUND

On August 17, 2007, W. Neudorff GmbH KG, submitted an application for the registration of the end use products (EP) NEU1173H Concentrate herbicide containing 26.52% w/w Iron HEDTA EPA Registration Number 67702-EA, and NEU1173H RTU, containing 1.5 w/w Iron HEDTA EPA Reg. Number 67702-ET. A notice of receipt of the application for registration of Iron HEDTA as a new active ingredient was published in the Federal Register on June 25, 2008 (73 FR 36076) with a 30-day comment period. No comments were received following this publication.

A. Classification

On April 02, 2001, the Biochemical Classification Committee determined that Iron HEDTA is not a biochemical pesticide, but is nonetheless eligible for treatment like a biochemical pesticide (see data requirements at 40 CFR Subpart U). Iron HEDTA has no direct lethal effects on the target pest, and appears to operate as oxidative agent on target pests.

B. Food Clearances/Tolerances

Currently, this active ingredient is not registered for use on food or feed commodities, and the applicant has not filed a petition for a tolerance (nor a tolerance exemption) for Iron HEDTA. As a result, a tolerance or exemption from the requirement of a tolerance is not relevant.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

Iron is a ubiquitous inorganic element in the environment. Iron HEDTA and other similar chelates like Fe EDTA have been applied as liquid fertilizers in soil and foliar applications for many years to address micronutrient deficiencies in plants.

The descriptions of the product formulation and production process, as well as the formation of impurities, were examined by the Agency and found to be acceptable in meeting current guideline standards. A preliminary analysis was conducted to determine Iron HEDTA content in five batches of the product, and the results were determined to be acceptable by the Agency. The analytical method used to determine the content of the active ingredient is also acceptable. Physical and chemical properties were submitted for the active ingredient and are adequate. Refer to Table 1 in Appendix A for a summary of product chemistry data requirements. Refer to Table 2 in Appendix A for the summary of physical and chemical characteristics for Iron HEDTA. All product chemistry data requirements for registration of Iron HEDTA have been **satisfied**.

B. Human Health Assessment

1. Toxicology

Toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient is classified into Toxicity Category I, II, III or IV where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.

Adequate mammalian toxicology data/information on the technical grade active ingredient (TGAI) are available to support registration of Iron HEDTA. All toxicology data requirements have been **satisfied**.

a. Acute Toxicity

Acute toxicity testing is required to 1) determine systemic toxicity from acute exposure via the dermal, inhalation and oral routes, 2) determine irritant effects from exposure to the eyes and 3) determine the potential for skin sensitization (allergic contact dermatitis).

The substance used in the toxicity studies was the TGAI/EP containing 26.52% Iron HEDTA. The substance is in Toxicity Category IV for acute oral, acute dermal, acute inhalation toxicity, and eye and dermal irritations. The substance is not a dermal sensitizer. Based on the review and analysis of the guideline studies, no additional toxicity data are required to support non-food uses of this biochemical.

For more information regarding the acute toxicity data requirements, refer to Table 3 in Appendix A.

b. Sub-chronic Toxicity

Sub-chronic data is required to determine a no-observed-effect-level (NOEL) and toxic effects (if any) associated with repeated or continuous exposure to a test substance for a period of 90 days.

The Agency received and accepted the registrant's waiver requests for 90-day Feeding Study (OPPTS 870.3100); 90-Day Dermal Study (OPPTS 870.3250); 90-Day Inhalation Study (OPPTS 870.3465); and Immune Response (OPPTS 880.3550).

The data requirement for 90-day Feeding Study (OPPTS 870.3100) is not applicable because the product will not be used on food commodities, and no repeated sub-chronic oral exposures are expected. Moreover, Tier I acute toxicity studies show toxicity category IV for all routes of exposure.

The waiver rationale for a 90-Day Dermal Toxicity Study (OPPTS 870.3250) was accepted because the product is not likely to result in prolonged skin exposure. Furthermore, iron is found abundantly in nature, and has low toxicity because of its low absorption through skin.

