Proposed Registration Decision PRD2017-04

Ammonium Salt of Fatty Acid

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Overview

Proposed Registration Decision for Ammonium Salt of Fatty Acid

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 Emerion 7005 Concentrate and AXXE Broad Spectrum Herbicide, containing the technical grade active ingredient ammonium salt of fatty acid, for contact spray control or burndown of weeds and grasses for interiorscapes and greenhouses.

Ammonium salt of fatty acid is currently registered for the control or burndown of weeds and grasses for ornamentals, turf, landscapes, and non-crop areas on farmsteads. The detailed review of ammonium salt of fatty acid can be found in Proposed Registration Decision PRD2008-12, *Ammonium Soap of Fatty Acid*.

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 Emerion 7005 Concentrate and AXXE Broad Spectrum Herbicide.

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[1] 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[2] 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 (for example, children) as well as organisms in the environment. 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

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "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."

assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on ammonium salt of fatty acid, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on ammonium salt of fatty acid, 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 Ammonium Salt of Fatty Acid?

Ammonium salt of fatty acid is a contact herbicide for control or suppression of weeds and liverworts. Ammonium salt of fatty acid does not move within plants or have any soil residual activity.

Health Considerations

Can Approved Uses of Ammonium Salt of Fatty Acid Affect Human Health?

AXXE Broad Spectrum Herbicide, containing ammonium salt of fatty acid, is unlikely to affect human health when it is used according to label directions.

Potential exposure to ammonium salt of fatty acid may occur when mixing, loading, and/or applying the product, as well as during clean-up and repair activities. 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.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

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

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

In laboratory animals, and based on publicly available information, the technical grade active ingredient (TGAI), Emerion 7005 Concentrate, containing ammonium salt of fatty acid, is of low acute toxicity, mildly to moderately irritating to the skin, moderately irritating to the eyes, and is not a dermal sensitizer. Consequently, the signal words "CAUTION – SKIN IRRITANT" and "WARNING- EYE IRRITANT" are required on the label for the TGAI.

Based on laboratory animal studies and publicly available information, the end-use product (EP), AXXE Broad Spectrum Herbicide, is of low acute toxicity, mildly to moderately irritating to the skin, moderately irritating to the eyes, and is not a dermal sensitizer. Consequently, the signal words "CAUTION – SKIN IRRITANT" and "WARNING- EYE IRRITANT" are required on the label for the EP.

Registrant-supplied waiver rationales, based on publicly available information, were assessed for the potential of ammonium salt of fatty acid to cause mutagenicity, genotoxicity, carcinogenicity, prenatal developmental toxicity, and reproductive toxicity. The available information suggests that ammonium salt of fatty acid is unlikely to cause these effects and thus, there are no health concerns when using the product according to the label.

Furthermore, consideration was given to the anticipated low exposure potential resulting from the intended use of the product, as well as the dietary and occupational exposure aspects outlined below.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Although proposed for greenhouse food crop use, AXXE Broad Spectrum Herbicide is not to be applied directly on the crop. Ammonium salt of fatty acid has a half-life of less than one day in both soil and water, thus the dietary risk from food and drinking water is not a concern.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is not of concern.

Residential and non-occupational exposure of individuals coming in contact with AXXE Broad Spectrum Herbicide during application is not expected to result in unacceptable risk when AXXE Broad Spectrum Herbicide is used according to label directions.

Occupational Risks From Handling AXXE Broad Spectrum Herbicide

Occupational risks are not of concern when AXXE Broad Spectrum Herbicide is used according to the label directions, which include protective measures.

Occupational exposure to individuals handling AXXE Broad Spectrum Herbicide is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary and hygiene statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Postapplication activities, such as scouting treated areas, may result in the exposure of workers re-entering areas treated with AXXE Broad Spectrum Herbicide. Moreover, this is not expected to result in any health risks of concern. Exposure is expected to be further reduced when re-entry into a treated area is restricted until dry.

Bystander exposure is not expected to result in unacceptable risk when the product is used according to label directions.

