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RD2009-03

## Registration Decision

# Ammonium Soap of Fatty Acid

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## Registration Decision for Ammonium Soap of Fatty Acid

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 Finalsan TGAI and two associated end-use products, Finalsan Concentrate and Finalsan Ready-to-Use, containing the technical grade active ingredient ammonium soap of fatty acid to control weeds, moss and algae in a variety of domestic sites.

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

These products were first proposed for registration in the consultation document<sup>1</sup>: Proposed Registration Decision PRD2008-12, *Ammonium Soap of Fatty Acid*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for ammonium soap of fatty acid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-12. This decision is consistent with the proposed registration decision stated in PRD2008-12.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2008-12, *Ammonium Soap of Fatty Acid*, that contains a detailed evaluation of the information submitted in support of this registration.

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

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

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

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

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

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

<sup>4</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."

environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at [www.hc-sc.gc.ca/cps-spc/pest/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php).

## **What is Ammonium Soap of Fatty Acid?**

Ammonium soap of fatty acid is a non-selective contact herbicide that does not translocate through the plant. The exact mechanism of necrosis is not completely understood, but it appears that ammonium soap of fatty acid causes a sudden drop in intracellular pH, which results in a loss of membrane integrity and rapid cell death.

## **Health Considerations**

### **Can Approved Uses of Ammonium Soap of Fatty Acid Affect Human Health?**

**Ammonium soap of fatty acid is unlikely to affect your health when used according to label directions.**

Potential exposure to ammonium soap of fatty acid may occur when handling and applying the products. When assessing health risks, two key factors are considered: the levels at which 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.

The technical grade active ingredient, ammonium soap of fatty acid, may cause eye irritation in animals. This warrants the signal words "WARNING—EYE IRRITANT" on the label of the end-use product Finalsan Concentrate and requires that goggles or a face shield be worn to avoid contact with eyes. The end-use product Finalsan Ready-to-Use contains a concentration of active ingredient that does not require goggles or a face shield.

Data on the specific technical grade active ingredient were limited; however, literature was available on similar compounds that did not indicate hazards that would be expected with the proposed use.

### **Residues in Water and Food**

**Dietary risks from ammonium soap of fatty acid on food are not of concern.**

Finalsan Concentrate and Finalsan Ready-to-Use are not applied directly to food, so residues on food are expected to be negligible.

## **Risks in Residential and Other Non-Occupational Environments**

**Residential risks are not of concern when Finalsan Concentrate and Finalsan Ready-to-Use are used according to label directions, which include protective measures.**

Residential exposure to individuals mixing or applying the product is not expected to result in unacceptable risk when Finalsan Concentrate or Finalsan Ready-to-Use is used according to label directions.

## **Environmental Considerations**

### **What Happens When Ammonium Soap of Fatty Acid Is Introduced Into the Environment?**

**Environmental risk associated with the use of ammonium soap of fatty acid is expected to be negligible.**

Ammonium soap of fatty acid is non-persistent in aerobic soil and water. Under environmental conditions, fatty acids are expected to adsorb onto soil where they are rapidly biotransformed into carbon dioxide and water. Ammonium soap of fatty acid is therefore not expected to leach to groundwater.

Ammonium soap of fatty acid presents a negligible risk to wild mammals, birds, bees, fish and earthworms. As expected for a herbicide, ammonium soap of fatty acid is toxic to freshwater algae and aquatic plants. Based on the use pattern, however, a negligible amount of ammonium soap of fatty acid is expected to enter aquatic systems; therefore, risk to aquatic organisms is expected to be negligible.

## **Value Considerations**

### **What Is the Value of Finalsan Concentrate and Finalsan Ready-to-Use?**

**Finalsan Concentrate and Finalsan Ready-to-Use are contact herbicides for domestic use in the control of weeds, moss and algae.**

Ammonium soap of fatty acid, formulated as Finalsan Concentrate Herbicide (22.10%) and Finalsan Ready-to-Use Herbicide (3.68%), is a contact herbicide that controls weeds within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel; and for the control of moss and algae around and on buildings, roofs, decks, sidewalks, fences, bark mulch, driveways, patios and gravel.

