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Registration Decision

RD2010-09

# FeHEDTA

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## Table of Contents

Registration Decision for FeHEDTA .....	1
What Does Health Canada Consider When Making a Registration Decision? .....	1
What Is FeHEDTA?.....	2
Health Considerations.....	2
Environmental Considerations.....	3
Value Considerations .....	4
Measures to Minimize Risk .....	4
Other Information .....	5
Appendix I    Comments and Responses.....	7
References.....	9

## Registration Decision for FeHEDTA

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of NEU1173H TGAI and the end-use products; NEU1173H RTU with Pull'N Spray Applicator, NEU1173H RTU with Quick Connect Sprayer, NEU1173H RTU, Fiesta Lawn Weed Killer Ready to Spray, Fiesta Lawn Weed Killer, NEU1173H Ready to Spray Large Size, NEU1173H Ready to Spray, NEU1173H Large Size, and NEU1173H, containing the technical grade active ingredient iron present as FeHEDTA (herein referred to as FeHEDTA), to control several broadleaved weed species that commonly occur in turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2010-03, *FeHEDTA*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for FeHEDTA and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2010-03.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-03, *FeHEDTA* that contains a detailed evaluation of the information submitted in support of this registration.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>3</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value<sup>4</sup> when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

<sup>3</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>4</sup> "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

## **What Is FeHEDTA?**

Iron is a metallic chemical element (symbol "Fe") that acts as a selective herbicide when chelated with hydroxyethylenediaminetriacetic acid (HEDTA) to form FeHEDTA. Broadleaved plants are generally more susceptible to the herbicidal effects of FeHEDTA than are grass species. The mechanism of selectivity is not entirely understood but is believed to relate in part to differences in uptake. As Fe can function as a catalyst for oxygen reduction, thereby producing unstable and highly reactive oxygen species, including hydroxyl radicals that cause cellular damage, the excessive uptake of FeHEDTA by many broadleaved species leads to tissue necrosis and ultimately plant death.

## **Health Considerations**

### **Can Approved Uses of FeHEDTA Affect Human Health?**

**FeHEDTA is unlikely to affect your health when used according to label directions.**

Exposure to FeHEDTA may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, FeHEDTA, is of low acute toxicity by the oral, dermal and inhalation routes and is minimally irritating to eyes, but non-irritating to skin. There is potential for skin sensitization to occur when skin is repeatedly exposed to FeHEDTA products. Therefore, cautionary statements alerting users to this sensitization concern are required on all product labels.

Dermal exposure is likely for commercial applicators, domestic users or anyone entering sprayed areas before the spray is dried. Children may also be exposed to FeHEDTA by direct dermal or hand-to-mouth contact if they were to play on freshly treated lawn surfaces. Therefore, a restricted entry statement is required on all product labels to mitigate this exposure concern.

Waivers were granted for short-term dermal toxicity, prenatal development toxicity and genotoxicity studies based on the low application rates, low dermal absorption, low toxicity of FeHEDTA, and on the strength of toxicological information on chemically similar EDTA compounds.

## **Residues in Water and Food**

### **Dietary risks from food and water are not of concern.**

End-use products containing FeHEDTA are not applied directly to food or feed crops, so residues on food are expected to be negligible.

## **Occupational Risks From Handling FeHEDTA**

### **Occupational risks are not of concern when FeHEDTA is used according to label directions, which include protective measures.**

Occupational and residential exposure is expected to be brief, and is not likely to result in unacceptable risk to commercial applicators, occupational workers, and domestic users if the end-use products are used according to label directions.

The proposed use of the end-use products may result in exposure to the commercial applicators, domestic-users, mixers, loaders, and those responsible for clean-up and maintenance activities, but significant risks from such exposures are not anticipated due to the low toxicity of FeHEDTA and adequate exposure mitigation measures recommended on the labels. For bystanders, exposure is expected to be negligible. Therefore, health risks to bystanders are not of concern.

Precautionary and hygiene statements on the labels are considered adequate to protect individuals from any unnecessary risk from occupational exposure.

## **Environmental Considerations**

### **What Happens When FeHEDTA Is Introduced Into the Environment?**

**FeHEDTA is expected to be non-persistent in the environment (terrestrial and aquatic) under neutral to alkaline aerobic conditions. FeHEDTA has a potential for high mobility in sandy soil with negligible organic matter. FeHEDTA is expected to impact broadleaf terrestrial plants; therefore, a precautionary label statement is needed for the protection of desirable plants.**

Iron is ubiquitous in the environment. FeHEDTA is widely used as a plant micronutrient fertilizer in agricultural industries. Based on its low volatility, FeHEDTA is not expected to enter the atmosphere. FeHEDTA is soluble in water where it is rapidly degraded by natural light. FeHEDTA is transformed by micro-organisms in soil and aquatic systems, although it is relatively stable in anaerobic soils. No major products are formed in soil and water. From the

proposed use pattern, the amount of FeHEDTA entering the environment will be lower than for other agricultural uses.