Environmental Considerations

What Happens When Ammonium Salt of Fatty Acid Is Introduced Into the Environment?

Ammonium salt of fatty acid is not expected to pose risks of concern to the environment when used according to label directions.

Ammonium salt of fatty acid may enter the environment when AXXE Broad Spectrum Herbicide is used to control weeds around ornamental plants, turf, greenhouses and other non-crop areas on farmsteads. Ammonium salt of fatty acid is soluble in water and can enter the atmosphere. In air, it would breakdown very quickly or would be removed by rain. Ammonium salt of fatty acid is not expected to move through soil. Fatty acids are a natural component in soil and water in the environment, and ammonium salt of fatty acid will be broken down quickly in soil and water by microorganisms. Build-up in the environment and long-term effects on plants and animals are not expected. Ammonium salt of fatty acid is also not expected to move through soil to groundwater.

Terrestrial plants may be damaged by contact with ammonium salt of fatty acid at high enough concentrations. Label directions will include precautions to avoid contact with desirable plants, including grass. Toxicity studies for plants were not available to determine if buffer zones from terrestrial habitats are needed. Therefore, only low drift application methods will be permitted at this time.

Fatty acids comprise a significant part of the normal daily diet of mammals, birds and terrestrial invertebrates. Based on laboratory studies, ammonium salt of fatty acid will not be toxic or pose a risk to birds and wild mammals. Honey bees are relatively insensitive to soap salts based on the results of laboratory studies.

Ammonium salt of fatty acid is slightly toxic to aquatic invertebrates and fish. Owing to the algicidal and herbicidal properties of ammonium salt of fatty acid, it is expected to be toxic to algae and aquatic vascular plants if exposed to high enough concentrations. Use of low drift application methods will minimize the potential for exposure of aquatic systems through this route. The quick breakdown of ammonium salt of fatty acid in soil and water will reduce the potential of exposure to aquatic organisms through overland runoff into nearby waterbodies. Precautionary label statements to provide guidance on how to control runoff will be required. Therefore, provided that label directions are followed, ammonium salt of fatty acid is not expected to pose risks of concern to the environment.

Value Considerations

What Is the Value of AXXE Broad Spectrum Herbicide?

AXXE Broad Spectrum is a contact herbicide that provides control or suppression of weeds and liverworts.

Application of AXXE Broad Spectrum at a 5% active ingredient (a.i.) concentration to the point of run-off provides control or suppression of numerous weeds, such as crabgrass, pigweeds, amaranth, carpetweed, and liverworts.

AXXE Broad Spectrum is a non-conventional herbicide and may be especially useful in situations where the use of conventional herbicides is not desirable or available. The registration of AXXE Broad Spectrum provides an alternative herbicide option for weed management in interiorscapes and greenhouses.

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 label of AXXE Broad Spectrum Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The personal protective equipment (PPE) for all mixing, loading, and/or application, as well as clean-up and repair activities required on the end-use product label includes a long-sleeved shirt, long pants, shoes, socks, chemical-resistant gloves, and goggles or a face shield. Personnel should also avoid inhaling spray mists. Care must be taken to avoid bystander exposure from drift during application and entry into treated areas is not permitted until dry.

Environment

Label statements will be required to indicate the hazard to aquatic organisms and terrestrial plants.

Next Steps

Before making a final registration decision on ammonium salt of fatty acid, the PMRA will consider any 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

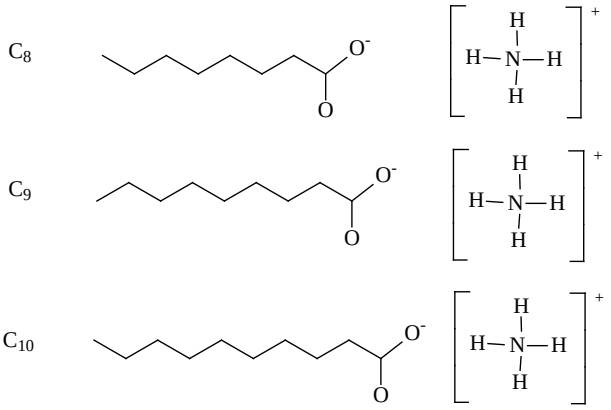
When the PMRA makes its registration decision, it will publish a Registration Decision on ammonium salt of fatty acid for contact spray control or burndown of weeds and grasses for interiorscapes and greenhouses (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ammonium Salt of Fatty Acid

