

PO Box 1749 Halifax, Nova Scotia B3J 3A5, Canada

Item No. 8.1 (i)
Halifax Regional Council
June 8, 2010
June 22, 2010

**TO:** Mayor Kelly and Members of Halifax Regional Council

SUBMITTED BY:

Wayne Anstey, Acting Chief Administrative Officer

**DATE:** May 18, 2010

**SUBJECT:** Amendment to Administrative Order #23, Respecting Pesticides,

Herbicides and Insecticides - Notice of Motion to Add FeHEDTA (for

lawn use) to the Permitted Pesticides List

#### **ORIGIN**

This report originates from Administrative Order 23, and staff receipt of Industry Requests for amendment.

#### RECOMMENDATION

It is recommended that Halifax Regional Council, approve in principle the addition of FeHEDTA, for lawn use, to the Permitted Pesticides List in Administrative Order #23 and direct staff to initiate the formal legislative process.

Amendment to Administrative Order #23,
Respecting Pesticides, Herbicides and Insecticides Notice of Motion to Add FeHEDTA (for lawn use)
to the Permitted Pesticides List - 2 Council Report

June 8, 2010

#### **BACKGROUND**

Administrative Order #23, Respecting Pesticides, Herbicides, and Insecticides Excluded From the Pesticide By-Law, is a companion document to the Pesticide By-Law P800, and provides a list of Permitted Pesticides that are excluded from the provisions of the Pesticide By-Law. It was approved by Regional Council in 2000. The list includes such products as Insecticidal Soaps, Bacillus Thuringgiensis, Dormant Oils, Lime Sulphur, etc.

In order to facilitate the addition/deletion of substances from Administrative Order #23, staff have provided a protocol to amend the Permitted Pesticides List. This protocol has resulted in the addition of Diatomaceous Earth, Acetic Acid and, most recently (in 2005), Corn Gluten Meal.

#### **DISCUSSION**

Staff have received a request from HalifaxSeed, Weedman, and Edmonds Landscaping to add FeHEDTA to the Permitted List in Administrative Order #23.

#### 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.

Attachment One is the submission (since approved) to Pesticide Management Regulatory Agency (PMRA). It provides much information on the product. Attachment Two is the PMRA Product Label. Attachment Three is the Ontario Approval.

According to the Procedures to Amend the Permitted Pesticides List in Administrative Order #23, substances must satisfy the following requirements:

- 1. Full disclosure of all ingredients of any material/substance being considered.
- 2. The material/substance must not be prohibited by OMRI (Organic Material Review Institute) in their generic names list.

Amendment to Administrative Order #23, Respecting Pesticides, Herbicides and Insecticides -Notice of Motion to Add FeHEDTA (for lawn use) to the Permitted Pesticides List - 3 -Council Report

June 8, 2010

- 3. The material/substance must not be prohibited from use in Canada.
- 4. Proposed substances/materials not presently listed on OMRI's generic names list shall be referred to OMRI for review and recommendation at the cost of the applicant.
- 5. Whereas advance notice to the public on Administrative Order #23 is required through brochures, newsletters, etc., it is recommended that unless there are exceptional circumstances, an annual process be completed by February 15<sup>th</sup> of each year to amend the list of Permitted Pesticides.
- 6. These procedures shall be reviewed periodically by the appropriate staff to help ensure they remain up to date and effective.

Since this protocol was created in 2001, other provinces and municipalities have adopted pesticide restriction and regulations. Recently, the Province of Nova Scotia passed legislation that will mirror the Ontario Pesticide regulations which will become effective in 2011.

Based on the Ontario Regulations (which the Union of Nova Scotia Municipalities) recommended the Province of Nova Scotia develop their pesticide legislation around), HRM staff are recommending support of this industry request for addition of this product to the Approved List. In reviewing the 2001 protocol, this request meets the primary requirements, with the exception of OMRI approval for the generic product. It is not specifically prohibited nor approved. Iron is approved, with restrictions for use for organic use.

In addition to the above protocol, Sustainable Environment Management Office (SEMO) staff conducted basic research on the usage of the product. It appears that this product meets the intent of the HRM Pesticide By-Law and should be on the permitted list.

Staff is committed to facilitating the widest possible list of acceptable permitted substances for use by HRM residents.

With the recently passed Provincial Legislation Respecting Pesticides, it is anticipated and planned that HRM will no longer administer its By-Law and Administrative Order after this season.

#### **BUDGET IMPLICATIONS**

There are no budget implication to this action. Existing staff resources will update the HRM literature on the internet site.

Amendment to Administrative Order #23,
Respecting Pesticides, Herbicides and Insecticides Notice of Motion to Add FeHEDTA (for lawn use)
to the Permitted Pesticides List - 4 Council Report

June 8, 2010

#### FINANCIAL MANAGEMENT POLICIES/BUSINESS PLAN

This report complies with the Municipality's Multi-Year Financial Strategy, the approved Operating, Project and Reserve budgets, policies and procedures regarding withdrawals from the utilization of Project and Operating reserves, as well as any relevant legislation.

#### **ALTERNATIVES**

Regional Council may choose to not approve adding FeHEDTA to the Approved List.

#### **ATTACHMENTS**

Attachment One: Submission to PMRA

Attachment Two: Label

Attachment Three: Ontario Approval

A copy of this report can be obtained online at <a href="http://www.halifax.ca/council/agendasc/cagenda.html">http://www.halifax.ca/council/agendasc/cagenda.html</a> then choose the appropriate meeting date, or by contacting the Office of the Municipal Clerk at 490-4210, or Fax 490-4208.

Report Prepared by: Richard MacLellan, Manager - SEMO, 490-6056

Financial Approval by:

Cathie O'Toole, CGA, Director of Finance, 490-6308

Report Approved by: Phillip Townsend, Director, Infrastructure and Asset Management, 490-7166

Killan Jacob

## **Proposed Registration Decision**

# **FeHEDTA**

PMRA Document Number: 1841244

#### Overview

## **Proposed Registration Decision for FeHEDTA**

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing 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.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments 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.

## 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>1</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 proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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 (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental

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

<sup>&</sup>quot;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."

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 PMRA's website at <a href="healthcanada.gc.ca/pmra">healthcanada.gc.ca/pmra</a>.

Before making a final registration decision on FeHEDTA, the PMRA will consider all comments received from the public in response to this consultation document<sup>3</sup>. The PMRA will then publish a Registration Decision<sup>4</sup> on FeHEDTA, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

#### 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

<sup>&</sup>lt;sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>&</sup>lt;sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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 enduse 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. 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.

## **Next Steps**

Before making a final registration decision on FeHEDTA, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

#### Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on FeHEDTA (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon

application, in the PMRA's Reading Room (located in Ottawa).

## **Science Evaluation**

#### **FeHEDTA**

## 1.0 The Active Ingredient, Its Properties and Uses

#### 1.1 Identity of the Active Ingredient

Active substance FeHEDTA
Function Herbicide

Chemical name

1. International Union of

Hydroxyethylethylenediaminetriacetic acid, ferric complex

Pure and Applied Chemistry (IUPAC)

2. Chemical Abstracts Service (CAS) Iron, [N-(2-[bis[(carboxy-.kappa.O)methyl]amino-.kappa.N]ethyl]-N-[2-ncm] amino-.kappa.N] am

(hydroxy-.kappa.O)ethyl]glycinato(3-)--.kappa.N,.kappa.O]-

**CAS number** 17084-02-5

Molecular weight 331.15

Structural formula

OH Fe³+ O N O O O O O O

Purity of the active ingredient

4.51 % as iron (present as FeHEDTA)

#### 1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

#### Technical Product—NEU1173H TGAI

Property	Result
Colour and physical state	Deep red liquid
Odour	Odourless
Melting range	Not applicable

Boiling point or range	106 °C			
Density	1.396 g/mL			
Vapour pressure at 20°C	Not applicable			
Ultraviolet (UV)-visible spectrum	medium acidic neutral basic	λ <sub>max</sub> (nn 210 210 219	<u>m)</u>	molar abs. (L/(mol*cm)) $6.60 \times 10^3$ $7.06 \times 10^3$ $4.27 \times 10^3$
Solubility in water at 20°C	Miscible in all proportions			
Solubility in organic solvents at 20°C	Solvent Solubility Hexanes completely immiscible Diethyl ether completely immiscible Acetone FeHEDTA immiscible aqueous portion miscible Methanol completely soluble		ely immiscible ely immiscible ΓA immiscible portion miscible	
$n$ -Octanol-water partition coefficient $(K_{OW})$	$\log K_{ow} < 0$ ,			
Dissociation constant (p $K_a$ )	$pKa_1 = 2.4, pKa_2 = 5.4, pKa_3 = 9.9$			
Stability (temperature, metal)	Stable at 54 °C, non-corrosive to glass, plastic, stainless steel, brass and aluminum. Corrosive to galvanized steel, zinc and copper.			

End-Use Product— NEU1173H, Fiesta Lawn Weed Killer, Fiesta Lawn Weed Killer Ready to Spray, NEU1173H Large Size, NEU1173H Ready to Spray, NEU1173H Ready to Spray Large Size

Property	Result
Colour	Deep Red
Odour	Odourless
Physical state	Liquid
Formulation type	SN - solution
Guarantee	4.43 % nominal
Container material and description	HDPE bottles
Density	1.40 – 1.42 g/mL
рН	$5.93 \pm 0.12$
Oxidizing or reducing action	No significant reaction with water, a 10 % monoammonium phosphate solution, iron powder or kerosene. Reducing activity seen with a 10 % potassium permanganate solution.
Storage stability	Accelerated storage shows a relative loss in assay of Fe of <1 % after 2 weeks storage at 54 °C and ~4.3 % loss after 2 months storage at 40 °C.
Corrosion characteristics	No evidence of corrosive effects on HDPE bottles used to store the product at ambient temperature for one year.
Explodability	Non-explosive

End-Use Product— NEU1173H RTU, NEU1173H RTU With Pull'N Spray Applicator, NEU1173H RTU with Quick Connect Sprayer

Property	Result
Colour	Deep Red
Odour	Odourless
Physical state	Liquid
Formulation type	SN - solution
Guarantee	0.25 % nominal
Container material and description	HDPE bottles
Density	1.01 – 1.02 g/mL
рН	$5.81 \pm 0.04$
Oxidizing or reducing action	No significant oxidizing or reducing activity observed
Storage stability	Accelerated storage shows a relative loss in assay of Fe of <1 % after 2 weeks storage at 54 °C and ~3.4 % loss after 2 months storage at 40 °C.
Corrosion characteristics	No evidence of corrosive effects on HDPE bottles used to store the product at ambient temperature for one year.
Explodability	Non-explosive

#### 1.3 Directions for Use

There are a total of nine herbicide end-use products that contain FeHEDTA in Concentrate, Ready-to-Spray and Ready-to-Use formats (Table 1.3).

**Table 1.3** Herbicides containing FeHEDTA

Products by format (marketing class)	Guarantee
Concentrate products	4.43% Fe
Fiesta Lawn Weed Killer (Commercial)	
NEU1173H Large Size (Domestic)	
NEU1173H (Domestic)	
Ready-to-Spray Products	4.43% Fe
Fiesta Lawn Weed Killer Ready To Spray (Commercial)	
NEU1173H Ready-To-Spray Large Size (Domestic)	
NEU 1173H Ready-To-Spray (Domestic)	
Ready-to-Use products	0.25% Fe
NEU1173H RTU with Pull'N Spray Applicator (Domestic)	
NEU1173H RTU with Quick Connect Sprayer (Domestic)	
NEU1173H RTU (Domestic)	

Each of these products is a selective herbicide for the control of several emerged broadleaved weed species in established turf (residential and commercial lawns, non-crop areas, including rights-of-ways, golf courses, parks, cemeteries, and athletic fields). Each of these products may be applied at up to two times per season, with no less than 4 weeks between applications, to control dandelion (*Taraxacum officinale*), English daisy (*Bellis perennis*), false dandelion

(Hypochaeris radicata), white clover (Trifolium repens), black medic (Medicago lupulina), bull thistle (Cirsium vulgare), Canada thistle (Cirsium arvense), common chickweed (Stellaria media), creeping buttercup (Ranunculus repens), narrow-leaved plantain (Plantago lanceolata), dovefoot geranium (Geranium molle), slender speedwell (Veronica filiformis), lawn burweed (Soliva pterosperma), moss (various species), and algae (various species), as well as to suppress broad-leaved plantain (Plantago major).

