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RD2008-04

## Registration Decision

# Ferric Sodium EDTA

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# Overview

## Registration Decision for Ferric Sodium EDTA

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, is granting full registration for the sale and use of Safer's Ferric Sodium EDTA Technical, Safer's Slug & Snail Bait II<sup>1</sup> and Safer's Slug & Snail Killer, containing the technical grade active ingredient ferric sodium EDTA to control slugs and snails in greenhouses and outdoors.

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

These products were first proposed for registration in the consultation document<sup>2</sup>: Proposed Registration Decision - *Ferric Sodium EDTA* ([PRD2007-13](#)). This Registration Decision<sup>3</sup> describes this stage of the PMRA's regulatory process for ferric sodium EDTA and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2007-13. This decision is consistent with the proposed registration decision stated in PRD2007-13.

For more details on the information presented in this Registration Decision, please refer to the related Proposed Registration Decision, *Ferric Sodium EDTA* (PRD2007-13), which contains a detailed evaluation of the information submitted in support of this registration.

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

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration.<sup>4</sup> The Act also requires that products have value<sup>5</sup> when used according

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<sup>1</sup> Name change: proposed name, Safer's Slug & Snail Bait (PRVD2007-13) is replaced with Safer's Slug & Snail Bait II.

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

<sup>3</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

<sup>4</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>5</sup> "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

to 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 contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present 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 [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca).

## **What Is Ferric Sodium EDTA?**

Ferric sodium EDTA is a molluscicide used to control slugs and snails in a variety of fruit trees, turf, grasses, vegetables, berries and ornamentals in greenhouses and outdoors. The proposed registration is for one commercial class product and one domestic class product. While the mode of action is not completely understood, it is known that iron salts are toxic to slugs and snails as a contact and stomach poison.

## **Health Considerations**

### **Can Approved Uses of Ferric Sodium EDTA Affect Human Health?**

**Ferric sodium EDTA is unlikely to affect human health when used according to label directions.**

Exposure to ferric sodium EDTA 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 (e.g. 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.

Although the technical grade active ingredient ferric sodium EDTA may cause eye corrosion in animals, given that the end-use products, Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer, are in pellet form and contain only 6% ferric sodium EDTA, a precautionary label statement indicating that contact with eyes must be avoided is sufficient. Ferric sodium EDTA did not cause cancer in animals and was not genotoxic. There was also no indication that ferric sodium EDTA causes damage to the nervous system.

When a similar chemical compound, disodium EDTA, was given to pregnant animals at a very high dose, effects on the developing fetus were observed at doses that were not toxic to the mother. This indicates that the fetus was more sensitive to disodium EDTA than the adult animal. These effects are believed to be the result of binding of the essential mineral zinc to EDTA in the pregnant animals and not directly due to the EDTA. To reduce the potential for exposure of sensitive populations to ferric sodium EDTA, the statement “Avoid hand-to-mouth contact” is required on the product labels.

## **Residues in Water and Food**

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

The acute toxicity of ferric sodium EDTA is low and there is no indication of genotoxicity, short-term or chronic toxicity, carcinogenicity, neurotoxicity, or reproductive toxicity in animal studies.

The overall low toxicity and use of ferric sodium EDTA are such that risks due to exposure of fruits and vegetables in the diet of the general population, including infants and children, are not of concern.

Safer’s Slug & Snail Bait II and Safer’s Slug & Snail Killer are to be applied to soil surface and not directly to water. Therefore, no risk from exposure to ferric sodium EDTA through drinking water is anticipated. As such, a quantitative assessment of residues in drinking water is not necessary.

The use of ferric sodium EDTA is not expected to result in residues that are of toxicological concern. Therefore, the establishment of a Maximum Residue Limit (MRL) is not required for ferric sodium EDTA under section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division B.15.002 of the Food and Drugs Regulations. The Agency is not aware of any country requiring a tolerance for ferric sodium EDTA, nor have any CODEX MRLs been established for any crop. In the U.S., the Environmental Protection Agency has proposed that EDTA chemicals be exempt from the requirement of a tolerance in or on raw agricultural commodities.

## **Occupational Risks From Handling Safer’s Slug & Snail Bait II and Safer’s Slug & Snail Killer**

### **Occupational risks are not of concern when Safer’s Slug & Snail Bait II and Safer’s Slug & Snail Killer are used according to label directions, which include protective measures.**

Farmers and pesticide applicators loading or applying Safer’s Slug & Snail Bait II as well as field workers re-entering freshly treated fields may have direct skin contact with ferric sodium EDTA. Applying Safer’s Slug & Snail Killer for domestic purposes can also result in direct skin contact with ferric sodium EDTA. Therefore, the label specifies that hands should be washed with soap and water after handling Safer’s Slug & Snail Bait II

and Safer's Slug & Snail Killer. Based on this label statement and the expectation that occupational exposure will be brief, these products are not likely to be a concern to farmers, applicators, workers or domestic users.

