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Proposed Re-evaluation Decision

PRVD2019-01

Iron (Present as Ferrous Sulfate Monohydrate and Ferrous Sulfate Heptahydrate) and Its Associated End-use Products

Consultation Document

(publié aussi en français)

5 March 2019

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2019-1E (print)
H113-27/2019-1E-PDF (PDF version)

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Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Science Evaluation	1
Proposed Regulatory Decision for Ferrous Sulfate	2
International Context	2
Next Steps.....	2
Additional Scientific Information.....	2
Science Evaluation.....	3
1.0 Introduction.....	3
2.0 The Technical Grade Active Ingredient: Its Properties and Uses.....	3
2.1 Identity of the Technical Grade Active Ingredient.....	3
3.0 Human Health	4
3.1 Toxicological Summary	4
3.2 Occupational Exposure and Risk	4
3.3 Residential and Bystander Exposure and Risk.....	5
3.4 Dietary Exposure and Risk.....	5
3.5 Aggregate Exposure Assessment	6
3.6 Cumulative Assessment	6
4.0 Environment.....	6
4.1 Environmental Fate and Toxicology	6
4.2 Environmental Exposure and Risk Assessment	7
4.2.1 Terrestrial Organisms.....	7
4.2.2 Aquatic Organisms.....	7
5.0 Value	8
6.0 Pest Control Product Policy Considerations	8
6.1 Toxic Substances Management Policy Considerations.....	8
6.2 Contaminants of Health or Environmental Concern	8
7.0 Incident Reports	9
8.0 Conclusion	9
Appendix I Registered Iron present as Ferrous Sulfate Products as of 10 January 2019	11
Appendix II Toxicity Effects of Iron present as Ferrous Sulfate on Terrestrial and Aquatic Organisms.....	12
Appendix III Label Amendments for Products Containing Iron (present as ferrous sulfate monohydrate or heptahydrate)	13
References.....	14

Proposed Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies to all re-evaluations.

Iron present as ferrous sulfate monohydrate or ferrous sulfate heptahydrate (hereafter referred to as ferrous sulfate) is an herbicide used to control the growth of moss in turf and lawns. End-use products are registered for commercial use and are formulated as soluble granules that are applied as either a liquid spray or a watered-in granule to areas of moss infestation.

This document presents the proposed regulatory decision for the re-evaluation of ferrous sulfate and includes the proposed label updates to meet the current standards, as well as the science evaluation on which the proposed decision was based. All products containing ferrous sulfate registered as a pesticide in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received during consultation.

Outcome of Science Evaluation

Both iron and sulfate ions are naturally occurring components of the environment, and ferrous sulfate is one of the few registered active ingredients in Canada for selective control of moss. In addition to pesticide use, ferrous sulfate is registered in Canada as a natural health product.

Ferrous sulfate is considered to be slightly acutely toxic by the oral route, and it is known to irritate the lungs and respiratory tract when inhaled. Ferrous sulfate is considered to be of low acute toxicity by the dermal route, and there is no evidence of carcinogenicity or concerns for developmental and reproductive toxicity.

In general with respect to human health, ferrous sulfate has a low toxicity profile, and when current label directions are followed, potential occupational exposures are not considered to be of concern through the use of ferrous sulfate as an herbicide. Similarly, potential risks are not considered to be of concern for bystanders (such as homeowners and golfers) from use of ferrous sulfate when current label directions are followed. Ferrous sulfate is not registered for use on food crops, and contamination of drinking water sources is not anticipated. When used according to label directions, dietary exposure and risk of ferrous sulfate (following use as an herbicide) through the consumption of food and drinking water is not considered to be of concern for all populations.

Both iron and sulfate ions are naturally occurring components of soil, and ferrous sulfate has a low toxicity profile in non-target species. Based on the use pattern, exposure to non-target organisms is expected to be limited, and the risk to the environment is not considered to be of concern.

Proposed Regulatory Decision for Ferrous Sulfate

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing ferrous sulfate (used as an herbicide) are acceptable for continued registration for use and sale in Canada.