#### 1.3.1 Concentrate products containing FeHEDTA

These products require dilution before application: 1 part of concentrate is to be mixed with 24 parts of water for a 4% solution. The mixed solution is to be applied at 200 - 400 ml/m² with a standard handheld or backpack sprayer. This equates to 0.5 - 1.0 g a.i./m². The lower rate is intended for control of smaller weeds and the higher rate is intended for control of larger weeds and on some perennial weeds. These products are intended for application over a large area or to larger patches of weeds.

#### 1.3.2 Ready-to-Spray products containing FeHEDTA

These products are automatically diluted to the correct concentration when applied via a hose connected to a water source. The spray is to be applied at 200 - 400 ml/m². Similar to the concentrate products, these products are intended for application over a large weed-infested area or to larger patches of weeds.

#### 1.3.3 Ready-to-Use products containing FeHEDTA

These products are ready to use and require no further dilution. They are intended for application to individual weeds or patches of weeds. Application is made until weed foliage is thoroughly wetted, just to the point of run-off.

#### 1.4 Mode of Action

The exact mode of action of iron is unknown but it may in part be based on differential uptake and transport of iron, when present in chelated form. Synthetic chelates of iron are known to be more available than non-chelated iron for uptake by broadleaved plants which may result in excessive iron uptake. Uptake of synthetic chelates of iron by grasses may be inefficient relative to that in broadleaved species thereby conferring a greater level of tolerance, although not all grass species are equally tolerant of synthetic chelates of iron. Iron is known to function as a catalyst for oxygen reduction, thereby producing unstable and highly reactive oxygen species, including hydroxyl radicals that cause cellular damage, leading to cell death. Chelated iron has not been classified into a mode of action group e.g. WSSA or HRAC.

## 2.0 Methods of Analysis

#### 2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in FeHEDTA have been validated and assessed to be acceptable for the determinations.

#### 2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

#### 2.3 Methods for Residue Analysis

Not required.

### 3.0 Impact on Human and Animal Health

#### 3.1 Toxicology Summary

The PMRA has conducted a detailed review of the submitted data and publicly available toxicological information for FeHEDTA. The database is considered adequate, consisting of an array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies and/or waiver requests for specific elements of information currently required for health hazard assessment purposes. The submitted toxicology studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is such that the database is considered adequate to qualitatively assess the toxicological hazards of this pest control product.

The applicant submitted acute toxicity, irritation, and sensitization studies performed with NEU1173H, one of the proposed end-use products which is similar to the technical product, to support registration of the technical grade active ingredient and the nine associated end-use products. The substance tested in the submitted studies was FeHEDTA (26.52% w/w). Although the PMRA requires toxicity and irritation studies to be conducted with each end-use product, given that none of the formulations contain formulants of toxicological concern, testing with NEU1173H representing all the formulations was considered acceptable.

FeHEDTA was of low acute toxicity by the oral, dermal, and inhalation routes in rats. It was minimally irritating to eyes and non-irritating to skin in rabbits. In a Local Lymph Node Assay (LLNA) in mice, FeHEDTA was a dermal sensitizer. There is apparent potential for skin sensitization associated with repeated dermal exposure to the technical and end-use products.

The applicant requested study waivers for short-term dermal (90-day, rodent), prenatal developmental toxicity (rodent), bacterial reverse mutation assay, and genotoxicity (in vitro mammalian cell assay) on the following basis:

1) The low toxicity of FeHEDTA as observed in the acute toxicology studies; 2) the low dermal absorption of FeHEDTA; 3) the information in the published literature on chemically similar EDTA compounds (PMRA PRD2007-13); 4) the low application rate of FeHEDTA (concentrate is diluted 1 in 25; concentration of iron in the end-use products ranges from 0.25–4%); 5) non-use on food or feed crops; 6) iron sodium EDTA (chemically similar substance) is used as a source of dietary iron for food fortification purposes in the United States and such a use is approved by the World Health Organization; 7) no report of toxicological concerns from the high volume use of this chemical worldwide as a fertilizer for counteracting iron deficiency in plants; 8) trisodium HEDTA which is the source of the HEDTA in the active ingredient is used in soaps and cosmetics.

Furthermore, the applicant provided a summary of the toxicity profile for ferric sodium EDTA, evaluated and registered by the PMRA as a molluscicide, from the PMRA document PRD 2007-13 to support the waiver requests (Table 2, Appendix I).

Published information demonstrating the chronic toxicity potential of FeHEDTA was not available for evaluation; therefore, information available from the evaluation on ferric sodium EDTA was used. HEDTA of the proposed compound differs from EDTA of the registered ferric sodium EDTA in that one of the carboxyl groups (COOH) of the EDTA has been replaced with a hydroxyl (CH<sub>2</sub>OH) group (Figure 1, Appendix I). Due to the close chemical similarity, biological effects of these iron chelates are not expected to be different, and the toxicity of HEDTA and its salts and EDTA and its salts is expected to be similar and low.

In the gastrointestinal tract (GI tract), ferric sodium EDTA, like other EDTA complexes, dissociates to form iron and an EDTA salt which are absorbed independently. Compounds of EDTA are poorly absorbed in the GI tract, do not undergo significant metabolic conversion, and have a low degree of acute oral toxicity. Metal ions on the EDTA-metal complex are freely exchanged in the GI tract; therefore, the toxicological effects of EDTA salts are likely to be similar irrespective of the salt form. In chronic toxicity studies, diets containing as much as 5% EDTA were without adverse effects. EDTA compounds were not carcinogenic in animal bioassays and are not directly genotoxic.

In humans, iron absorption from ferric sodium EDTA is related to body iron reserves. Generally, ferric (Fe<sup>3+</sup>) iron in food and supplements is poorly absorbed because it is precipitated from solution at a pH above 3.5, and insoluble precipitate is poorly absorbed in the upper small intestine by humans, where most non-heme iron is absorbed, unless suitable complexing agents are present. Publicly available information suggests that normal individuals are capable of controlling iron absorption and that chronic toxicity (namely, hemochromatosis) is generally limited to individuals with inherited metabolic disorders affecting maintenance of iron balance in the body. In swine, exposure to radiolabelled ferric sodium EDTA (Na<sup>55</sup>Fe-[2-<sup>14</sup>C] EDTA, 5 mg introduced into the esophagus) resulted in 95% recovery in the feces and 0.3% in the urine. Absorption of a single, nonlethal, oral dose of ferric sodium EDTA introduced into the esophagus was anticipated to be poor, with nearly complete excretion in the feces. Metabolism of ferric sodium EDTA is anticipated to be negligible based on a review of published scientific information.

The requirement for short term dermal toxicity testing was waived because like other EDTA compounds iron HEDTA is not likely to be readily absorbed through the skin and has low acute dermal toxicity. A clinical study in human males reported almost no absorption of calcium disodium EDTA following dermal exposure.

The requirement for a prenatal developmental toxicity study was also waived based on the summary of reproduction and developmental toxicity studies for ferric sodium EDTA. Administration of a large quantity of disodium EDTA (954 mg/kg bw/day) in the diet of pregnant CD rats (day 7 through 14 of gestation) resulted in maternal effects marked by weight loss, decreased food consumption and diarrhea in all test animals and gross fetal malformations.

When disodium EDTA (3% by weight) was added to the diet of pregnant Sprague Dawley rats from days 6 to 14 of gestation or from day 6 to term, the majority of fetuses were grossly malformed. When the diet of exposed rats was supplemented with zinc (1000 ppm), no fetal malformations were noted, suggesting that the malformations were not directly caused by EDTA but were the result of secondary effects due to sequestering of zinc required for normal fetal development. It seems that by binding to divalent and trivalent cations EDTA in large amounts can cause mineral deficiencies; thereby, resulting in toxicological effects.

The requirement for a genotoxicity/mutagenicity study was waived based on the available information from the evaluation of ferric sodium EDTA. There was no evidence of genotoxicity/mutagenicity when trisodium EDTA was tested in Salmonella typhimurium strains (TA 98, TA100, TA1535, TA1537, and TA1538), Escherichia coli (WP2uvrA) and in mouse lymphoma cells with and without metabolic activation. This suggests that the EDTA moiety is not mutagenic/genotoxic. There was evidence of genotoxic potential of ferric sodium EDTA in mouse lymphoma cells in the presence and absence of metabolic activation. It should be noted, however, that it is anticipated that the Fe and EDTA will dissociate in solution and that Fe uptake by a transferrin independent transport system requires reduction of Fe<sup>3+</sup> to Fe<sup>2+</sup> at the cell surface. The ferrous ion is then subject to Fenton reaction:  $Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + .OH + OH$ . The hydroxyl free radical is expected to attack the DNA, resulting in the observed genotoxicity. The genotoxic reaction is therefore likely to be an indirect result of iron and not of the ferric sodium EDTA. The genotoxic nature of iron is not a concern because it is an essential element required by the human body and is readily available from food. The adverse effects of excess dietary iron in normal individuals have not been reported. For iron, the Recommended Dietary Allowance (RDA) is 8 mg/day for all age groups of men and postmenopausal women and 18 mg/day for premenopausal women. The tolerable upper intake level (UL) for adults is 45 mg/day iron, based on gastrointestinal distress as an adverse effect.

Results of the acute tests with FeHEDTA and chronic tests for ferric sodium EDTA conducted on laboratory animals, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Tables 1 and 2 of Appendix I.

#### 3.2 Determination of Acceptable Daily Intake (ADI)

As the end-use products are not intended for direct application to food crops, determination of an acceptable daily intake is not required.

#### 3.3 Determination of Acute Reference Dose (ARfD)

As the end-use products are not intended for direct application to food crops, determination of an acute reference dose is not required.

#### 3.4 Occupational and Residential Risk Assessment

#### 3.4.1 Use Description/exposure Scenario

Product use

The end-use products are to be applied onto individual weeds at a rate of 200–400 mL/m<sup>2</sup> (2000 to 4000 L/ha). For best results, the labels instruct to re-apply with no less than 4 weeks between applications up to a maximum of 2 applications per year per treatment site.

Ready-To-Use End-use products: NEU1173H RTU With Pull 'n Spray Applicator, NEU1173H RTU With Quick Connect Sprayer, NEU1173H RTU (Iron present as FeHEDTA 0.25%)

Application of these products does not involve mixing or loading as they are ready-to-use formulations applied with the integrated applicator on the product container. The nozzle is to be adjusted to achieve a desired spray pattern. For these products, on average, a residential user would be treating a lawn area of 0.0093 ha per treatment per day with 18.6–37.2 L of the end-use products, and the estimated amount of active ingredient used would be 0.047 to 0.094 kg of iron present as FeHEDTA.