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ammonium salt of fatty acid
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not provided
2. Chemical Abstracts Service (CAS)	Fatty acids, C8 - 18 and C18-unsaturated, ammonium salts
CAS number	84776-33-0
Molecular formula	$C_9H_{17}O_2^-(NH_4)^+$ for predominant C9 species
Molecular weight	175.3 for predominant C9 species
Structural formula	
Purity of the active ingredient	36.0%

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

Technical Product—Emerion 7005 Concentrate

Property	Result
Colour and physical state	Colourless to pale yellow liquid
Odour	Slight fatty acid odour
Melting range	Not applicable
Boiling point or range	100°C
Density at 25°C	1.00-1.03 g/cm^3
Vapour pressure	17.5 mm Hg (20°C) and 23.8 mm Hg (25°C) (aqueous solution of ammonium nonanoate)
Henry's law constant at 20°C	8.2 x 10^{-5} atm x m^3/mol
Ultraviolet (UV)-visible spectrum	Not expected to absorb UV
Solubility in water	Completely miscible with water
Solubility in organic solvents	Soluble in acetone; immiscible with diethyl ether and hexanes
n-Octanol-water partition coefficient (K_{ow})	Not applicable as the product is completely miscible with water
Dissociation constant (pK_a)	The dissociation constant of the dominant species, pelargonic acid, is pK_a = 4.95.
Stability (temperature, metal)	Relatively stable with aluminum and stainless steel; reacts with brass, galvanized metal, zinc and copper.

End-Use Product—AXXE Broad Spectrum Herbicide

Property	Result
Colour	Colourless to pale yellow
Odour	Slight fatty acid odour
Physical state	Liquid
Formulation type	Solution
Guarantee	36.0%
Container material and description	Plastic bottle, jug or tote, 1 L – 1050 L
Density at 25°C	1.00-1.03 g/cm^3
pH of 1% dispersion in water	8 - 9
Oxidizing or reducing action	The product is not an oxidizing or reducing agent
Storage stability	Salts of fatty acids (i.e., soaps) have been commonly and routinely packaged in plastic containers for several decades and remain stable for longer than 24 months.
Corrosion characteristics	Salts of fatty acids have been routinely packaged in plastic containers without exhibiting corrosive properties.
Explodability	Not explosive

1.3 Directions for Use

AXXE Broad Spectrum, which is formulated with ammonium salt of fatty acid, is a non-selective contact herbicide for control or suppression of weeds, such as crabgrass, pigweeds, amaranth, carpetweed, and liverworts in interiorscapes and greenhouses. Efficacy is maximized when applied to young and actively growing weeds, and with complete coverage. It is recommended for application at a 5% a.i. concentration.

Repeat applications every two to three weeks may be necessary to achieve desired weed control results, as well as to control new weeds emerging from seed or re-growth of biennial and perennial weeds.

Since AXXE Broad Spectrum is a non-selective contact herbicide, care must be taken to avoid spraying desirable plants. Injury will occur to any plant part contacted with AXXE Broad Spectrum.

1.4 Mode of Action

When ammonium salt of fatty acid is applied to the weeds, it penetrates cell walls to disrupt cellular organization and physiological functions. Weed growth ceases when cellular contents are mixed. Ammonium salt of fatty acid does not translocate in plants or have any soil residual activity.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The method provided for the analysis of the active ingredient in the technical product have been validated and assessed to be acceptable for the determination.