Registered pesticide product labels include specific instructions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of ferrous sulfate, no additional risk mitigation measures are proposed by the PMRA. To meet current labelling standards, the following label updates are proposed (Refer to the details in Appendix III):

- Environmental hazard label statements; and
- Updated restricted-entry interval statement.

International Context

Ferrous sulfate is currently acceptable for use as an herbicide in other Organisation for Economic Co-operation and Development (OECD) member countries, including Australia, Norway, European Union Members, and the United States of America. No decision by an OECD member country to prohibit all uses of ferrous sulfate for health or environmental reasons has been identified.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit comments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document.² The re-evaluation decision document will include the final re-evaluation decision, the reasons for it, and a summary of comments received on the proposed re-evaluation decision along with the PMRA's responses.

Additional Scientific Information

No additional data are required.

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

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

Science Evaluation

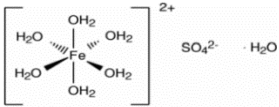
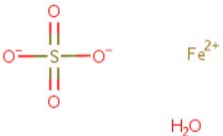
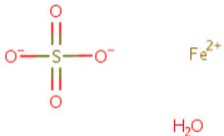
1.0 Introduction

Ferrous sulfate, as an herbicide, offers control of moss in turf and lawns. It is registered as a commercial class product for use on lawns of residential premises and golf courses. Ferric sulfate is formulated into soluble granules and is applied either as a liquid spray or as granules that are watered-in in the spring and fall, when moss is actively growing. Ferrous sulfate can be applied several times per year using a backpack sprayer or granule applicator, and three to four weeks must be allowed before turf and lawns can be re-treated with ferrous sulfate. In Canada, ferrous sulfate is also registered as a natural health product.

Currently registered products are listed in Appendix I.

2.0 The Technical Grade Active Ingredient: Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Ferrous sulfate		
Function	Herbicide		
Chemical Family	Inorganic		
Chemical name			
1 International Union of Pure and Applied Chemistry (IUPAC)	Iron(2+)sulfate Iron(2+) sulfate hydrate (1:1:1) Iron(2+) sulfate hydrate (1:1:7)		
2 Chemical Abstracts Service (CAS)	Sulfuric acid, iron(2+) salt (1:1) Sulfuric acid, iron(2+) salt (1:1), monohydrate Sulfuric acid, iron(2+) salt, heptahydrate (1:1:7)		
Technical Registration No.	23873	23874	23875
CAS Registry No.	Ferrous sulfate heptahydrate : 7782-63-0	Ferrous sulfate monohydrate : 17375-41-6	Ferrous sulfate monohydrate : 17375-41-6
Molecular Formula	FeH ₁₄ O ₁₁ S	FeH ₂ O ₅ S	FeH ₂ O ₅ S
Structural Formula	FeSO ₄ ·7H ₂ O: 	FeSO ₄ ·H ₂ O: 	FeSO ₄ ·H ₂ O: 

3.0 Human Health

Based on the registered use pattern, exposure to iron from ferrous sulfate use as an herbicide can occur through working as a commercial mixer/loader/applicator and/or by entering treated sites as a postapplication worker or bystander. Two key factors are considered when assessing health risks: the levels at which no health effects occur, and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having acceptable health risks.

3.1 Toxicological Summary

Iron is distributed throughout plants and animals, and it is an important biological trace metal. Ferrous sulfate is considered to be slightly acutely toxic by the oral route, and it can irritate the lungs and respiratory tract when inhaled. Ferrous sulfate is unlikely to be absorbed through intact skin in any significant amount (being an inorganic salt) and is thus considered to be of low acute toxicity by the dermal route. Available information indicates that ferrous sulfate is irritating to the skin and potentially corrosive to the eyes. Ferrous sulfate is not considered a dermal sensitizer.