Ready-To-Spray: NEU1173H Ready-to-Spray Large Size, NEU1173H Ready-to-Spray (Iron present as FeHEDTA 4.43%)

Application of these products does not involve mixing or loading as they are ready-to-use formulations and will be applied using a hose-end sprayer attached to the product container. A garden hose is to be attached to the hose-end sprayer as per the label instructions and the sprayer is to be calibrated to achieve a dilution ratio of 1:24 in water. For these products, on average, a residential user would be treating a lawn area of 0.10 ha per treatment per day with 8–16 L of the end-use products, and the estimated amount of active ingredient used would be 0.51 to 1.02 kg iron present as FeHEDTA.

Hand-held or Backpack application: NEU1173H Large Size, NEU1173H (Iron present as FeHEDTA 4.43%)

The proposed application is by any standard hand-held or backpack sprayer. The product is to be loaded and mixed with water at 1:24 ratio and sprayed to achieve a uniform coverage of the area to be treated. To reduce spray drift, the labels instruct users to set sprayers to a coarse nozzle setting. For application, a residential user would be treating an average lawn area of 0.0093 ha per treatment per day with 0.74–1.48 L of the end-use products, and the estimated amount of active ingredient used would be 0.047 to 0.094 kg iron present as FeHEDTA.

Fiesta Lawn Weed Killer Ready to Spray (Iron present as FeHEDTA 4.43%)

There is no mixing or loading involved as the product is a ready-to-use formulation to be applied using a hose-end sprayer attached to the product container. A garden hose would be attached to the hose-end sprayer as per the label instructions, and the sprayer is to be calibrated to achieve a dilution ratio of 1:24 in water. At a maximum application rate, 20.2 ha can be treated in a day with 1616–3232 L of the end-use product, and the estimated amount of active ingredient handled by a commercial applicator in a day would be 101 kg to 202 kg iron present as FeHEDTA.

Fiesta Lawn Weed Killer (Iron present as FeHEDTA 4.43%)

The product is to be transferred to any standard hand-held or backpack sprayer and would be diluted with water at 1:24 ratio. To reduce spray drift, the label instructs users to set sprayers to a coarse nozzle setting. At a maximum application rate, 2.02 ha can be treated in a day with 161.6—323.2 L of the end-use product, and the estimated amount of active ingredient handled in a day by a commercial applicator would be 10.1 kg to 20.2 kg iron present as FeHEDTA.

#### 3.4.2 Toxicological Endpoints

Occupational and residential exposures to end-use products are expected to be short-term in duration and predominantly by the dermal route during handling and application and from dermal contact of wet treated surfaces. Inhalation of spray mist is also possible, but is likely to be a minor route of exposure. The end-use products are anticipated to be of low acute toxicity by the oral, dermal, and inhalation routes. They are likely to be nonirritating to the skin, but minimally irritating to eyes, and are likely to be skin sensitizers. Repeated dermal exposure to end-use products can result in skin sensitization. The proper use and handling of the proposed end-use products, following label directions, is not likely to result in repeated or prolonged human exposure by any routes at a concentration that is likely to raise toxicological concerns. The publicly available information on the active ingredient suggests that the proposed use of end-use products is unlikely to have any short-term or prenatal developmental effects or genotoxic effects.

#### 3.4.3 Dermal Absorption

As the available published literature suggests negligible dermal absorption for EDTA compounds, and since the product labels have adequate precautionary and hygiene statements to prevent repeated and prolonged dermal exposure, a dermal absorption study was not considered necessary to complete the health hazard assessment of FeHEDTA.

#### 3.4.4 Mixer, Loader and Applicator Exposure and Risk Assessment

The proposed use of the commercial products may result in exposure to the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities, but significant risks from such exposures are not anticipated due to the low toxicity of the end-use products and adequate exposure mitigation measures recommended on the labels. Loading and mixing is required only for one of the two commercial products. Applicators may be exposed through inhalation of spray drift and also dermally through contact with wet sprayed surfaces. The end-use products have low toxicity by the inhalation route, but may act as respiratory irritants. The end-use products are poorly absorbed through skin; they are not toxic or irritating to skin, but are potential skin sensitizers. Dermal exposure can be mitigated by restricting entry or re-entry to the freshly treated sites until the applied spray is dried. Ocular exposure to the end-use products is likely to cause minimal eye irritation.

#### 3.4.5 Residential Risk Assessment

The proposed use of the domestic products and also commercial products may result in exposure to users and bystanders, but significant risks from such exposures are not anticipated due to the low toxicity of the end-use products and adequate exposure mitigation measures recommended on the labels. Loading and mixing is required only for products using standard hand-held or backpack sprayer application; that is, two domestic end-use products. Applicators may be exposed through inhalation of spray drift and also dermally through contact with wet sprayed surfaces. The end-use products have low toxicity by the inhalation route, but may act as respiratory irritants. Prolonged dermal exposure is not likely and end-use products are poorly absorbed through skin. Exposure to children from direct dermal or hand-to-mouth contact is possible if they were to play on lawns freshly treated with FeHEDTA. Restricting entry or re-entry to the freshly treated sites until the spray has dried can mitigate this exposure.

Exposure reduction statements including the requirement for personal protective equipment and mitigative and hygiene statements on the labels are adequate to protect domestic users and bystanders against any unnecessary risk from residential exposure if label directions are followed.

#### 3.5 Food Residues Exposure Assessment

FeHEDTA products are not applied directly to food. The risk from dietary exposure is considered negligible, so a food residue exposure assessment was not required.

#### 4.0 Impact on the Environment

#### 4.1 Fate and Behaviour in the Environment

FeHEDTA is chemically similar to other iron salts of EDTA such as Ferric sodium EDTA and Ferric EDTA, based on their physical properties relevant to environmental chemistry and fate. In

the terrestrial environment, FeHEDTA is not expected to volatilize under field conditions (i.e from dry, wet or moist surfaces). FeHEDTA is expected to be less stable in alkaline and calcareous soils (pH 7-8) where iron ion is displaced by calcium ion and precipitates as Fe(OH)<sub>3</sub>. FeHEDTA is expected to be rapidly transformed by natural light in water. Based on the proposed use pattern (mode of application, application rate and use areas), the risk for potential leaching and exposure of FeHEDTA to drinking water (surface or ground water) will be low.

Data on the fate and behaviour of FeHEDTA are summarized in Table 3 of Appendix I.

#### 4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

#### 4.2.1 Risks to Terrestrial Organisms

Risk to terrestrial organisms was based upon the evaluation of FeHEDTA toxicity data for the following (Appendix I, Table 4):

- one species of honey bee (oral and contact exposure) representing invertebrates; and
- two bird and one mammal species representing vertebrates (acute and dietary).

The uncertainty factors used in adjusting the toxicity values are summarized in Appendix I, Table 5.

For an assessment of bees, a screening level EEC for acute oral or contact exposure to residues is 62.4 kg FeHEDTA/ha. For bees, the LD<sub>50</sub> values in  $\mu g$ /bee were converted to the equivalent rates in kg/ha by multiplying with 1.12. The converted LD<sub>50</sub> value was 93.7 kg FeHEDTA/ha. The screening level RQ value was <0.66; therefore, negligible risk to honey bees is expected.

For the assessment of birds and small wild mammals, the EEC values for FeHEDTA in potential food items were determined for a direct application immediately after a spray of 59 kg FeHEDTA/ha. The screening level estimated daily exposure (EDE) values were dependent on the body weight of an organism (20, 100, 1000 g for birds and 15, 35, 1000 g for mammals), food preferences (100% small insects for insectivores, 100% fruits for frugivores, 100% grain and seeds for granivores, and 100% leaves and leafy crops for herbivores), and amount consumed on a daily basis. The FeHEDTA toxicity endpoints used were LD<sub>50</sub> >530.4 mg/kg bw for acute exposure and >307.13 mg/kg bw/day for dietary assessment of birds, and LD<sub>50</sub> > 1326 mg/kg bw for acute assessment of small mammals. Most of the screening level and refined RQ values were higher than 1 for birds and small wild mammals due to the high application rate for turf (Appendix I, Table 6 & Table 8). However, based on the limited exposure expected from use on turf, which involves localized foliar treatment using standard hand-held or backpack sprayers, and coarse droplets sprays, the risk to birds and mammals is expected to be minimal.

FeHEDTA, at appropriate rates, is used as a broadleaf herbicide. Thus, precautionary label statements are required to prevent damage to desirable plants.

#### 4.2.2 Risks to Aquatic Organisms

Risks of FeHEDTA to aquatic organisms were based upon the evaluation of FeHEDTA data for the following (Appendix I, Table 4):

- one freshwater invertebrate daphnid species (acute exposure); and
- one freshwater fish species (acute exposure).

The uncertainty factors used in modifying the toxicity values are summarized in Appendix I, Table 5. Where no dose-related effects were observed, the uncertainty factors were not used.

Screening level EEC values for FeHEDTA in water were calculated assuming a reasonable conservative scenario of direct application to water bodies of two different depths (80 cm and 15 cm). The 80-cm water body is chosen to represent a permanent body of water and 15 cm is chosen to represent a seasonal body of water. The pesticide is assumed to be instantaneously and

completely mixed within the water body.

For assessment of fish and aquatic invertebrates, a screening level EEC of FeHEDTA in permanent water body (80-cm water depth) is 7.8 mg/L based on an application rate of 59 kg FeHEDTA/ha, two times per year. All screening level RQ values were <1 (Appendix I, Table 8c). Therefore, there are negligible risks to fish and aquatic invertebrates, on an acute basis.

For assessment of amphibians, a screening level EEC of FeHEDTA in a seasonal water body (15-cm water depth) is 41.6 mg/L based on an application rate of 59 kg FeHEDTA/ha, two times per year. Based on fish toxicity data, RQ values were <1.5 for acute exposure (Appendix I, Table 7) indicating that the level of concern may be exceeded for amphibians.

Available information on the effects of iron in ferric sodium EDTA on non-target organisms indicates that the iron in these chelates interacts with the hemocyanin in the bloodstream of molluses and crustaceans, and would be toxic to these organisms. However, exposure to freshwater molluses and crustaceans as well as amphibians is unlikely to occur given the intended use of FeHEDTA as a broadleaf herbicide applied directly to targeted terrestrial plants.

#### 5.0 Value

### **5.1** Effectiveness Against Pests

#### 5.1.1 Acceptable Efficacy Claims

Efficacy data were submitted from 35 trials conducted in 2005, 2006 and 2007. Nineteen of these trials were conducted in the field in Saanichton, British Columbia (17 trials), Ridgetown, Ontario, and Fresno, California. The remaining 16 trials were conducted in the greenhouse in Saanichton, B.C. The application rates tested varied by trial and included rates from 0.4 to 1.6 g a.i./m². A second application was made 2-4 weeks after the first in 17 of the 35 trials. All greenhouse trials were replicated 4 to 10 times with each treatment-replicate combination consisting of one plant in one pot. Treatments were replicated two or four times in field trials except for two trials that were unreplicated.

In greenhouse trials, applications were made to single plants in single pots by a hand trigger sprayer or a hand pump sprayer. In field trials, application was made by a hand pump sprayer, pressurized pump sprayer, hose sprayer, or hand trigger sprayer. Efficacy was visually assessed from 1 to 42 days after application, or 5-28 days after a second application, and was reported as percent phytotoxicity, percent injury, percent stand reduction, or percent control. The number and timing of evaluations was specific to trial.

The submitted efficacy data conditionally support the efficacy claims summarized in Table 5.1.1 for the NEU1173H products applied at 0.5 - 1.0 g a.i./m<sup>2</sup>. The minimum rate is intended for application to smaller weeds while the maximum rate is intended for application to larger weeds

or more difficult to control perennial weeds. Data were adequate to support a maximum of two applications per season with no less than 4 weeks between applications. Data were adequate to support a rainfast interval of 3 hours.

Table 5.1.1. Weed species for which efficacy claims are conditionally supported for the

NEU1173H products applied at 0.5 - 1.0 g a.i./m<sup>2</sup>.