The 90-Day Inhalation Toxicity Study (OPPTS 870.3465) waiver request was accepted because the use pattern of the product is not expected result in repeated inhalation exposure at a concentration which is likely to be toxic.

c. Developmental Toxicity and Mutagenicity

Acceptable waiver request was submitted to address the data requirements for Developmental toxicity and Mutagenicity (OPPTS 870.3700). The Agency concluded that human's are regularly exposed to iron found abundantly in nature and from the use of iron chelates as fertilizers. No negative effects of Iron HEDTA have been reported because of its low toxicity, and low water solubility, which would decrease its absorption across the intestine. Moreover, the active ingredient is not a mutagen nor is it related to any known classes of mutagens

e. Effects on the Endocrine System

EPA is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), 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).

The Agency is not requiring information on the endocrine effects of Iron HEDTA at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect on humans similar to an effect produced by naturally-occurring estrogen or other endocrine effects. There is no known metabolite that acts as an endocrine disrupter produced by this active ingredient. Based on the low potential exposure level associated with the proposed use, the Agency expects no incremental adverse effects to the endocrine or immune systems.

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 drinking water exposure is expected from accumulation of Iron HEDTA in the aquatic environment when products containing the active ingredient are used according to label directions. Moreover, Iron HEDTA degrades readily in the environment.

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

a. Occupational Exposure and Risk Characterization

The potential for dermal, eye, and inhalation exposure to Iron HEDTA for handlers and applicators is mitigated as long as products are used according to label directions. The Agency will require labels to include the appropriate signal word and precautionary statements, including the requirement for personal protective equipment, to mitigate any risk of exposure.

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

No indoor residential, school, or day care uses are currently approved for products containing Iron HEDTA.

5. Risk Characterization

The Agency considered human exposure to Iron HEDTA 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 Iron HEDTA when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

Adequate non-target toxicology data/information are available to support registration of Iron HEDTA. All non-target toxicology data requirements for Iron HEDTA have been **satisfied**.

Iron HEDTA and other similar chelates have been applied as liquid fertilizers in soil and foliar applications for many years to address the micronutrient deficiencies in plants. No reports of negatives effects have been documented for the use of these chelates.

According to an avian acute oral toxicity study, Iron HEDTA is considered to be practically non-toxic to birds via the oral route of exposure ($LD_{50} > 2000$). Iron HEDTA is considered to be practically non-toxic to freshwater fish based on a freshwater fish toxicity study (96-hour $LC_{50} > 100$ mg/L). It is also no-toxic to freshwater invertebrate (48-hour $LC_{50} > 100$ mg/L).

Non-target insect studies submitted showed that Iron HEDTA has no toxic effect on honey bee (Oral 83.7 μ g a.i./bee; Contact: 48 hr > 10 μ g a.i./bee).

For more information regarding the non-target toxicity data requirements, refer to Table 4 in Appendix A.

2. Environmental Fate and Ground Water Data

Iron HEDTA is chemically similar to ferric EDTA and thus the two chelates follow the same pathways of degradation, photodegradation and microbial degradation in waste water, sediments and soils. According to Sykora et al. (2001) biological degradation of ethylenediamine-based complexing agents decreases in order of the following substitutes: $-\text{COOH}_3$, $-\text{CH}_3$, $-\text{C}_2\text{H}_5$, $-\text{CH}_2\text{CH}_2\text{OH}$ and $-\text{CH}_2\text{COOH}$ suggesting that HEDTA may be more susceptible to degradation than EDTA. Ferric complexes of EDTA, HEDTA and DTPA are decomposed on exposure to daylight (Hill-Cottingham, 1995). The half-life of ferric EDTA is calculated between 11.3 min to more than 100 h for surface waters containing Fe(III)EDTA (Frank and Rau, 1989; Kari et al, 1995; Svenson et al., 1989). The differences observed in the half-life rates are likely due to differences in light conditions of the experiments. The wavelength of light that is required to photodegrade Fe(III)EDTA is the fraction of sunlight below 400 nm (i.e. in the UV range) (Bucheli-Witschel and Egli, 2001). The rate of photodegradation is also dependent on pH but at measured pH 4 and 8, Fe(III)EDTA was completely degraded in 24 and 32 hours (Lockhart, 1975). Ferric EDTA degrades to ED3A, EDDA-N,N', EDDA-N,N, EDMA, IMDA, glycine and formaldehyde all of which are biodegradable (Metsarinne, 2001). Microbial degradation of ferric EDTA has been documented in numerous studies. In a mixed culture of microorganisms (genus *Methylobacterium*, *Variovarax*, *Enterobacter*, *Aureobacterium* and *Bacillus*) 60% of Fe(III)EDTA was degraded (Bucheli-Witschel, 2001). Ninety percent degradation of ferric EDTA was achieved with a pure culture of *Agrobacterium* sp. (Lauff, 1990). Ferric EDTA was microbially degraded in naturally occurring soils and sediments (Tiedje, 1975 and 1977). Likewise, ferric EDTA was degraded in mixed microbial populations collected from an aerated lagoon (Belly, 1974).