The toxicity of iron salts, such as ferrous sulfate, depends on the amount of bioavailable iron, and for iron to be bioavailable, it must be present or reduced to the ferrous (Fe^{2+}) form. Nonetheless, the uptake of bioavailable (ferrous) iron by humans is tightly regulated (homeostatic control): low iron stores results in increased absorption and sufficient stores results in decreased iron absorption. As such, ferrous sulfate has a low toxicity profile, and in cases of iron deficiency, about 10-60% of iron sulfate is absorbed following oral exposure.

In a short-term (90-days) oral toxicity study in mice, liver and spleen effects (hemosiderosis) have been reported for iron sulfate. In almost all of the long-term oral bioavailable (Fe^{2+}) iron exposure reports in humans, the liver, central nervous system, cardiovascular system, and gastrointestinal tract were identified as target organs. As such, long-term intake of absorbable/bioavailable (Fe^{2+}) iron is likely to present as a blood disorder and/or, in severe cases, liver cirrhosis. No evidence of carcinogenicity from iron exposure exists, and no concerns for developmental toxicity were identified in the available information.

Given the low toxicity profile of ferrous sulfate, no toxicological endpoints have been established for quantitative risk assessment by the PMRA. As a result, the PMRA has used a qualitative approach to assess the potential risks of ferrous sulfate to human health.

3.2 Occupational Exposure and Risk

Ferrous sulfate end-use products are applied as a ground-directed spot treatment on moss problem areas of lawns and turf using either a backpack sprayer for liquid application or a granular spreader followed by watering-in for granular application.

Workers can be exposed to ferrous sulfate through mixing, loading, applying, and/or through clean up and maintenance activities. Workers can also be exposed to residues when entering a treated site to conduct postapplication activities such as turf maintenance (lawn mowing).

Based on current label directions, mixer/loader/applicator exposure is expected to be primarily via the dermal and inhalation routes (limited to the spring and fall months when moss is actively growing). Exposure to the eyes from dust or spray mist is also possible. Nonetheless, exposure to ferrous sulfate from the current use pattern is expected to be limited due to adequate personal protection equipment requirements (for example, wearing a long sleeved shirt and pants, rubber or nitrile gloves, safety goggles, dust mask, shoes, and socks) and mitigative statements present on the current end use product label (for example, “Wash exposed skin with soap and water after use”). On this basis and combined with the low toxicity profile of ferrous sulfate, the risk for workers mixing, loading, applying, and/or performing clean up or maintenance activities are considered to be acceptable. No additional mitigation measures are proposed.

Postapplication and re-entry tasks for workers may include scouting, gardening, mowing, and/or weeding, and dermal exposure is considered to be the primary postapplication exposure route. Exposure to re-entry workers is expected to be minimal given that (1) the current label indicates to allow treated surface to dry before re-entry is acceptable; (2) treatment of large areas on lawn and/or turf is not likely (since moss grows mainly in shaded areas); and (3) being an inorganic salt, ferrous sulfate is unlikely to be absorbed through intact skin in significant amounts. Combined with the low toxicity profile of ferrous sulfate, the risk for workers re-entering treated areas is considered to be acceptable. No additional mitigation measures are proposed.

To meet the current standard, updates to labels related to the re-entry interval are proposed (Appendix III).

3.3 Residential and Bystander Exposure and Risk

Homeowners and bystanders can be exposed to iron (present as ferrous sulfate) through entering a residential treated lawn for various activities such as gardening, mowing, or enjoying the area (general walking, children and pets playing). Following application to golf course turf, golfers can also be exposed when entering the treated site to play golf. Dermal contact in treated areas is expected to be the prominent exposure route. Minimal exposure to homeowners and bystanders is expected as current label directions include measures to minimize drift while applying the product as a liquid, and, when applying the product as a granule, exposure is minimized through watering in of the product following application. As such, residential and bystander exposure is expected to be equivalent to or less than occupational re-entry exposure. Based on the above considerations, the potential risk is considered to be acceptable for all populations with the current label directions. No additional mitigation measures are proposed.