Pest species or group	Scientific name	Other common names	Life cycle
Claim of control			
Dandelion	Taraxacum officinale	common dandelion	P
English daisy	Bellis perennis	European daisy	P
False dandelion	Hypochaeris radicata	spotted cat's ear, common cat's ear, hairy cat's ear, coast dandelion	P
White clover	Trifolium repens	Dutch clover, creeping white clover	P
Black medic	Medicago lupulina	hop clover	A or B
Bull thistle	Cirsium vulgare	common thistle,	WA, B, or MP
Canada thistle	Cirsium arvense	creeping thistle, field thistle	P
Common chickweed	Stellaria media	chickweed, common starwort	A, WA or SLP
Creeping buttercup	Ranunculus repens	buttercup, creeping crowfoot	P
Slender speedwell	Veronica filiformis	creeping speedwell	P
Narrow-leaved plantain	Plantago lanceolata	English plantain, buckhorn, buckhorn plantain, black plantain, lance-leaved plantain, ribgrass	Р
Dovefoot geranium	Geranium molle	dove's-foot geranium, dove's-foot, crane's-bill, woodland geranium	A, B, or P
Lawn burweed	Soliva pterosperma or S. sessilis	spurweed	WA
Moss	various species		
Algae	various species		
Claim of suppression			
Broadleaf plantain	Plantago major	common plantain, plantain	P

A: annual; WA: winter annual; B: biennial; P: perennial; MP: monocarpic perennial; SLP: short-lived perennial.

### **5.2** Phytotoxicity to Host Plants

## **5.2.1** Acceptable Host Tolerance Claims for the NEU1173H Products

Data were submitted from 11 trials in which the tolerance of turfgrasses to one or two Page 21

applications of the NEU1173H products was evaluated. The tolerance of perennial ryegrass was evaluated in seven greenhouse trials conducted in 2006 and 2007 in Saanichton, British Columbia. The tolerance of established turf to the NEU1173H products was evaluated in three field trials conducted in 2005 and 2006 at Saanichton, B.C., two of which were situated on "Park" turf consisting of about 65% perennial ryegrass and 25% of a mixture of chewings fescue and creeping fescue; the turf species composition in the third trial was unknown. The tolerance of established turf consisting of mainly Kentucky bluegrass with some chewings fescue and perennial ryegrass was evaluated in one field trial conducted in 2005 at Ridgetown, Ontario. There were no studies in which the tolerance of fescue grasses to the NEU1173H products was specifically assessed.

The application rates tested varied by trial and ranged from  $0.5 - 1.0 \, g$  a.i./m<sup>2</sup> in the greenhouse trials and from  $0.56 - 1.66 \, g$  a.i./m<sup>2</sup> in the field trials. A second application was made 2-4 weeks after the first in three greenhouse trials and two weeks after the first in the one field trial that was conducted on turf of unknown species composition.

In greenhouse trials, there were ten pots (replicates) per treatment of perennial ryegrass seedlings from 3.5 - 9 weeks old. Applications were made by a hand trigger sprayer.

In field trials, application was made by a hand pump sprayer (2 trials), hand trigger sprayer (1 trial), or a hose sprayer (1 trial). Treatments were replicated twice in the three field trials conducted at Saanichton and four times in the trial at Ridgetown.

Phytotoxicity was visually assessed from 1 - 43 days after application, or 5 - 21 days after a second application (made 14 - 29 days after the first), and was reported as percent phytotoxicity or percent injury. The number and timing of evaluations was specific to trial.

Overall injury to turf was low and consisted mainly of leaf darkening and some necrosis. These effects had usually diminished by 4 weeks after application in field trials. In greenhouse trials, the low injury initially observed to perennial ryegrass seedlings did not decrease by the last evaluation conducted 2-4 weeks after a first application of 0.4 - 1.0 g a.i./m². In two of the three greenhouse trials, injury to perennial ryegrass one week following a second application of 0.8 or 1.0 g a.i./m² was greater than that observed one week following the first application. In the one field trial in which two applications of 0.8 g a.i./m² was made, injury was greater following the second application.

The submitted tolerance data conditionally support a claim of tolerance for established turf comprised of one or more of Kentucky bluegrass, perennial ryegrass, and fescue treated with 0.5 - 1.0 g a.i./m². The submitted tolerance data are adequate to support a maximum of two applications per season with no less than 4 weeks between applications.

#### 5.3 Impact on Succeeding Crops

Not applicable as the NEU1173H products are for application to established turf.

#### 5.4 Economics

No market analysis was conducted or reviewed for the NEU1173H products.

#### 5.5 Sustainability

#### 5.5.1 Survey of Alternatives

Where manual removal of weedy plants in turf is not considered to be practical, herbicides may be used. The most common conventional herbicides used for broadleaved weed control on turf are those that belong to the synthetic auxin group and include 2,4-D, mecoprop, mecoprop-p and dicamba. In many herbicide-only products as well as in fertilizer-herbicide combination products, 2,4-D is included alone, in combination with mecoprop, or in combination with both mecoprop and dicamba. The spectrum of weeds controlled varies by the herbicide or combination of herbicides included in the product. Products that contain three-way mixtures of 2,4-D, mecoprop, and dicamba, generally include control claims for the greatest number of weed species. Other herbicides, including clopyralid, picloram, triclopyr, and dichlorprop are registered for use on non-crop areas, including roadsides, but are not for use on fine turf.

Interest in alternative turf herbicides is increasing. Corn gluten is a registered 'natural' alternative to synthetic herbicides for domestic and commercial use. Corn gluten may inhibit the seed germination of crabgrass and dandelion when used in conjunction with a sound lawn maintenance program. Acetic acid (e.g. EcoClear) is registered for domestic and commercial use for control of broadleaved weeds in and around the garden, including as a spot application in turf. Potassium salts of fatty acids (e.g. Safer's De-Moss Moss Killer Herbicide) are registered for domestic and commercial use for the control of moss in turf. Ferrous sulfate (e.g. Greenleaf Moss Control) is registered for moss control in turf. No product is registered for the control of algae in turf.

## 5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Cultural measures can be taken to discourage weed infestations, including proper fertilization and watering regimes that encourage development of dense turf thereby inhibiting establishment of weeds, mowing at the correct height (no less than 5 cm) and frequency (removing no more than one-third of biomass), and aerating and dethatching when necessary. Use of the NEU1173H products is compatible with such practices, particularly in that it is applied only when weeds have emerged and is not used as a "preventative" treatment. Patches of broadleaved weeds may be treated with spot applications of the NEU1173H products. Small patches or individual weeds may be treated with the NEU1173H products in the Ready-to-Use format.

## 5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

The excessive level of iron that occurs in susceptible plants treated with the NEU1173H products

is believed to be the result of uncontrolled uptake of iron that is chelated with HEDTA. Development of resistance to uptake of this synthetic iron chelate is not expected.

#### 5.5.4 Contribution to Risk Reduction and Sustainability

The availability of the NEU1173H products provides an alternative herbicide option and mode of action to commonly used herbicides for broadleaved weed control in turf.

## **6.0** Pest Control Product Policy Considerations

#### **6.1** Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, FeHEDTA and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03<sup>1</sup> and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- FeHEDTA does not meet Track 1 criteria, and is therefore not considered a Track 1 substance. See Appendix 1, Table 10 for comparison with Track 1 criteria.
- Transformation of FeHEDTA does not result in any transformation products that meet Track 1 criteria.

#### 6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*<sup>2</sup>. The list is used as described in the PMRA Notice of Intent NOI2005-01<sup>3</sup> and is based on existing policies

<sup>&</sup>lt;sup>1</sup> DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

<sup>&</sup>lt;sup>2</sup> Canada Gazette, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

<sup>&</sup>lt;sup>3</sup> NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

and regulations including: DIR99-03; and DIR2006-02<sup>4</sup>, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

• Technical grade FeHEDTA and the NEU1173H end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02<sup>5</sup>.

## 7.0 Summary

#### 7.1 Human Health and Safety

The available information for FeHEDTA is adequate to qualitatively define the majority of toxic effects that may result from human exposure to FeHEDTA. Overall, FeHEDTA is of low acute toxicity irrespective of the exposure routes. It is not irritating to skin, but minimally irritating to eyes, and is a potential skin sensitizer. Repeated dermal exposure to technical product and associated formulations can result in skin sensitization.

Commercial applicators, loaders, mixers, and those involved in clean-up and maintenance activities, domestic-users, and/or bystanders are not likely to be exposed to levels of FeHEDTA that will result in unacceptable risk when the product formulations are used according to label directions. Children could be exposed to FeHEDTA by direct dermal or hand-to-mouth contact if they were to play on freshly treated lawn surfaces. To minimize this potential for exposure, a restricted entry statement will be added to the product labels prohibiting entry or re-entry to treated areas until the spray has dried. Exposure mitigation measures are adequate to protect human health from residential and occupational exposure. A maximum residue limit was not promulgated because the proposed use is non-food; therefore, exposure from food is unlikely.

#### 7.2 Environmental Risk

Limited environmental risks were identified as a result of the assessment of the proposed use of FeHEDTA. Use of FeHEDTA and the NEU1173H end-use products on turf at the maximum annual application rate is expected to pose negligible acute risk to aquatic and terrestrial organisms. This is due to the limited exposure to the environment resulting from hand-held or backpack sprayers on turf, which use a coarse nozzle size to minimize spray drift. As FeHEDTA does, however, act as a herbicide against broadleaf plants, a precautionary label statement is needed to prevent damage to desirable plants.

<sup>5</sup> DIR2006-02. PMRA Formulants Policy.

<sup>&</sup>lt;sup>4</sup> DIR2006-02, PMRA Formulants Policy.

#### 7.3 Value

The data submitted are adequate to conditionally support the registration of the NEU1173H products for use on established turf consisting of one or more of perennial ryegrass, Kentucky bluegrass, and fescue for control or suppression of several broadleaved weeds, moss, and algae.

The availability of the NEU1173H products provides an alternative herbicide option and mode of action to commonly used herbicides for broadleaved weed control in turf.

#### 7.4 Unsupported Uses

No data were provided to support efficacy claims for the following weed species: heal-all (*Prunella vulgaris*), silver cinquefoil (*Potentilla anserina*), shepherd's purse (*Capsella bursa-pastoris*), Persian speedwell (*Veronica persica*), wild chamomile (*Matricaria chamomilla*), and liverworts (various species), and lichens (various species). No efficacy or tolerance data were provided to support more than two applications per season. Data were insufficient to support use on newly sown turf (turf grass seedlings).