## Measures to Minimize Risk

Registered pesticide product labels 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 Finalsan Concentrate and Finalsan Ready-to-Use to address the potential risks identified in this assessment are as follows:

### Key Risk-Reduction Measures

#### Human Health

As there is concern of eye irritation, users must avoid getting the product/mist in their eyes. Goggles or a face shield (protective eyewear) are required during mixing/handling of the active ingredient and Finalsan Concentrate. To avoid inhaling/breathing mist, the product must be used only in well ventilated areas.

#### Environment

The labels indicate not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

### Other Information

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

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the 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>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.

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## References

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

#### 1.0 Chemistry

<b>PMRA Document Number</b>	<b>Reference</b>
1280517	2006, Binder 2 Part 2 Chemistry Requirements, 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.
1280518	2006, CBI Reference Document to Binder 2, DACO: 2.11.2, 2.11.3, 2.12.1 CBI
1280519	2005, Storage Stability of NEU1170H SL, DACO: 2.14.14
1406267	2007, Revised Binder 2 RTU, DACO: 2.0, 2.1, 2.10, 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
11286764	2006, Binder #2 Part 3 Product Chemistry, Binder #2, MRID: 444830-01, 444830-02, 444830-03, 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.
1286765	2002, Storage Stability of NEU1170H, NEU1170-990409, DACO: 3.5.10
1286766	1998, Product Chemistry Review of EP, DACO: 3.7
1404858	2007, Revised Binder 2 Concentrate, 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, 3.7
1286829	2006, Binder #2 Part 3 Product Chemistry, Binder #2, MRID: 443656-01, 443656-02, 443656-03, 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.
1286830	2006, CBI Reference Document to Binder 2, CBI to Binder 2, MRID: 443656-01, 443656-02, DACO: 3.2.1, 3.2.2, 3.3.1 CBI

- 1286831 2002, Storage Stability of NEU1170H RTU, NEU1170RTU 96-923, DACO: 3.5.10
- 1286832 1998, Product Chemistry Review of EP, DACO: 3.7
- 1404870 2007, Revised Binder 2 RTU, 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, 3.7

## 2.0 Human and Animal Health

PMRA Document Number	Reference
1280521	Assessment of Acute Oral Toxicity with NEU 1170 H in the Rat. Report number: 197009. NOTOX Project 197009. DACO 4.2.1.
1280522	Assessment of Acute Dermal Toxicity with NEU 1170 H in the Rat. Report number: 197011. NOTOX Project 197011. DACO 4.2.2.
1280523	4-Hour Acute Inhalation Toxicity Study with NEU 1170 H in Rats. Report number: 97 10 42 026. DACO 4.2.3
1280524	NEU 1170 H 21% Acute Eye Irritation/Corrosion- First Amendment. Report number: 97 10 42 803 B. DACO 4.2.4
1280525	NEU 1170 H 22%ig Acute Eye Irritation/Corrosion- Second Amendment. Report number: 97 10 42 803 B. DACO 4.2.4
1280526	Acute Eye Irritation/Corrosion NEU 1170 H 21%. Report number: 97 10 42 803 B. DACO 4.2.4
1280528	Acute Dermal Irritation/Corrosion NEU 1170 H 21% ig. Report number: 97 10 42 803 A. DACO 4.2.5
1280529	Assessment of Contact Hypersensitivity to NEU 1170 H in the Albino Guinea Pig (Maximisation-Test). Report number: 274591. NOTOX Project 274591. DACO 4.2.6
1286838	Acute Eye Irritation/Corrosion Study with NEU 1170 H RTU in the Rabbit. Report number: 207934. DACO 4.6.4.