3.4 Dietary Exposure and Risk

Both iron and sulfate ions are naturally occurring components of the environment, and iron is a normal constituent of the human diet. Based on the current use pattern, ferrous sulfate herbicidal end-use products are not registered for use on any food crops. As well, ferrous iron is not expected to run-off or leach into drinking water sources because, in soil, it rapidly oxidizes into

iron oxides and hydroxides and is expected to be strongly adsorbed to soil. As such, drinking water exposure is expected to be negligible when end-use products are used according to current label directions. On this basis, dietary risk from both food and drinking water is considered to be acceptable for all populations. No additional mitigation measures are proposed.

3.5 Aggregate Exposure Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal, and inhalation). As exposure from food and drinking water is expected to be negligible, aggregate exposure is limited to residential bystander exposure. However, given the limited exposure potential and combined with the low toxicity profile of ferrous sulfate, aggregate exposure is considered to be acceptable for all populations under the current conditions of use.

3.6 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. While ferrous sulfate may share a common moiety with other iron-based active ingredients, the potential risks from cumulative exposure to ferrous iron are considered to be acceptable given the low toxicity profile and the limited exposure potential.

4.0 Environment

Ferrous sulfate will enter the environment through application to lawns and turf, and there is a potential that non-target terrestrial and aquatic habitats may be exposed to the herbicide as a result of application.

4.1 Environmental Fate and Toxicology

When released into the environment, ferrous sulfate dissociates in soil to ferrous and sulfate ions, and both ions are naturally occurring components of terrestrial ecosystems. Ferrous ions rapidly oxidize to ferric (Fe^{3+}) ions in the environment and these are strongly adsorbed to soil. As such, minimal run-off and leaching of ferrous sulfate to aquatic systems is expected.

Current directions on end-use product labels recommend application of ferrous sulfate only to areas of moss infestation. Since moss grows mainly in shaded, damp areas, application is expected to be limited and through controlled spot treatment. Iron ions are naturally occurring components of the environment, and when current label directions are followed, the amount of ferrous ions that would be released in the environment following application, in general, is considered insignificant to the chemistry and fate of iron-based compounds that are naturally present.

Ferrous sulfate is relatively non-toxic to earthworms, birds, fish, and aquatic invertebrates. Relevant toxicity data from the review of ferrous sulfate to non-target species are summarized in Appendix II.

4.2 Environmental Exposure and Risk Assessment

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 are concentrations of pesticide in various environmental media, such as food, water, soil and air. The estimated environmental exposures 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 (in other words, 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 (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient is calculated by dividing the exposure estimate by an appropriate toxicity value (risk quotient = exposure/toxicity), and the risk quotient is then compared to the level of concern. 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 may be 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.

4.2.1 Terrestrial Organisms

The screening-level terrestrial risk assessment evaluated exposure to birds and earthworms using maximum Canadian application rates. Considering the registered use pattern (for example, localized treatment to infested areas using backpack sprayers and/or application of granules that are thoroughly watered-in), limited exposure to terrestrial organisms is expected. Combined with the relatively non-toxic nature of ferrous sulfate (Appendix II), the risk to terrestrial organisms is considered to be acceptable.

No additional risk mitigation measures are proposed.

4.2.2 Aquatic Organisms

The screening-level risk assessment evaluated exposure to freshwater invertebrates, algae, vascular plants, freshwater fish, and amphibians using maximum Canadian application rates. Based on the current use pattern (for example, localized treatment using a backpack sprayer or application of granules that are thoroughly watered-in), minimal exposure to the aquatic environment via spray drift and/or run-off is expected. Combined with the relatively non-toxic nature of ferrous sulfate (Appendix II), the potential risk to aquatic organisms from use of

ferrous sulfate as an herbicide is considered to be acceptable. No additional risk mitigation measures are proposed.

Updates to labels to meet the current labelling standard for run-off are proposed (Appendix III).

5.0 Value

Ferrous sulfate has value in that it is one of only a few registered active ingredients in Canada used to immediately alleviate moss infestation on turf sites. Furthermore, it is one of the few products available for selective control of moss in turf and lawns. Combined with measures to eliminate conditions which favour moss growth, ferrous sulfate has value in playing a vital role to control or eliminate moss infestation and to create permanent, healthy turf and lawns.