## 8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing 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.

#### List of Abbreviations

μg micrograms
 a.i. active ingredient
 ADI acceptable daily intake
 ARfD acute reference dose
 BAF Bioaccumulation Factor
 BCF Bioconcentration Factor

BW Body weight bw body weight

CAS Chemical Abstracts Service

cm centimetres

 $DT_{50}$  dissipation time 50% (the dose required to observe a 50% decline in

concentration)

dw dry weight

EC<sub>50</sub> effective concentration on 50% of the population

EDE estimated daily exposure

EDTA ethylenediaminetetraacetic acid

EEC estimated environmental exposure concentration  $EC_{25}$  effective concentration on 25% of the population

EP end-use product

ER<sub>50</sub> effective rate for 50% of the population

Fe iron

FeHEDTA hydroxyethylenediaminetriacetic acid, ferric complex

g gram ha hectare(s)

HDPE high-density polyethylene

HEDTA hydroxyethylenediaminetriacetic acid HPLC high performance liquid chromatography

HR<sub>5</sub> 5<sup>th</sup> percentile hazard rate

HRAC Herbicide Resistance Action Committee

IUPAC International Union of Pure and Applied Chemistry

kg kilogram

 $K_d$  soil-water partition coefficient  $K_{oc}$  organic-carbon partition coefficient  $K_{ow}$  n-octanol-water partition coefficient

L litre

LC<sub>50</sub> lethal concentration 50%

LD<sub>50</sub> lethal dose 50%

LOEC low observed effect concentration

m<sup>2</sup> square metre(s) mg milligram mL millilitre

MAS maximum average score MRL maximum residue limit

NOAEL no observed adverse effect level NOEC no observed effect concentration

NOEL no observed effect level
OC organic carbon content
PCPA Pest Control Product Act
dissociation constant

PMRA Pest Management Regulatory Agency

PPE personal protective equipment

ppm parts per million

PRD proposed registration decision RDA recommended dietary allowance

RTU ready-to-use

SSD Species sensitivity distribution

 $t_{1/2}$  half-life

TGAI technical grade active ingredient
TSMP Toxic Substances Management Policy

USEPA United States Environmental Protection Agency

UV ultraviolet

WSSA Weed Science Society of America 2,4-D 2,4-dichlorophenoxyacetic acid

## **Appendix I Tables and Figures**

Toxicology Profile for FeHEDTA (26.52% w/w).\* Table 1

STUDY	SPECIES/STRAIN DOSES	RESULT	TARGET ORGAN,
	DOSES		SIGNIFICANT EFFECTS, COMMENTS
Oral	Rat – Wistar	LD <sub>50</sub> ♀	Low toxicity
Exposure by gavage	3 ♀ rats/dose	> 5000 mg/kg bw	
Limit test	Dosed at 5000 mg/kg bw		
14-day observation			
Dermal	Rat – Wistar	LD <sub>50</sub> ♂ & ♀ > 5000 mg/kg bw	Low toxicity
Limit test, 24-hour	5 rats/sex/dose	> 5000 mg/kg bw	
exposure by topical application.	Dosed at 5000 mg/kg bw		
14-day observation			
Inhalation	Rat – Wistar	LC <sub>50</sub> ♂ & ♀ > 5.43 mg/L	Low toxicity
Limit test, 4-hour	5 rats/sex/dose	> 3.43 Hig/L	Slight breathing abnormalities observed
exposure (nose-only inhalation chamber).	Dosed at 5.43 mg/L		during exposure, and discolouration of fur observed on animals after exposure.
14-day observation			
Eye irritation	Rabbit - New Zealand White	MAS <sup>a</sup> =2.2/110	Minimum III. in the discrete
	$(3 \ )$	MIS $^{b} = 4/110$	Minimally irritating to eye
Draize method.	Dose: 0.1mL; treated eye left	MIS - 4/110	Grade 1 redness of conjunctiva observed in all animals at 1-, 24-, and 48-hour
72-hour observation.	unwashed and observed at 1 hour, 24, 48 and 72 hours post-		observations. Grade 1 chemosis was observed in all animals at 24-hour
	instillation.		observation. Irritation was completely resolved by 72-hour observation.
Dermal irritation	Rabbit - New Zealand White	MAS = 0/8	Non-irritating to skin
4-hour exposure	(3 ♀)	MIS = 0/8	
	Dose: 0.5 mL		
Dermal Sensitization LLNA <sup>c</sup>	Mice: CBA/Ca01aHsd (5♀/group)	Positive results Increase in lymph node	Dermal sensitizer
	Groups: 25% and 50% test substance with vehicle (3:1	weight in 25% and 50% dosage groups with SI <sup>d</sup> more	
	acetone /olive oil), 100% test substance, and vehicle control.	than 3. SI: 3.2 (25%)	
		3.2 (50%) 1.3 (100%)	
		EC3 value was calculated to be at a test item	
		concentration of 33%.	

<sup>\*</sup>Test substance: Neu1173H (26.52% w/w FeHEDTA containing 4.43% w/w iron)

<sup>&</sup>lt;sup>a</sup> MAS = Maximum Average Score for 24, 48, and 72 hrs
<sup>b</sup> MIS = Maximum Irritation Score
<sup>c</sup>LLNA = Local lymph node assay

<sup>&</sup>lt;sup>d</sup>SI = Stimulation index

Table 2 Summary of toxicology from PRD2007-13.

Table 2 STUDY	Summary of toxicology f SPECIES, STRAIN AND DOSES		•
STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
DEDDODUCTION	LAND DEVELOPMENTAL TOYICI	mg/kg bw/day	
	AND DEVELOPMENTAL TOXICI		
Single generation	F <sub>0</sub> : 0, 0.5, 1 and 5% Na <sub>2</sub> EDTA in diet for 12 weeks.	NOAEL 1% Na <sub>2</sub> EDTA	Animals mated once they were 100 days old and 10 days after weaning.
	Rats (number per dose not disclosed)	LOAEL 5% Na <sub>2</sub> EDTA	Diarrhea and o food consumption at 5%.
			Test animals produced normal first and second litters, except at 5%, where dams failed to produce litters
Developmental toxicity	0 and 954 mg of EDTA/kg bw/day in diet for days 7 to 14 of gestation. Administered Na <sub>2</sub> EDTA.	NOAEL < 954 mg of EDTA/kg w/day	Maternal Toxicity  € weight loss (p < 0.001)
	CD rats	LOAEL 954 mg of EDTA/kg bw/day	o food consumption (p < 0.001) Severe diarrhea in all animals
			Fetal Toxicity o fetal weight (p < 0.001)
			f mean percentage of resorptions/litter (p <0.001)
			$\mathfrak{t}$ mean percentage of malformed fetuses/litter (p < 0.001)
			Gross fetal malformations marked by cleft palate, micrognathia, microphthalmia, menigocoele, phocomelia, clubfoot and electrodactyly, umbilical hernia, and short curly tail.
			Internal malformations included great vessel anomalies, interventricular septal defects, small or missing lung lobes, missing thymus, small kidneys with associated hydronephrosis and hydroureter, and small undifferentiated gonads lateral to the kidneys.
			Skeletal malformations included extreme dysplasia, including shortened, missing or wavy ribs, misaligned and fused centra, as well as anomalies associated with external defects. Gross external brain malformations were also noted.
Developmental toxicity	3% (w/w) of Na <sub>2</sub> EDTA in diet from day 6 to 14 of gestation or from day 6 to term. Sprague Dawley rats	Could not identify a NOAEL or LOAEL from the available information.	Addition of 100 ppm zinc to the diet Gross fetal malformations marked by cleft lip and palate, hydrocephalus, anencephalus, hydranencephalus, exencephalus, micro or anophthalimia, micro or agnathia, clubbed legs, fused or missing digits, curly, short or missing tail were noted in a significant portion of the fetuses.
			Addition of 1000 ppm zinc to the diet No fetal malformations observed.
GENOTOXICITY		r	
STUDY	SPECIES and STRAIN or CELL T AND CONCENTRATIONS or DOS		CS .

Gene mutations in bacteria	Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538; E. Coli WP2uvrA Up to 1000 μg/plate without activation Up to 1000 μg/plate with activation GENOTOXICITY	Negative for Na <sub>3</sub> EDTA.
STUDY	SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES	RESULTS
Gene mutations in mammalian cells in vitro	L5178Y TK +/- mouse lymphoma cells 0-5000 µg/ml without activation 0-5000 µg/ml with activation	Negative for Na <sub>3</sub> EDTA.
Gene mutations in mammalian cells in	L5178Y TK +/- mouse lymphoma cells 0–325 µg Fe/mL without activation	Positive for NaFeEDTA.
vitro	0–6.5 μg Fe/mL with activation	Likely due to hydroxyl free radical produced from Fenton reaction of the available iron, not the direct result of NaFeEDTA.

 Table 3
 Fate and Behaviour in the Environment

Property Fate	Test substance		Value Value	Comments	Reference		
rroperty	1 est substance		v alue	Comments	PMRA#		
Biotransformation							
Biotransformation in	FeEDTA	pH 5.7 & 6.1	75-90 %	persistent*	1122092		
aerobic soil	Reaction	r	remaining after 30 d				
Study carried out in	between Fe and						
aerated soil	Na 14C-labeled	pH 6.75	15-20%	slightly			
suspensions from 5	EDTA	Ī	remaining after 30 d	persistent*			
types of soils of				1			
different pHs.		pH 7.3 & 7.85	<5%	non-			
ī		1	remaining after 30 d	persistent*			
Biotransformation in	FeEDTA	pH 6.0		stable	1566548		
anaerobic soil				(no CO <sub>2</sub> was			
			not	produced)			
Study carried out in	Reaction	pH 6.4	transformed				
anaerobic soils from 3	between FeCl <sub>3</sub>						
types of agricultural	salt and	pH 7.4					
soils of different pHs.	[ <sup>14</sup> C]EDTA						
		Mobility	7				
Adsorption /	FeEDTA	K <sub>d-ads</sub>	$K_{d-ads:}$ 0.57	highly	1566532		
desorption in soil		values of K <sub>d</sub>		mobile in			
		were estimated		sand			
Study carried out on		from break-					
Rehovot sand (sand,		through curves					
88%; silt, 5%; clay,		of column					
7%) [pH 7.1 -7.2 ] in		experiments					
Batches equilibrium		No K <sub>oc</sub> was					
studies and column		calculated					
studies. Only results							
from column studies							
were valid.				1			

Table 4 Toxicity to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
					PMRA#

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference PMRA #		
	Terrestrial						
Invertebrates: Bee	Oral	NEU 1173 H <sup>b</sup>	NOEL:12.5 μg FeHEDTA/bee LD <sub>50</sub> : 83.68 μg FeHEDTA/bee	Relatively non-toxic	1566585		
	Contact	NEU 1173 H	NOEC:100 μg FeHEDTA/bee LC <sub>50</sub> >100 μg FeHEDTA/bee	Relatively non-toxic	1566585		
Birds:  Bobwhite quail	Acute	NEU 1173 H	LD <sub>50</sub> >530.4 mg FeHEDTA/kg bw NOEL: 132.6 mg FeHEDTA/kg bw	Slightly toxicity	1566588		
	Dietary	NEU 1173 H	LD <sub>50</sub> > 307.13 mg FeHEDTA/kg bw/day NOEL: 307.13 mg FeHEDTA/kg bw/day	No toxicity at the highest dose	1566589		
Rat	Acute oral	NEU 1173 H	LD <sub>50</sub> > 1326 mg FeHEDTA/kg bw	No toxicity at the highest dose	1566576		
			Aquatic				
Invertebrates: Daphnia magna	Acute	NEU 1173 H	EC <sub>50</sub> > 27.7 mg FeHEDTA/L NOEC: 27.7 mg FeHEDTA/L	No toxicity at the highest concentration	1566586		
Fish: Rainbow trout	Acute	NEU 1173 H	LC <sub>50</sub> > 27.7 mg FeHEDTA/L NOEC: 27.7 mg FeHEDTA/L	No toxicity at the highest concentration	1566587		

<sup>&</sup>lt;sup>a</sup> Atkins et al. (1981) for bees and US EPA classification for others, where applicable b containing 26.52% FeHEDTA.