FeHEDTA is expected to pose negligible risk to terrestrial and aquatic organisms under conditions of use for application to turf.

## **Value Considerations**

### **What Is the Value of FeHEDTA**

FeHEDTA controls several broadleaved weed species that commonly occur in turf. It is an alternative to conventional herbicides. FeHEDTA is compatible with integrated weed management practices in that it is applied only when weeds have emerged and is not used as a “preventative” treatment.

### **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of the end-use products NEU1173H RTU with Pull’N Spray Applicator, NEU1173H RTU with Quick Connect Sprayer, NEU1173H RTU, Fiesta Lawn Weed Killer Ready to Spray, Fiesta Lawn Weed Killer, NEU1173H Ready to Spray Large Size, NEU1173H Ready to Spray, NEU1173H Large Size, and NEU1173H to address the potential risks identified in this assessment are as follows.

### **Key Risk-Reduction Measures**

#### **Human Health**

Because there is a concern with domestic-users coming into direct contact with FeHEDTA on the hands and then transferring to mouth, the labels recommend “avoid hand-to-mouth contact” and require commercial applicators/domestic-users and workers to wash hands thoroughly with soap and water after handling the products and before eating, drinking, and chewing gum or chewing tobacco.

The labels specify that anyone handling or applying these products should “avoid breathing vapour or spray mist” and “avoid contact with skin or clothing.” Domestic product labels should include the statement “DO NOT get in eyes.”

To protect children and adults from dermal exposure to FeHEDTA from wet treated turf, the labels should include the restricted entry statement, “Do not re-enter or allow re-entry into treated areas until the spray is dried.”

The signal words “POTENTIAL SKIN SENSITIZER” and the statement “May cause skin sensitization” are required on the principal and the secondary display panels, respectively, of both the technical and end-use product labels.

To prevent inappropriate use, the secondary display panel of the technical label should include the statement “PREVENT ACCESS BY UNAUTHORIZED PERSONNEL.”

Personal protective equipment (PPE) recommended include protective eye-wear for commercial products and waterproof gloves for both commercial and domestic products which require loading, mixing, and for repair/clean-up activities.

The application of commercial products is recommended only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal; taking into consideration wind speed, wind direction, temperature, application equipment, and sprayer settings.

## **Other Information**

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa). For more information, please contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)).

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada’s website (Request a Reconsideration of Decision, [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)) or contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)).

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<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.





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## Appendix I Comments and Responses

### 1. Comments on the registering of products for domestic use.

A comment was received in which the suitability of registering domestic products was questioned due to the potential for misuse by non-licensed users.

#### **Response:**

The assessment of risk for domestic products takes into consideration the proposed use pattern and the target user while addressing exposure to sensitive populations (such as children and nursing mothers). Residential exposure for these products is expected to be brief, and is not likely to result in unacceptable risk to domestic users, sensitive populations or bystanders when the end-use products are used according to label directions.

### 2. Comments on the use of independent scientific data.

In the document Proposed Registration Decision – *FeHEDTA* (PRD2010-03), it was noted that the data used to support the value review was generated by the applicant and it was recommended that independent scientific value data should be considered.

#### **Response:**

Health Canada carefully evaluates new pesticides according to rigorous scientific standards to ensure that the product poses no risk to human health or the environment, and has value when used according to the directions on the product label.

Companies applying to register a pesticide in Canada are required to develop a comprehensive database of studies that will allow Health Canada to determine the potential risks posed to human health and the environment and the pesticides' value. It is the responsibility of the manufacturer to carry out these detailed scientific studies in accordance with internationally accepted test guidelines.

The use of internationally accepted test guidelines promote the quality and validity of test data by addressing the organizational process and conditions under which studies are planned, performed, monitored, recorded and reported. Independent trial audits may be conducted under the good laboratory practices guidelines at anytime to verify the integrity of data.

Health Canada requires product specific value data as the formulation in an end use product can have an affect on the performance of an active ingredient. For the application to register *FeHEDTA* and its end use products, the value data submitted by the registrant were found to be sufficient to demonstrate acceptable control of the weeds that will appear on the product label with the condition that additional confirmatory data for the listed weeds be submitted.

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**Comments on the application rates and potential phytotoxicity to turf.**

In the document Proposed Registration Decision – *FeHEDTA* (PRD2010-03), two comments on the potential for phytotoxicity to turf grass were received. It was questioned if the application rate could be lowered in order to remove any possibility of damage to turf grass.

**Response:**

The efficacy information submitted indicates that the application rates supported by the PMRA are required for control of the weeds listed on the product label.

The product label contains statements warning of possible, but transient injury to turf grass, and advises the user to test the product on a small area. In consideration of the low levels of injury reported in the information submitted by the registrant (generally 5-7% or less, and declining over time), in combination with the efficacy of the product for control of several common broadleaved turf weeds, the level of tolerance of the labeled turf grasses to these products is considered to be acceptable. Given the range of factors that may influence a plant's response to a herbicide application, it is not possible to provide a quantification of potential levels of injury on a product label. The precautionary statements are therefore added to indicate that the potential for injury to the turf exists.