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, in other words, those that meet all four criteria outlined in the policy: 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*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, ferrous sulfate was assessed in accordance with the PMRA Regulatory Directive DIR99-03³ and evaluated against the Track 1 criteria. Ferrous sulfate does not meet all the Track 1 criteria and is not considered a Track 1 substance.

6.2 Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient 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*.⁴ The list is used as described in the PMRA Notice of Intent NOI2005-01⁵ and is based on existing policies and regulations including DIR99-03 and DIR2006-02,⁶ and taking into

³ DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the *Toxic Substances Management Policy*

⁴ *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.*

⁵ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act*.

⁶ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

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:

- Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.
- Other impurities (heavy metals) are not expected to be present at levels of health or environmental concern in ferrous sulfate.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and DIR2006-02.

7.0 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. As of 10 January 2019, the PMRA had received three domestic animal incidents involving ferrous sulfate. No human or environment incidents involving ferrous sulfate were submitted to the PMRA.

One domestic animal incident was considered to be related to the reported pesticide. In this incident, a dog experienced bloody diarrhea and vomiting after ingesting a ferrous sulfate product, which is no longer registered for use in Canada. The pet had access to the product bag resulting in exposure.

The labels of the ferrous sulfate products currently registered in Canada do contain a storage statement requiring the product to be stored away from children and pets, and no additional mitigation measures are recommended based on the incident report review.

8.0 Conclusion

Both iron and sulfate ions are naturally occurring components of the environment. Ferrous sulfate has value in that it is one of few registered active ingredients in Canada for selective control of moss in turf grass.

With respect to human health, ferrous sulfate has a low toxicity profile in humans, and when current label directions are observed, the potential human health risk from its use as a herbicide is considered acceptable for all populations. Based on the use pattern, significant exposure to non-target organisms is not expected, and the risk is considered acceptable under the current conditions of use.

On this basis, Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act and Regulations*, is proposing continued registration of herbicidal products containing ferrous sulfate for sale and use in Canada.

Updates to label directions and precautions are being proposed to meet the current labeling standards and for consistency.

Appendix I Registered Iron present as Ferrous Sulfate Products as of 10 January 2019

Registration No.	Marketing Class	Registrant	Product Name	Formulation	Active Ingredient
23866	Manufacturing	Loveland Products Canada Inc.	EVERGRO FERROUS SULFATE	Granular	Ferrous Sulfate, 85%
23873	Technical	QC Corporation	FERROUS SULFATE HEPTAHYDRATE	Solid	Ferrous Sulfate, 55%
23874	Technical	QC Corporation	FERROUS SULFATE MONOHYDRATE	Solid	Ferrous Sulfate, 85%
23875	Technical	Scotts Canada Ltd	FERROUS SULFATE (FOR MANUFACTURING, FORMULATING, OR REPACKAGING)	Solid	Ferrous Sulfate, 53%
23876	Manufacturing	Premier Tech LTD.	WILSON MOSSOUT FERROUS SULFATE	Granular	Ferrous Sulfate, 54%
31162	Commercial	TerraLink Horticulture Inc.	RICHGROW MOSS CONTROL	Soluble Granules	Ferrous Sulfate, 55%
33026	Commercial	TerraLink Horticulture Inc.	RICHGROW MOSS CONTROL BROADCAST GRADE	Granular	Iron (present as ferrous sulfate monohydrate), 85%

Appendix II Toxicity Effects of Iron present as Ferrous Sulfate on Terrestrial and Aquatic Organisms

Organism	Exposure	Endpoint / Toxicity
Invertebrates		
Earthworm	14 d-Acute	LC ₅₀ > 7000 mg a.i./kg soil
Birds		
Bobwhite quail (<i>Colinus virginianus</i>)	Acute oral	LD ₅₀ : > 2250 mg a.i./kg bw
	Acute dietary	LC ₅₀ : > 5620 mg a.i./kg diet
Freshwater species		
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Acute	LC ₅₀ = 82.4 mg a.i./L.
Daphnia (<i>Daphnia pulex</i>)	Acute	EC ₅₀ = 57 mg a.i./L
Duckweed (<i>Lemna gibba</i>)	7 day (semistatic)	EC ₅₀ > 189 mg a.i./L (Biomass, growth rate, frond number)
Algae (<i>Anabaena variabilis</i>)	96 hour (static)	EC ₅₀ = 66.2 mg a.i./L (biomass)