Table 5 Endpoints used for risk assessment and the uncertainty factors applied

Taxonomic group	Exposure	Endpoint	Uncertainty Factor
Earthworm	Acute	LC <sub>50</sub>	0.5
	Chronic	NOEC	1.0
Bees	Acute	$LD_{50}$	1.0
Other non-target arthropods	Acute	LR <sub>50</sub>	1.0
Birds	Acute oral	LD <sub>50</sub>	0.1
	Dietary	$LD_{50}$	0.1
	Reproduction	NOEL	1.0
Mammals	Acute oral	$LD_{50}$	0.1
	Reproduction	NOEL	1.0
Non-target terrestrial plants	Acute	HR <sub>5</sub> of SSD of ER <sub>50</sub> <sup>6</sup>	1.0
Aquatic invertebrates	Acute	EC <sub>50</sub>	0.5
	Chronic	NOEC	1.0

<sup>&</sup>lt;sup>6</sup> 5<sup>th</sup> percentile hazard rate of the species sensitivity distribution of ER50 values Page 32

Taxonomic group	Exposure	Endpoint	Uncertainty Factor
Fish	Acute	LC <sub>50</sub>	0.1
	Chronic	NOEC	1.0
Amphibians	Acute	Fish LC <sub>50</sub>	0.1
	Chronic	Fish NOEC	1.0
Algae	Chronic	EC <sub>50</sub>	0.5
Aquatic vascular plants	Chronic	EC <sub>50</sub>	0.5

 Table 6
 Screening Level Risk Assessment on Non-target Species

Risks to b	irds and mamr							
Exposure type	Toxicity endpoint	Food guild	In-fie	eld	Off-fie	eld	LOC exceed	ed
	(mg FeHEDTA /kg bw/d)		EDE (mg FeHEDT A /kg bw)	RQ	EDE (mg FeHEDT A /kg bw)	RQ	In- field	Off- field
Small bird	ls (0.02 kg)		1 8 /		•			
Acute	53.04	Insectivore (small insects)	7082.6	133.5	212.4	4.0		
	53.04	Granivore (grain and seeds)	1770.6	33.3	53.1	1.0	Y	es
	53.04	Frugivore (fruit)	3541.3	66.7	106.2	2.0		
Dietary	307.13	Insectivore (small insects)	7082.6	23.0	212.4	0.7	Yes	No
	307.13	Granivore (grain and seeds)	1770.6	5.7	53.1	0.1		
	307.13	Frugivore (fruit)	3541.3	11.5	106.2	0.3		
Medium S	ized Bird (0.11							
Acute	530.4	Insectivore (small insects)	5527.2	104.2	165.8	3.1		Yes
	530.4	Insectivore (large insects)	1381.8	26.0	41.4	0.7		
	530.4	Granivore (grain and seeds)	1381.8	26.0	41.4	0.7	Yes	No
	530.4	Frugivore (fruit)	2763.6	52.1	82.9	1.5		Yes
Dietary	307.13	Insectivore (small insects)	5527.2	17.9	165.8	0.5		No
	307.13	Insectivore (large insects)	1381.8	4.4	41.4	0.1		
	307.13	Granivore (grain and seeds)	1381.8	4.4	41.4	0.1		
	307.13	Frugivore (fruit)	2763.6	8.9	82.9	0.2		
Large Size	ed Birds (1kg)							
Acute	530.4	Insectivore (small insects)	1613.7	30.4	48.4	0.9		
	530.4	Insectivore (large insects)	403.4	7.6	12.1	0.2	_	No
	530.4	Granivore (grain and seeds)	403.4	7.6	12.1	0.2		
	530.4	Frugivore (fruit)	806.8	15.2	24.2	0.4		
-	530.4	Herbivore (short grass)	5767.4	108.7	173.0	3.2	Yes	
	530.4	Herbivore (long grass)	3521.4	66.4	105.6	1.9	1 68	
	530.4	Herbivore (forage crops)	5336.1	100.6	160.0	3.0		Yes
	530.4	Herbivore (leafy foliage)	10869.8	204.9	326.0	6.1		

Exposure Toxicity type endpoint		Food guild	In-fi	eld	Off-fie	eld	LOC exceed	ed
(mg Fel	(mg FeHEDTA /kg bw/d)		EDE (mg FeHEDT A /kg bw)	RQ	EDE (mg FeHEDT A /kg bw)	RQ	In- field	Off- field
Dietary	307.13	Insectivore (small insects)	1613.7	5.2	48.4	0.1		
	307.13	Insectivore (large insects)	403.4	1.3	12.1	0.0		
	307.13	Granivore (grain and seeds)	403.4	1.3	12.1	0.0		No
	307.13	Frugivore (fruit)	806.8	2.6	24.2	0.0		
	307.13	Herbivore (short grass)	5767.4	18.7	173.0	0.5		
	307.13	Herbivore (long grass)	3521.4	11.4	105.6	0.3	1	
	307.13	Herbivore (forage crops)	5336.1	17.3	160.0	0.5		
	307.13	Herbivore (leafy foliage)	10869.8	35.4	326.0	1.0		Yes
Small Man	nmal (0.015 kg	` ' ' '		50		1.0		
Acute	1326	Insectivore (small insects)	4073.6	3.0	122.2	0.1	Yes	
	1326	Granivore (grain and seeds)	1018.4	0.7	30.5	0.0	No No	No
	1326	Frugivore (fruit)	2036.8	1.5	61.1	0.0	Yes	
Medium Si	zed Mammal	<del> </del>	•		•	•	•	•
Acute	1326	Insectivore (small insects)	3571.0	2.7	107.1	0.0	Yes	No
	1326	Insectivore (large insects)	892.7	0.6	26.7	0.0		
	1326	Granivore (grain and seeds)	892.7	0.6	26.7	0.0	No	No
	1326	Frugivore (fruit)	1785.5	1.3	53.5	0.0		1
	1326	Herbivore (short grass)	12762.9	9.6	382.8	0.2		
	1326	Herbivore (long grass)	7792.7	5.8	233.7	0.1	Yes	
	1326	Herbivore (forage crops)	11808.4	8.9	354.2	0.2	_	
	1326	Herbivore (leafy foliage)	24054.2	18.1	721.6	0.5		
Large Size	d Mammal (1)			_	_			
Acute	1326	Insectivore (small insects)	1908.1	1.4	57.2	0.0	Yes	
	1326	Insectivore (large insects)	477.0	0.3	14.3	0.0		1
	1326	Granivore (grain and seeds)	477.0	0.3	14.3	0.0	No	Ma
	1326	Frugivore (fruit)	954.0	0.7	28.6	0.0		No
	1326	Herbivore (short grass)	6819.6	5.1	204.5	0.1		
	1326	Herbivore (long grass)	4163.9	3.1	124.9	0.1	Yes	
	1326	Herbivore (forage crops)	6309.6	4.7	189.2	0.1	1 65	
	1326	Herbivore (leafy foliage)	12852.9	9.7	385.5	0.2		

 Table 7
 Screening Level Risk Assessment on Non-Target Species

	<del>-</del>	Teloff Telogeophicite off	- 10				
Risk to aquatic organisms							
Organism	Exposure	Endpoint value (mg	EEC	RQ	LOC		
		FeHEDTA/L)	(mg FeHEDTA/L)		exceeded		
Freshwater species	Freshwater species						
Daphnia magna	Acute	$EC_{50} \div 2 > 13.85$	7.8	< 0.56	No		
Rainbow trout	Acute	$LC_{50} > 27.7$	7.8	< 0.28	No		
Amphibian	Acute	LC <sub>50</sub> >27.7	41.6	<1.5	Yes		

**Table8** Refined Risk Assessment on Non-Target Species

Table8		ed Risk Assessment of	1 Non-Targ	get Sp	ecies			
Refined F	Risks to birds	and mammals						
Exposure	Toxicity	Food guild	Mean nomogram residues					
type	endpoint		In-field			Off-field		
	(mg		EDE (mg	RQ	LOC	EDE (mg	RQ	LOC
	FeHEDTA		FeHEDTA		exceeded	FeHEDT		exceeded
	/kg bw/d)		/kg bw)			A /kg bw)		
	ls (0.02 kg)	I	T			1		
Acute	53.04	Insectivore (small insects)	2156.1	40.6		64.6	1.2	Yes
	53.04	Granivore (grain and seeds)	460.9	8.6		13.8	0.2	
	53.04	Frugivore (fruit)	921.9	17.3	Vac	27.6	0.5	
Dietary	307.13	Insectivore (small insects)	2156.1	7.0	Yes	64.6	0.2	No
	307.13	Granivore (grain and seeds)	460.9	1.5		13.8	0.0	
	307.13	Frugivore (fruit)	921.9	3.0		27.6	0.1	
Medium S	ized Birds (0.1	` /	1 - 1					
Acute	53.04	Insectivore (small insects)	1682.6	31.7		50.4	0.9	
	53.04	Insectivore (large insects)	359.7	6.7	1	10.7	0.2	1
	53.04	Granivore (grain and seeds)	359.7	6.7	1	10.7	0.2	1
	53.04	Frugivore (fruit)	719.4	13.5		21.5	0.4	No
Dietary	307.13	Insectivore (small insects)	1682.6	5.4	Yes	50.4	0.1	
	307.13	Insectivore (large insects)	359.7	1.1		10.7	0.0	1
	307.13	Granivore (grain and seeds)	359.7	1.1		10.7	0.0	
	307.13	Frugivore (fruit)	719.4	2.3	-	21.5	0.0	-
Lauga Siga	d Birds (1kg)	Flugivore (Hult)	/19.4	2.3		21.3	0.0	<u> </u>
	530.4	Insectivore (small insects)	491.2	9.2		14.7	0.2	No
Acute	530.4	Insectivore (smail insects)	105.0	1.9		3.15	0.2	NO
	530.4	Granivore (grain and seeds)	105.0	1.9	-	3.13	0.0	1
	530.4	Frugivore (fruit)	210.0	3.9		6.3	0.0	1
	530.4	Herbivore (short grass)	1118.0	21.0	Yes	33.5	0.6	1
	530.4	Herbivore (long grass)	627.6	11.8	105	18.8	0.3	
	530.4	Herbivore (forage crops)	962.9	18.1	1	28.8	0.5	
	530.4	Herbivore (leafy foliage)	1961.4	36.9		58.8	1.1	Yes
Dietary	307.13	Insectivore (small insects)	491.2	1.5		14.7	0.0	105
Dietai,	307.13	Insectivore (large insects)	105.0	0.3		3.1	0.0	1
	307.13	Granivore (grain and seeds)	105.0	0.3	No	3.1	0.0	
	307.13	Frugivore (fruit)	210.0	0.6	1	6.3	0.0	
	307.13	Herbivore (short grass)	1118.0	3.6		33.5	0.1	No
	307.13	Herbivore (long grass)	627.6	2.0	Var	18.8	0.0	1
	307.13	Herbivore (forage crops)	962.9	3.1	Yes	28.8	0.0	1
	307.13	Herbivore (leafy foliage)	1961.4	6.3	1	58.8	0.1	1
Small Mar	nmal (0.015 kg							
Acute	1326	Insectivore (small insects)	1240.1	0.9	No	37.2	0.0	
Medium S	ized Mammals							
Acute	1326	Insectivore (small insects)	1087.1	0.8	No	32.6	0.0	
	1326	Frugivore (fruit)	464.8	0.3	110	13.9	0.0	
	1326	Herbivore (short grass)	2474.2	1.8	]	74.2	0.0	No
	1326	Herbivore (long grass)	1388.9	1.0	Yes	41.6	0.0	1
	1326	Herbivore (forage crops)	2130.8	1.6	103	63.9	0.0	]
	1326	Herbivore (leafy foliage)	4340.6	3.2		130.2	0.0	
	d Mammals (1		1	_	, ·			
Acute	1326	Insectivore (small insects)	580.8	0.4	No	17.4	0.0	]
	1326	Herbivore (short grass)	1322.0521	0.9		39.6	0.0	

Refined Risks to birds and mammals								
Exposure	Toxicity	Food guild		N	Iean nomogi	ram residues		
type	endpoint		In-field Off-field					
	(mg		EDE (mg	RQ	LOC	EDE (mg	RQ	LOC
	FeHEDTA		FeHEDTA		exceeded	FeHEDT		exceeded
	/kg bw/d)		/kg bw)			A /kg bw)		
	1326	Herbivore (long grass)	742.1880	0.5		22.2	0.0	
	1326	Herbivore (forage crops)	1138.5844	0.8		34.1	0.0	
	1326	Herbivore (leafy foliage)	2319.3386	1.7	Yes	69.5	0.0	

Table 9 Toxic Substances Management Policy (TSMP) Considerations-Comparison to Toxic Substances Management Policy

		ees management I on	1 *
TSMP Track 1	TSMP Tr	ack 1 Criterion value	Active Ingredient
Criteria			Endpoints
CEPA toxic or CEPA	Yes		Yes
toxic equivalent <sup>1</sup>			
Predominantly	Yes		Yes
anthropogenic <sup>2</sup>			
Persistence <sup>3</sup> :	Soil	Half-life	Not expected to be persistent
		$\geq$ 182 days	
	Water	Half-life	
		$\geq$ 182 days	14 - 56.8 min
		_ ,	
	Sediment	Half-life	< 5 d (aerobic aquatic system)
		$\geq$ 365 days	
	Air	Half-life $\geq 2$ days or	Not expected to be volatile
		evidence of long range	
		transport	
Bioaccumulation <sup>4</sup>	Log K <sub>OW</sub> ≥	<u>5</u>	<0
	BCF ≥ 500	00	Not required
	BAF ≥ 500	00	Not required
Is the chemical a TSMP	Track 1 sub	ostance (all four criteria	No, does not meet TSMP Track 1 criteria.
must be met)?		`	
			I

<sup>&</sup>lt;sup>1</sup>All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (id est, all other TSMP criteria are met).