**Comments on the use of the term 'natural'.**

In the document Proposed Registration Decision – *FeHEDTA* (PRD2010-03), Section 5.5.1 Survey of Alternatives, the term 'natural' was used to describe a registered active ingredient. The comment was that the use of this term is not consistent with the advice to registrants and applicants in the Regulatory Directive, DIR96-02: *Environmental Label Claims and Advertising of Pest Control Products*.

**Response:**

DIR96-02 is intended to inform the pesticide industry of the requirements for using environmental claims on pest control products, in order to ensure responsible labeling and advertising. In DIR96-02 it states that "no further consideration will be given to the use of the term "natural" as an environmental claim for pest control products".

The PMRA acknowledges that the term 'natural' was inadvertently used in error in PRD2010-03.

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## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

PMRA Document Number	Reference
1753329	1753329 2009, Binder 2 Amended, DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.16, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
1791534	2009, NEU1173H TGAI Clarification Response, DACO: 0.1.6003, 2.11.2, 2.11.3, 2.12.2, 2.13.1 CBI
1753341	2009, 5-batch Analysis of NEU1173H TGAI - HEDTA, DACO: 2.13.3 CBI
1768339	2009, 5-Batch Analysis of Neu 1173H TGAI, DACO: 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
1768340	2009, 5-Batch Analysis of Neu 1173H TGAI Appendices, DACO: 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
1768341	2009, 5-Batch Analysis of Neu1173H TGAI for Nitrilotriacetate, Ethylenediaminetetraacetate and Hydroxyacetate, DACO: 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
1753345	2009, Analysis of Iron in NEU1173H by ICP-MS in support of Eco-Care Study 1173-2W54-2M40-081216 "Accelerated (w weeks 54C, 2 months 40C) Storage Stability of NEU1173H", DACO: 2.14.14 CBI
1791535	2007, Method SOP IC/003, DACO: 2.13.1 CBI
1791536	2008, Method SOP 91-CM-006-00, DACO: 2.13.1 CBI
1791537	2009, NEU1173H TGAI Chromatograms, DACO: 2.11.3 CBI
1791534	2009, NEU1173H TGAI Clarification Response, DACO: 0.1.6003, 2.11.2, 2.11.3, 2.12.2, 2.13.1 CBI
1768838	Binder 2 Addendum June 23, 2009, DACO: 2.0, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI

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1566571	2008, Binder 2, DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
1566574	2008, Ambient (1 year) Storage Stability of NEU1173H, DACO: 2.14.14 CBI
1753343	2009, UV Visible Absorption, DACO: 2.14.12 CBI
1753390	2009, Binder 2 Addendum, DACO: 3.0, 3.2.1, 3.2.2, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.5, 3.5.10, 3.5.6, 3.5.7, 3.5.8, 3.7 CBI
1566835	2008, CBI Reference Document to Binder 2, DACO: 3.2.1, 3.2.2, 3.3.1 CBI
1566831	2008, Binder 2, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9
1566834	2008, Ambient (1 year) Storage Stability of NEU1173H RTU, DACO: 3.5.10
1753394	2008, Physical and Chemical Characteristics: Oxidation/Reduction, DACO: 3.5.8 CBI
1753395	2009, Analysis of Iron in Neu1173H RTU by ICP-MS in support of eco-Care Study 1173RTU-2W54-2M40-081216 "Accelerated (2 weeks, 54C, 2 months, 40C) Storage Stability of NEU1173H RTU, DACO: 3.5.10 CBI
1790668	2009, Storage Stability Data, DACO: 3.5.10 CBI
1753404	2009, Binder 2 Addendum, DACO: 3.0, 3.2.1, 3.2.2, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.5, 3.5.10, 3.5.6, 3.5.7, 3.5.8, 3.7 CBI
1753410	2009, Analysis of Iron in Neu1173H by ICP-MS in support of eco-Care Study 1173-2W54-2M40-081216 "Accelerated (2 weeks, 54C, 2 months, 40C) Storage Stability of NEU1173H", DACO: 3.5.10 CBI
1567217	2008, Binder 2, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9
1567219	2008, Storage Stability 1 year, DACO: 3.5.10
1753409	2008, Physical and Chemical Characteristics: Oxidation/Reduction, DACO: 3.5.8 CBI
1790663	2009, Storage Stability Data, DACO: 3.5.10 CBI

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- 1566579 2007, Acute (4-hour) inhalation toxicity study with NEU1173H in rats, DACO: 4.6.3.
- 1566580 2007, Acute Eye Irritation/Corrosion with NEU1173H, DACO: 4.6.4.
- 1566581 2006, Acute Dermal Irritation/Corrosion with NEU1173H, DACO: 4.6.5.
- 1566582 2006, Test for Sensitization (Local Lymph Node Assay - LLNA) with NEU1173H, DACO: 4.6.6.
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