Appendix III Label Amendments for Products Containing Iron (present as ferrous sulfate monohydrate or heptyhydrate)

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

FOR ALL END-USE PRODUCT LABELS:

I) Under **PRECAUTIONS:**

Replace “DO NOT allow entry into treated areas until the surface is dried.” with “DO NOT enter or allow worker entry into treated areas until sprays have dried.”

II) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS.**

“To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.”

“Avoid application when heavy rain is forecast.”

“Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.”

ON END-USE PRODUCT LABEL 31162:

I) On the principal display panel:

Replace “KEEP OUT OF REACH OF CHILDREN.” with “KEEP OUT OF REACH OF CHILDREN AND PETS.”

II) Under **PRECAUTIONS:**

Replace “KEEP OUT OF REACH OF CHILDREN.” with “KEEP OUT OF REACH OF CHILDREN AND PETS.”

References

I) LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT(S)

UNPUBLISHED

PMRA Document Number	Reference
2756789	2017, DACO 2.11 - Manufacturing Method [CBI Removed], DACO: 2.11 CBI
2756790	2017, DACO 2.11 - Manufacturing Method [CBI Removed], DACO: 2.11 CBI
2773282	2017, Preliminary Analysis of Ferrous Sulfate Monohydrate, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2773283	2017, Preliminary Analysis of Ferrous Sulfate Heptahydrate, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2756791	2016, DACO 2.13.3 - Batch Data [CBI Removed], DACO: 2.13.3 CBI
2756792	2017, DACO 2.13.3 - Batch Data [CBI Removed], DACO: 2.13.3 CBI
2756794	2017, DACO 2.13.4 - Impurities [CBI Removed], DACO: 2.13.4 CBI
2756793	2016, DACO 2.13.4 - Impurities [CBI Removed], DACO: 2.13.4 CBI
1806603	Product Chemistry, Manufacturing Method, Specifications, Quality Control Method, Analytical Data and Method, Chemical and Physical Properties. Appendix A - Laboratory Reports, Appendix B - Testing Methods, Analytical Data Monohydrate and Heptahydrate, DACO: 2.1,2.11.1,2.12,2.13,2.14.1,2.14.13,2.14.14,2.14.2,2.14.3,2.14.6,2.14.7,2.2,2.3,2.5, 2.6,2.7,2.8,2.9
2834934	2017, DESCRIPTION OF STARTING MATERIALS, DACO: 2.11.2 CBI
2834935	2017, MANUFACTURING SUMMARY, DACO: 2.11.1,2.11.2,2.11.3 CBI
2911529	2018, CONFIRMATION OF IDENTITY, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2941795	2018, BATCH DATA, DACO: 2.11.2,2.13.3 CBI
2773282	2017, ESTABLISHING CERTIFIED LIMITS, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2773283	2017, ESTABLISHING CERTIFIED LIMITS, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2852128	2018, MANUFACTURING SUMMARY, DACO: 2.11.1,2.11.2,2.11.3 CBI
2852129	2015, DESCRIPTION OF STARTING MATERIALS, DACO: 2.11.2 CBI

II) ADDITIONAL INFORMATION CONSIDERED**PUBLISHED**

PMRA Document Number	Reference
2315953	Evaluation Report for Category B, Subcategory 2.1, 3.1, 3.14, 3.4 Application
2854061	Evaluation Report for Category B, Subcategory 2.1, 3.1 Application
1174775	RE-REGISTRATION ELIGIBILITY DOCUMENT (RED), IRON SALTS, EPA, R.E.D. FACTS, APPENDICES, AND ATTACHMENTS (738-S-93-001;738-F-93-002;CASE 4058)