Figure 1. Structural formulas of EDTA and HEDTA.

<sup>&</sup>lt;sup>2</sup>The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

<sup>&</sup>lt;sup>3</sup> If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met. <sup>4</sup>Field data (exempli gratia, BAFs) are preferred over laboratory data (exempli gratia, BCFs) which, in turn, are preferred over chemical properties (exempli gratia, log K<sub>OW</sub>).

EDTA HEDTA (ethylenediaminetetraacetic acid) (hydroxyethylethylenediaminetriacetic acid)

# References

# A. List of Studies/Information Submitted by Registrant

## 1.0 Chemistry

1.0	Chemsuy
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
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, 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

## 2.0 Human and Animal Health

1566576	2006, Acute oral toxicity limit test with NEU1173H, DACO: 4.6.1.
1566578	2006, Acute dermal toxicity (limit test) with NEU1173H, DACO: 4.6.2.
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.
1753319	2009, MSDS NEU1173H TGAI, DACO: 0.9.
1753320	Dow Chemical Company, 2007, MSDS Versenol 120 Chelating Agent, DACO: 0.9.1.
1753323	Sigma Aldrich, 2006, MSDS Ethylenediamine-N, N-Diacetic Acid, DACO: 0.9.1.
1753351	2009, Binder #3 Addendum, DACO: 4.3.4, 4.5.2, 4.5.4, 4.5.5, 4.8.

1753352	2007, USA EPA DER: Acute Oral Toxicity - Rat, DACO: 4.8.
1753353	2007, USA EPA DER: Acute Dermal Toxicity - Rat, DACO: 4.8.
1753354	2007, Acute (4-hour) Inhalation Toxicity Study with NEU 1173 H in Rats, DACO: 4.8.
1753355	2007, DER: Primary Eye Irritation - Rabbit, DACO: 4.8.
1753356	2007, DER: Primary Dermal Irritation - Rabbit, DACO: 4.8.
1753357	2007, DER: Skin Sensitization - Guinea Pig, DACO: 4.8.
1753358	Candela, E. et.al., 1984, Iron Absorption by Humans and Swine from Fe (III)-EDTA. Further Studies, Candela, E., et al., Iron Absorption by Humans and Swine from FE (111)-EDTA. Further Studies, J. Nutr. 114:2204-2211, 1984., DACO: 4.8.
1753359	Dunkel, V.C, et al, Genotoxicity of Iron Compounds in Salmonella typhimurium and L5178Y Mouse Lymphoma Cells, Environmental and Molecular Mutagenesis 33:28-41 (1999).
1753360	US EPA, 2006, Fifty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator of the EPA; Receipt of Report and Request for Comments; Notice, Environmental Protection Agency, Fifty-Eighth Report of the TSCA Interagency Testing Committee.
1753361	US EPA, 2005, Ferric Sodium EDTA; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food, Environmental Protection Agency.
1753362	Heimbach, J. et. al., 1999, Safety Assessment of Iron EDTA [Sodium Iron (Fe3+) Ethylenediaminetetraacetic Acid]: Summary of Toxicological, Fortification and Exposure Data.
1753363	Kimmel, C.A., 1976, Effect of Route of Administration on the Toxicity and Teratogenicity of EDTA in the Rat, Toxicology and Applied Pharmacology 40, 299-306 (1977).
1753364	McGregor, D.B. et. al., 1988, Responses of the L5178Y tk+/tk- Mouse lymphoma Cell Forward Mutation Assay: III. 72 Coded Chemicals.
1753365	National Cancer Institute, 1977, Bioassay of Trisodium Ethylenediaminetetraacetate Trihydrate (EDTA) for Possible Carcinogenicity, National Cancer Institute, Carcinogenesis, Technical Report Series, No. 11, 1977.
1753366	Oser, B.L. et al, 1962, Safety Evaluation Studies of Calcium EDTA, Toxicology and Applied Pharmacology 5, 142-162 (1963), DACO: 4.8.
1753368	Swenerton, H. and L.S. Hurley, 1971, Teratogenic Effects of a Chelating Agent and their Page 41

	Prevention by Zinc, DACO: 4.8.	
1753369	Munro, I.C., 2005, Sodium Iron EDTA (WHO Food Additives Series 32), DACO: 4.8.	
1753370	Yang, S.S. and M.S. Chan, 1964, Summaries of Toxicological Data: Toxicology of EDTA, Yang, S.S. and M.S. Chan, Summaries of Toxicological Data: Toxicology of EDTA, Fd Cosmet, Toxicol. Vol. 2, pp. 763-767. Pergamon Press 1964, Printed in GB, DACO: 4.8.	
1753380	US EPA, 2008, Iron HEDTA, Biopesticides Registration Action document. DACO: 12.5.2, 12.5.4, 12.5.8, 12.5.9, 2.16, 4.8, 8.6, 9.9.	
1768343	2009, Proposition 65 Assessments: Nitrilotriacetic Acid in Neudorff NEU1173H RTU and NEU1173H Concentrate, DACO: 2.13.4 CBI.	
1768344	2009, Proposition 65 Assessment Neudorff, DACO: 2.13.4 CBI	
1789702	DACO 5.2. (Use description Scenario). Clarification response, Eco-Care Technologies Inc. Saanichton. CA. August-12-2009.	
1789703	DACO 5.2. (Use description Scenario). Clarification response, Eco-Care Technologies Inc. Saanichton. CA. August-12-2009.	
1789690	DACO 5.2. (Use description Scenario). Clarification response, Eco-Care Technologies Inc. Saanichton. CA. August-12-2009.	
1789692	DACO 5.2. (Use description Scenario). Clarification response, Eco-Care Technologies Inc. Saanichton. CA. August-12-2009.	
1789706	DACO 5.2. (Use description Scenario). Clarification response, Eco-Care Technologies Inc. Saanichton. CA. August-12-2009.	

## 3.0 Environment

PMRA#	Reference		
1566526	Anonymous, 1993, Reregistration Eligibility Document, Iron Salts, DACO: 0.17		
1566530	R.T. Belly, J.J. Lauff and C.T. Goodhue, 1975, Degradation of ethylenedieminetetraacetic acid		
	by microbial populations from an aerated lagoon, Applied Microbiology, Vol 26, No. 6 pages 787-794,		
	DACO: 0.17,8.6		
1566532	M. Bucheli-Witschel and T. Egli, 2001, Environmental fate and microbial degradation of		
	aminopolycarboxylic acids, FEMS Microbiology Reviews, Vol 25, DACO: 0.17,8.6		
1566534	R. Frank and H. Rau, 1990, Photochemical Transformation in Aqueous Solution and Possible		
	Environmental Fate of Ethylene diamine tetraacetic acid (EDTA), Ecotoxicology and Environmental		
	Safety, Vol 19, pp 9. DACO: 0.17,8.6		
1566537	F.G. Kari, S. Hilger and S. Canonica, 1995, Determination of the Reaction Quantum Yield for the		
	Photochemical Degradation of Fe(III)-EDTA: Implications for the Environmental Fate of EDTA in		
	Surface Waters, Environmental Science and Technology, Vol 229, pp 10. DACO: 0.17,8.6		

1566538	J.J. Lauff, D.B. Steele, L.A. Coogan and J.M Breitfeller, 1990, Degradation of the Ferric Chelate of		
	EDTA by a Pure Culture of an Agrobacterium sp., Applied and Environmental Microbiology, Vol 56,		
	No 11, pp 8. DACO: 0.17,8.6		
1566540	H.B. Lockhart, Jr., and R.V. Blakeley, 1975, Aerobic Photodegradation of Fe(III)-(Ethylenedinitrilo)		
	tetraacetate (Feric EDTA), Environmental Science and Technology, Vol 9, No 12, pp 4. DACO:		
	0.17,8.6		
1566544	A. Svenson, L. Kaj and H. Bjorndal, 1989, Aqueous photolysis of the iron (III) complexes of NTAS,		
	EDTA and DTPA, Chemosphere, Vol 18, No 9/10, pp 4. DACO: 0.17,8.6		
1566545	V. Sykora, P. Pitter, I. Bittnerova and T. Lederer, 2001, Biodegradability of Ethylenediamine-Based		
	Complexing Agents, Water Research, Vol 35, No 8, pp 8. DACO: 0.17,8.6		
1566546	R.A.P. Thomas, K. Lawlor, M. Bailey and L.E. Macaskie, 1998, Biodegradation of Metal-EDTA		
	Complexes by an Enriched Microbial Population, Applied and Environmental Microbiology, Vol 64,		
	No 4, pp 4. DACO: 0.17,8.6		
1566547	J.M. Tiedje, 1975, Microbial degradation of Ethylenediaminetetraacetate in soils and sediments,		
	Applied Microbiology, Vol 30, No 2, pp 3. DACO: 0.17,8.6		
1566548	J.M. Tiedje, 1977, Influence of Environmental Parameters on EDTA Biodegradation in Soils and		
	Sediments, Journal of Environmental Quality, Vol 6, No 1, pp 6. DACO: 0.17,8.6		
1566566	2004, MSDS Dissolvine H-88X, DACO: 0.9.1		
1566569	2003, MSDS Dissolvine H-FE-4.5, DACO: 0.9.1		
1566583	2008, Part 8 Environmental Chemistry and Fate, DACO: 8.1,8.2,8.2.1,8.2.2,8.2.2.1,8.2.2.2,		
	8.2.2.3,8.2.2.4, 8.2.3,8.4,8.4.1,8.5,8.5.1,8.6		
1566584	2008, Part 9 -Environmental Toxicology:		
	DACO:9.1,9.2.1,9.2.3,9.2.4.1,9.2.4.2,9.2.4.3,9.2.5,9.2.6,9.2.7,		
1566505	9.3.1,9.3.2,9.4.1,9.5.1,9.5.2,9.5.2.1,9.5.2.2,9.5.3,9.6.1,9.6.2.1,9.6.2.4,9.6.2.5,9.6.3,9.7,9.8.1,9.9		
1566585	2007, Assessment of Side Effects of NEU1173H to the Honey Bee, Apis mellifera L. in the Laboratory,		
1566586	DACO: 9.2.4.1,9.2.4.2 2007, Assessment of Toxic Effects of NEU1173H on Daphnia magna using the 48 h Acute		
1300380	Immobilisation Test, DACO: 9.3.2		
1566587	2007, Acute Toxicity Testing of NEU1173H in Rainbow Trout (Oncorhynchus mykiss), DACO:		
1300367	9.5.2.1		
1566588	2007, Avian Acute Oral Toxicity Study of NEU1173H - Bobwhite quail, DACO: 9.6.2.1		
1566589	2007, Avian Dietary Toxicity Study of NEU1173H by Oral Administration via the diet to birds		
	(Bobwhite quail), DACO: 9.6.2.4		
1566590	2008, Part 12 Comprehensive Data Summaries - NEU1173H TGAI, DACO: 12.7		
1753350	Lockhart, Jr., H.B. and R.V. Blakeley, 1975, Aerobic Photodegradation of Fe(III)-(ethylenedinitrilo)		
	tetraacetate (Ferric EDTA) Implications for Natural Waters, DACO 2.16		
1753371	2009, Part 8, Environmental Chemistry and Fate, DACO: 8.6		
1753372	2007, Data Evaluation Record NEU1173H: Fate, Transport and Transformation, DACO: 8.6		
1753373	2007, Binder #5 Addendum - Part 9, Environmental Toxicology, DACO: 9.9		
1753374	2007, Data Evaluation Record NEU1173H (Iron HEDTA) Honeybee Testing, Tier I, DACO: 9.9		
1753375	2007, Data Evaluation Record NEU1173H (Iron HEDTA) Honey bee acute contact toxicity, DACO:		
	9.9		
1753376	2007, Data Evaluation Record NEU1173H: (Iron HEDTA) Aquatic Invertebrate Acute Toxicity,		
	DACO: 9.9		
1753377	2007, Data Evaluation Record NEU1173H (Iron HEDTA) Freshwater Fish Acute Toxicity, DACO:		
	9.9		
1753378	2007, Data Evaluation Record NEU1173H (Iron HEDTA) Avian Acute Oral Toxicity Study, DACO:		
	9.9		
1753379	2007, Data Evaluation Record NEU1173H (Iron HEDTA) Avian Dietary Study, DACO: 9.9		
1753380	2008, Biopesticides Registration Action document, DACO:		
	12.5.2,12.5.4,12.5.8,12.5.9,2.16,4.8,8.6,9.9		