3. Ecological Exposure and Risk Characterization

The potential for exposure to non-target wildlife is minimal. Based on the results/information presented in the Environmental Fate and Groundwater Data section above, it is highly unlikely that non-target organisms, particularly aquatic organisms, would be exposed to potentially toxic levels of Iron HEDTA via runoff and/or movement through the soil. Iron HEDTA undergoes rapid biodegradation in soil and water, and no unreasonable adverse effects to the environment are expected from the use of Iron HEDTA when label instructions are followed.

4. Endangered Species Assessment

Due to chemical similarity between Iron HEDTA and Ferric EDTA, the biological effects of these chelates are comparable. Available information on the effects of iron in sodium ferric EDTA on non-target organisms indicates that the iron in these chelates interacts with the hemocyanin in the bloodstream of molluscs and crustaceans, and it would be toxic to mollusks and crustaceans. However, exposure to freshwater crustaceans or mollusks is unlikely to occur given the intended use of this product as herbicide applied directly to terrestrial plants.

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 lawns, rights-of-ways, golf courses, parks, playgrounds, cemeteries, and athletic fields. The habitats of currently listed as threatened or endangered mollusks and crustacean species range from isolated caves and streams to woods or forests.

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).

A series of greenhouse and field trials were conducted to evaluate the efficacy of NEU1173H (a.i., 26.52% w/w Iron HEDTA) against a variety of weeds including dandelion, white clover, English daisy, creeping buttercup, black medick, chickweed, and moss. When applied at the label-recommended rate, the test material was effective against the tested weeds, and its efficacy increased when a second application was made 14 to 28 days after the first one. Lower application rates were less effective. Phytotoxicity to various grasses was normally minimal, and in the few tests where up to 20% of grass was affected, recovery was complete by the end of the test period.”

EPA calculates the application rate used in Test 1 (430 mL/m², calculated to be 460 al/A) slightly exceeds the label recommended rate (5-10 gal/1000 ft², calculated to be 218 – 436 gal/A) for the handheld sprayer used in the test. The application rates in Tests 2 – 17 (200 or 400 mL/m²) are slightly below the recommended rate. In Tests 18 and 19, the reviewer calculates the application rates of 8.9, 17.7, and 26.6 mL/m² to be 9.5, 18.9, and 28.4 gal/A, respectively. The 18.9 gal/A rate slightly exceeds, and the 28.4 gal/A rate greatly exceeds, the label recommended rate of 1 gal/2500 ft² (calculated to be 17 gal/A) for the hose-end sprayers used in the test. Therefore the results for the 26.6 mL/m² rate should be discounted. When used at the recommended application rate, the test material was effective against a variety of weeds, and its efficacy increased when a second application was made (Tests 1, 2, 5, 12, and 19). The product label recommends a second application after three to four weeks. The second application in Tests 1, 2, and 5 was made after two weeks, and in Tests 12 and 19 after about four weeks. Phytotoxicity to grasses was normally minimal (<5%), although it reached 20% in one test. However, by the end of the test the grass had recovered. The application rates and re-application times do not coincide with those recommended on the label. In most cases, the study demonstrates the performance of the product

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 Iron HEDTA. 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, Iron HEDTA is eligible for registration for the labeled uses.