1286842 Primary Skin Irritation/Corrosion Study with NEU 1170 H RTU in the Rabbit (4-Hours Semi-Occulsive Application). Report number: 207934. Project 207923. DACO 4.6.5

### 3.0 Environment

PMRA Document Number	Reference
1280533	2006, Binder 5 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, 8.2.3.1, 8.2.3.2, 8.2.3.3, 8.2.3.3.1, 8.2.3.3.2, 8.2.3.3.3, 8.2.3.4, 8.2.3.4.2, 8.2.3.4.4, 8.2.3.5, 8.2.3.5.2, 8.2.3.5.4, 8.2.3.5.6, 8
1280534	1990, Testing the biological degradability of Neudosan in two soils, DACO: 8.2.3.4.2
1280535	2002, Ready Biodegradability of Pelargonic Acid in a Manometric Respirometry Test, 14737160, DACO: 8.2.3.4.2
1280536	2006, Binder 6 Part 9 Environmental Toxicology, DACO: 9.1, 9.2, 9.2.1, 9.2.3, 9.2.4, 9.2.4.1, 9.2.4.2, 9.2.4.3, 9.2.5, 9.2.6, 9.2.7, 9.3, 9.3.1, 9.3.2, 9.3.3, 9.4, 9.4.1, 9.5, 9.5.1, 9.5.2, 9.5.2.1, 9.5.2.2, 9.5.3, 9.5.3.1, 9.6, 9.6.1, 9.6.2, 9.6.2.1, 9.6.2.4, 9.6.2.5, 9
1280537	1998, Acute Toxicity of NEU1170H on Earthworms, <i>Eisenia foetida</i> , Using an Artificial Soil Test, 97253/01-NLEf, DACO: 9.2.3
1280538	1998, Assessment of Side Effects of NEU1170H to the Honey Bee, <i>Apis mellifera</i> L. in the Laboratory, 97253/01-BLEU, DACO: 9.2.4.1, 9.2.4.2
1280539	1998, Acute Immobilization Test Daphnia - <i>Daphnia magna</i> , 98 10 48 039, DACO: 9.3.2
1280540	1999, Acute Toxicity Testing of NEU1170H in Rainbow trout ( <i>Oncorhynchus mykiss</i> ), 99024/01-AAOm, DACO: 9.5.2.1
1280541	1999, Acute Toxicity Testing of NEU1170H in Golden Ite ( <i>Leuciscus idus</i> ), 99024/01-AALi, DACO: 9.5.2.2
1280542	1999, 28-Day prolonged toxicity test of NEU1170H in Rainbow Trout ( <i>Oncorhynchus mykiss</i> ), 99024/01-ACOm, DACO: 9.5.3.1

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- 1280543 1997, 5-Day Dietary Toxicity Study in Bobwhite Quail with Neudosan NEU, 185085, DACO: 9.6.2.1
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- 1280545 2003, Avian Dietary Toxicity Test of NEU1170H in the Japanese Quail, 10-16-0146-03, DACO: 9.6.2.4
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- 1280550 1999, Assessment of Toxic Effects of NEU1170H on Aquatic Plants using the Duckweed *Lemna gibba*, 99024/01-AALg, DACO: 9.8.5
- 1406268 2007, Binder #5 - Addendum, DACO: 8.1, 8.2.3, 8.2.3.1
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- 1406273 H.C. Reeves et. al., 1967, Fatty Acid Synthesis and Metabolism in Microorganisms, DACO: 8.1, 8.2.3, 8.2.3.1
- 1406274 T. Ramakrishnan et. al., 1972, Intermediary Metabolism of Mycobacteria, DACO: 8.1, 8.2.3, 8.2.3.1
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## 4.0 Value

<b>PMRA Document Number</b>	<b>Reference</b>
1280506	Low Risk Rationale Finalsan TGAI
1286754	Binder 4-Value
1286756	Herbicidal Activity of Non-Selective Weed Killers
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1286756	Herbicide Trial
1286759	Efficacy of NEU1170H and NEU1170H AF to control mono- and dicotyledonous weeds, mosses and algae on paths and open areas with tree growth, mono- and dicotyledonous weeds in ornamentals and mosses in lawns
1565978	Annex IIIA data
1280518	CBI Reference Document to Binder 2
1406268	Binder #5-Addendum
1347074	Finalsan Efficacy Summary 1106

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

#### **i) Published Information**

##### **1.0 Human and Animal Health**

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## **2.0 Environment**

### **PMRA Document Number**

### **Reference**

1588847

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