For bystanders, exposure is expected to be negligible. Therefore, health risks to bystanders are not of concern.

The wheat in Safer's Slug & Snail Killer and Safer's Slug & Snail Bait II may be of concern to individuals with wheat sensitivities. Therefore, the precautionary label statement "Warning, contains the allergen wheat" is required.

## **Environmental Considerations**

### **What Happens When Ferric Sodium EDTA Is Introduced Into the Environment?**

Ferric sodium EDTA is nonpersistent in aerobic soils, although it is relatively stable in anaerobic soils. Ferric sodium EDTA is soluble in water, where it is rapidly degraded by natural light. No major breakdown products are formed in soil and water. Ferric sodium EDTA or EDTA associated with another metal may leach to groundwater under acidic and sandy soil conditions ( $\text{pH} < 5$ ). Based on its low volatility, ferric sodium EDTA is not expected to enter the atmosphere.

Ferric sodium EDTA is ubiquitous in the environment as a result of its widespread use in detergents, pharmaceuticals, food additives, analytical chemistry, textile, metal treatment and agricultural industries. For the use pattern, negligible ferric sodium EDTA will enter the environment as compared to other industrial, agricultural and domestic uses.

Ferric sodium EDTA is expected to pose negligible risk to terrestrial and aquatic organisms under conditions of use.

## **Value Considerations**

### **What Is the Value of Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer?**

**Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer are lower risk alternatives to conventional molluscicides used to control slugs and snails in a variety of vegetable, fruit, grass and ornamental crops in greenhouses and outdoors.**

Safer's Ferric Sodium EDTA Technical is to be used in two end-use products: a new commercial class molluscicide, Safer's Slug & Snail Bait II, and a domestic class molluscicide, Safer's Slug & Snail Killer. Both end-use products are to be applied around various vegetable, fruit, grass and ornamental crops, both in greenhouses and outdoors, to control slugs and snails. The efficacy data demonstrates that slugs and snails can be adequately controlled using Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer at the application rate of 11 to 22 kg product/ha.

## 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 on the labels of Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer to address the potential risks identified in the assessment are as follows.

### Key Risk-Reduction Measures

- **Human Health**

Because there is a concern that users coming into direct contact with ferric sodium EDTA on the hands and then transferring it to the eyes, anyone loading, applying or cleaning up after applying Safer's Slug & Snail Bait II and Safer's Slug & Snail Killer must wash hands with soap and water after handling.

To reduce the potential for exposure of sensitive populations from ingestion of ferric sodium EDTA during hand-to-mouth contact, the product label advises against this type of contact.

### Other Information

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

Any person may file a notice of objection<sup>6</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, [www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html](http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html)) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca)).

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<sup>6</sup> As per subsection 35(1) of the *Pest Control Products Act*.



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### A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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PMRA 1122106	2005, 2.1 to 2.9, N/A, MRID: N/A, DACO: 2.1
PMRA 1122107	2005, 2.11.1 to 2.11.4, N/A, MRID: N/A, DACO: 2.11
PMRA 1122108	2001, Ferric Sodium EDTA (Technical Grade Material) or Dissolvine E-Fe-13 EDTA Series 62, PLT-201, MRID: N/A, DACO: 2.12.1
PMRA 1122109	2001, Ferric Sodium EDTA (Technical Grade Material) or Dissolvine E-FE-13 EDTA 62 Series, PLT-201, MRID: N/A, DACO: 2.13
PMRA 1122110	2002, Ferric Sodium EDTA (Technical Grade Material) or Dissolvine E-FE-13 EDTA 63 Series, PLT-205, MRID: N/A, DACO: 2.14
PMRA 1122111	2003, Ferric Sodium EDTA (Technical Grade Material) - Determination of Storage Stability, 03004, MRID: N/A, DACO: 2.14.14
PMRA 1122112	2005, 2.15 Sample, N/A, MRID: N/A, DACO: 2.15
PMRA 1122113	2002, Volume 11 Active Substance Identity, N/A, MRID: N/A, DACO: 2.16
PMRA 1122114	2002, Volume 12 Active Substance Physical and Chemical Properties, N/A, MRID: N/A, DACO: 2.16
PMRA 1281979	Volume 5 Australian Submission - Sax's Dangerous Properties of Industrial Materials, Eight Edition, Volume II, DACO: 2.16

##### End-use products

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PMRA 1113969	2003, Product Chemistry of Slug & Snail Control q, N/A, MRID: 45848101, DACO: 3.3.1

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## 2.0 Impact on Human and Animal Health

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- PMRA 1122051 Merkel, D.J. (2001) *Primary eye irritation study in rabbits*. Product Safety Labs. Laboratory Study Number 11270, December 6, 2001.
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## 5.0 Value

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## **B.     ADDITIONAL INFORMATION CONSIDERED**

### **I)     Published Information**

#### **1.0    Impact on Human and Animal Health**

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#### **2.0    Impact on the Environment**

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