B. Regulatory Decision

The data submitted fulfill the requirements of registration for use in households (residential) and on lawns, commercial right of ways, golf courses, parks and playgrounds to control weeds, algae and moss using ground equipment. 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 Iron HEDTA 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 Iron HEDTA, 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 Iron HEDTA 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.

Notwithstanding 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 (MRID 475387-01)	Results
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfy the requirements for product identity, manufacturing process, and discussion of formation of impurities.
830.1700	Analysis of samples	Submitted data satisfy the requirements for analysis of samples.
830.1750	Certification of limits	Limits listed in the CSF are adequate / acceptable.
830.1800	Analytical method	Acceptable.

TABLE 2. Physical and Chemical Properties of Active Ingredient (40 CFR § 158.2030) MRID 475387-01, 02		
OPPTS Guideline No.	Property	Description of Result
830.6302	Color	Deep red
830.6303	Physical State	Liquid at room temperature
830.6304	Odor	Odorless
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Not required for EP
830.6315	Flammability	Not applicable. The product does not contain any combustible ingredients
830.6317	Storage Stability	No change in Iron HEDTA content when stored for a month at 50 degree C
830.6319	Miscibility	Not applicable, the product is not to be mixed with petroleum solvents. Miscible with water in all proportions
830.6320	Corrosion Characteristics	No evidence of corrosive effects on HDPE bottles or caps after one month of storage at 50°C.
830.7000	pH	6.50 ± 0.50
830.7050	UV/Visible Light Absorption	Not required for EP.
830.7100	Viscosity	6 cPs at 30 rpm 11.5 cPs at 60 rpm 4 cPs at 30 rpm Measured with spindle LV1 after one minute at 20°C
830.7200	Melting Point/Range	Not applicable, product is a liquid.
830.7220	Boiling Point/Range	Not required for EP
830.7300	Density	Density is 1.29 g/mL at 20°C
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not applicable, product is a liquid.
830.7550 830.7560 830.7570	Partition Coefficient (n- Octanol/Water)	Not required for EP.
830.7840	Water Solubility	Not required for EP.
830.7950	Vapor Pressure	Not required for EP.

Table 3. Human Toxicology Data Requirements for Iron HEDTA (40 CFR § 158.2050)

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Acute Oral Toxicity/OPPTS 870.1100	> 5000 mg/kg	IV	472074-04
Acute Dermal Toxicity/OPPTS 870.1200	> 5000 mg/kg	IV	472074-05
Acute Inhalation Toxicity/OPPTS 870.1300	> 5.43 mg/L	IV	472074-06
Acute Eye Irritation/OPPTS 870.2400	Mildly irritating	IV	472074-07
Acute Dermal Irritation/OPPTS 870.2500	Non-irritating	IV	472074-08
Skin Sensitization/OPPTS 870.2600	Not skin sensitizer	IV	472074-09

TABLE 4. Non-Target Organism Toxicity Requirements for active ingredient (40 CFR § 158.2060)

<u>Study/OPPTS Guideline No.</u>	<u>Results (LD₅₀/LC₅₀)</u>	<u>Toxicity Category/Description</u>
Avian acute oral toxicity <i>Colinus virginianus</i> (850.2100)	>2000 mg/kg bw	Practically non-toxic (MRID 47207410)
Avian dietary toxicity <i>Colinus virginianus</i> (850.2200)	> 5000 ppm	Practically non-toxic (MRID 47233001)
Aquatic invertebrate acute toxicity <i>Daphnia magna</i> (850.1010)	48 hr > 100 mg/L	Practically non-toxic (MRID 47233003)
Freshwater fish LC ₅₀ <i>Oncorhynchus mykiss</i> (850.1075)	96 hours > 100 mg / L	Practically non-toxic (MRID 47233002)
Non-target insects Honey bee acute and contact toxicity LD 50 (880.3020)	Oral: 83.7 µg a.i./bee Contact: 48 hr > 100 µg a.i./bee	Toxic Practically no-toxic (MRID 47233004)

VIII. Appendix B.

For product specific information, please refer to PPLS

IX. Appendix C.

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Include link to Scientific Term Glossary