1763724	Lockhart, Jr., H.B. and R.V. Blakeley, 1975, Aerobic Photodegradation of Fe(III)-	
	(Ethylenedinitrilo)tetraacetate (Ferric EDTA), DACO: 2.16	
1768345	Lockhart, Jr., H.B. and R.V. Blakeley, 1975, Aerobic Photodegradation of Fe(III)-	
	(Ethylenedinitrilo)tetraacetate (Ferric EDTA), DACO: 2.16	

#### 4.0 Value

1634529 2008. Binder 4 Value.

1618279 2008. Revised Binder #4: Part 10, Value – EIP.

### **B.** Additional Information Considered

## i) Published Information

## 1.0 Chemistry

Anonymous, Dissolvine Product Guide Akzo Nobel Sept. 2007

#### 2.0 Human and Animal Health

1805169	2007. Encyclopedia of Food Additives; DACO: 4.8 http://www.bizlink.com/foodfiles/PDFs/food_additives_2007.pdf		
1811894	1990, Nitrilotriacetic Acid (NTA), DACO: 4.8		
1811903	Whittaker, P. et al., 2001, Genotoxicity of Iron Chelators in L5178Y Mouse Lymphoma Cells, Environmental and Molecular Mutagenesis 38:347–356 (2001), DACO: 4.8		
1811906	Eaton, J.W. and Qian, M., 2002, Serial Review: Iron and Cellular Redox Status. Guest Editor: Mario Comporti. MOLECULAR BASES OF CELLULAR IRON TOXICITY, Free Radical Biology & Medicine, Vol. 32, No. 9, pp. 833–840, 2002, DACO: 4.8		
1812862	Emerit, J. et al., 2001, Iron metabolism, free radicals, and oxidative injury, Biomed Pharmacother 2001; 55 : 333-9, DACO: 4.8		
1812884	U.S. EPA, 1993, EPA R.E.D. FACTS Iron Salts, DACO: 4.8		
1812895	2009, <a href="http://www.inchem.org/documents/jecfa/jecmono/v18je18.htm">http://www.inchem.org/documents/jecfa/jecmono/v18je18.htm</a> 13/, 571. Iron (WHO Food Additives Series 18) <a href="http://www.inchem.org/documents/jecfa/jecmono/v18je18.htm">http://www.inchem.org/documents/jecfa/jecmono/v18je18.htm</a> 13/, DACO: 4.8		
1812903	http://ijt.sagepub.com/cgi/content/abstract/21/2_suppl/95, Final Report on the Safety Assessment of EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, Disodium EDTA, TEA-EDTA, Tetrasodium EDTA, Tripotassium EDTA, Trisodium EDTA, and HEDTA		

Pra, D et al., 2007, Genotoxicity and mutagenicity of iron and copper in mice, Biometals (2008) 21:289-297, DACO: 4.8

#### 3.0 Value

Romheld, V. and H. Marschner. 1986. Evidence for a Specific Uptake System for Iron Phytosiderophores in Roots of Grasses. Plant Physiol. 80: 175-180.

# NEU1173H RTU WITH PULL'N SPRAY® APPLICATOR

Solution

DOMESTIC READY-TO-USE SELECTIVE HERBICIDE

GUARANTEE: Iron (present as FeHEDTA) 0.25%

Contains 5-chloro-2-methyl-4-izothiazolin-3-one at 0.0007571% and 2-methyl-4-izothiazolin-3-one at 0.0002479%, as preservatives

REG. NO.: 29531 P.C.P. ACT

READ THE LABEL BEFORE USING KEEP OUT OF REACH OF CHILDREN

POTENTIAL SKIN SENSITIZER

**NET CONTENTS: 5 L** 

Registrant:
W. Neudorff GmbH KG
An der Muhle 3, Postfach 1209
D-31860 Emmerthal, Germany
www.neudorff.com

Canadian Agent: Eco-Care Technologies Inc., 8233 Thomson PI, Saanichton, BC V8M 1S1 Telephone: 250-652-5510 For use on lawn turf consisting of one or more of Kentucky bluegrass, perennial ryegrass, and fescue (tall fescue, chewings fescue, and/or creeping fescue) for control or suppression of broadleaf weeds.

#### PESTS/SITES:

Controls the following lawn weeds: Dandelion, English daisy, False dandelion, White clover, Black medic, Bull thistle, Canada thistle, Common chickweed, Creeping buttercup, Slender speedwell, Narrow-leaved plantain, Broad-leaved plantain (suppression only), Dove's-foot geranium, Lawn burweed, Moss, and Algae.

#### With pressure sprayer.

[Text for inside Arrow]

Pull'N Spray® Applicator

#### [ILLUSTRATION #1]

- Remove sprayer from side carrier and unwrap hose completely.
- Insert plug at end of hose into spout on cap <u>until it clicks</u>.
- Flip up spout.

#### **ILLUSTRATION #21**

- Point sprayer away from body.
- Grasp sprayer by the handle.
- SLOWLY pull ring at bottom of sprayer handle until it stops to ready the sprayer.

#### [ILLUSTRATION #3]

Twist nozzle at end of sprayer to adjust spray pattern.

#### [ILLUSTRATION #4]

- Press button on sprayer to begin spraying and hold down for continuous spray.
- Pull ring at sprayer bottom again as needed for additional spraying.

#### **DIRECTIONS FOR USE**

**SHAKE WELL BEFORE USING.** Do not dilute. Follow illustrations and instructions to ready the sprayer. Twist nozzle at end of sprayer to open and adjust spray pattern. Point sprayer away from body and press sprayer button to begin spraying. Pull ring at base of sprayer as needed to continue spraying. Hold down for continuous spray. Spray weeds until foliage is thoroughly wetted, just to the point of run-off. Repeat treatment once in four or more weeks after the first treatment if necessary.

Visible signs of control may be seen within several hours after application. Susceptible weeds, moss or algae will turn brown or black. Occasionally a darkening of the grass leaf blades can occur after treatment; however the grass will recover within a few days to weeks. May stain thatch (dead grass under lawn); this does not affect the health of the grass.

**Use Precautions:** Do not apply to drought stressed grass; ensure lawn is well watered prior to application. Do not apply when the daytime temperature will exceed 30°C. Do not apply to bentgrass. If unsure of grass sensitivity, test spray a small area of your lawn. Apply to established turf only. Do not apply to newly seeded areas or to turf generated from seed and that is less than one year old. Avoid spraying desirable

plants. Any desirable plants or structures accidentally contacted should be rinsed with water. To avoid staining, wait until treated area dries before re-entry. Do not apply if rainfall is expected within 3 hours of application. Do not irrigate within 3 hours of application. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

#### PRECAUTIONS:

CAUTION: KEEP OUT OF REACH OF CHILDREN. Causes slight eye irritation. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, and chewing gum or chewing tobacco. DO NOT get in eyes. Avoid hand-to-mouth contact. Avoid breathing spray mist. Do not re-enter or allow re-entry into treated areas until the spray is dried. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

#### FIRST AID:

If swallowed:

Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control centre or doctor for treatment advice.

If inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.

If in eyes:

Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

#### **TOXICOLOGICAL INFORMATION:**

Treat symptomatically.

#### STORAGE:

Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals. Store unused material, tightly closed, in original container only, away from open flame. Protect from freezing. To prevent contamination store this product away from food or feed.

#### **DISPOSAL:**

Do not reuse empty container. Dispose of empty container with household garbage. Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites.

#### **NOTICE TO USER:**

This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way

that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.



Pull'N Spray® is a registered trademark of OMS Investments, Inc., used under license by Scotts Canada Ltd.

## SELECTIVE BROADLEAF HERBICIDE

Made with iron

People and pets can enter treated area when spray dries.

No unpleasant odor.



**Ministry of the Environment** Pesticides Advisory Committee

P.O.Box 2434 2300 Yonge Street, Suite 1701 Toronto ON M4P 1E4

Tel: 416/314-9235/9230 Fax: 416-314-9237 www.opac.gov.on.ca Ministère de l'Environnement Comité consultative sur les pesticides

C.P. 2434 2300, rue Yonge, Bureau 1701 Toronto ON M4P 1E4

Tél.: 416-314-9235/9230 Téléc.: 416-314-9237 www.opac.gov.on.ca

May 5, 2010

W. Neudorff GmbH KG Germany

Dear Registrant:

This letter is to advise that the following product(s) has been classified by the Director under the Pesticides Act in accordance with Ontario Regulation 63/09:

Reg#	Class	Name
29535	4	Fiesta Lawn Weed Killer
29539	6	NEU117311

This product(s) was classified on April 30, 2010 and effective this date it is legal for sale and use in Ontario. Classified products will be posted on the Ministry of the Environment website: <a href="http://www.ene.gov.on.ca/en/land/pesticides/class-pesticides.php">http://www.ene.gov.on.ca/en/land/pesticides/class-pesticides.php</a> and updated in the ministry's pesticide database.

If you have any questions concerning this decision please contact the Ontario Pesticide Advisory Committee (OPAC) office at 416-314-9230.

Note that section 8 of Ontario Regulation 63/09 requires registrants whose products are classified into Classes 1 to 7 to notify OPAC of any changes in a pesticide's registration or label within 30 days after you were notified of the change by Health Canada's Pest Management Regulatory Agency.

Yours truly,

Douglas Mewett Executive Secretary

Dog Ca Mewell