2.2 Method for Formulation Analysis

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

2.3 Methods for Residue Analysis

No methods are required to quantify residues of ammonium salt of fatty acid due to its low toxicity, rapid biotransformation in the environment, and its history of use as a food additive, in cosmetics, and in household cleaning products.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for the ammonium salt of fatty acid was conducted by the PMRA. The database for the ammonium salt of fatty acid is considered to be sufficiently complete (Appendix I, Tables 1 & 2) and of sufficient scientific quality on which to assess the toxic effects that may result from exposure to the ammonium salt of fatty acid.

A request by the applicant to waive the Part 4, toxicology data requirements, except the eye irritation study, based on foreign reviews (USEPA RED, 1992, and USEPA BRAD, 2008) of ammonium nonanoate and soap salts, which are considered to be synonymous to ammonium salt of fatty acid, was accepted by the PMRA. Based on the publicly available information, Emerion 7005 Concentrate was shown to have low toxicity via the oral, dermal and inhalation routes of exposure. Emerion 7005 Concentrate was also determined to be mildly to moderately irritating to the skin on prolonged exposure, but was not a dermal sensitizer.

As per an animal study, ammonium salt of fatty acid (40% w/w) was found to be moderately irritating to the eyes of rabbits. Treated eyes exhibited corneal opacity, iritis and conjunctivitis one hour after instillation. Ocular irritation was observed to be severe on day seven after which time the study was terminated. Due to the potential for mucosal irritation, Emerion 7005 Concentrate is likely to be a respiratory tract irritant.

Foreign reviews and publicly available scientific information indicate that ammonium salt of fatty acid is not mutagenic, genotoxic, or carcinogenic. Also, Emerion 7005 Concentrate is not expected to be a concern with respect to reproductive toxicity and developmental toxicity.

AXXE Broad Spectrum Herbicide is of low acute toxicity by the oral, dermal, and inhalation routes, is mildly to moderately irritating to the skin, moderately irritating to the eyes, and is not a dermal sensitizer.

The formulants in AXXE Broad Spectrum Herbicide are supported for the proposed uses.

Health Incident Reports

As of June, 2016, the PMRA has received 10 human incidents and two domestic animal incidents involving pesticide products containing ammonium salts of fatty acids. Minor skin effects were frequently reported in humans following exposure to diluted products, mostly during application. As well, a few cases of eye, nose, or throat irritation were also reported. Dogs had transient gastrointestinal effects.

Overall, the assessment of incident reports involving ammonium salts of fatty acids did not identify any health effects of concern. The additional PPE proposed for AXXE Broad Spectrum Herbicide are suitable to mitigate the types of exposures reported in the Canadian database.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Dermal Absorption

Dermal absorption of AXXE Broad Spectrum Herbicide is not expected to be of concern due to the low toxicity of the EP via the dermal route.

3.2.2 Use Description

AXXE Broad Spectrum Herbicide is proposed for the control or burndown of weeds and grasses for interiorscapes and greenhouses. The method of application is by hand-held, pressure, and hose-end sprayers. AXXE Broad Spectrum Herbicide is to be applied prior to seeding or transplanting, before germination or sprouting occurs, after crops are harvested, or as required to actively growing weeds. Reapplication may be performed every two to three weeks to actively growing weeds that are less than 12 cm high.

The amount of AXXE Broad Spectrum Herbicide applied ranges from 20.8 to 529 L/day when applied by handheld sprayers. Applicators will typically handle 1.04 to 26.8 kg a.i./day when using a handheld sprayer.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

Exposure to workers mixing, loading, and applying AXXE Broad Spectrum Herbicide is expected to be short-term in duration and to occur primarily by the dermal route but inhalation and incidental ocular exposure to the eyes is also possible.

The risk due to exposure from mixing, loading, applying, clean-up, and maintenance of machinery for workers is considered to be acceptable when used according to the label, which includes adhering to the label precautions.

3.2.4 Postapplication Exposure and Risk

There is a potential for exposure to workers re-entering areas treated with AXXE Broad Spectrum Herbicide. Given the nature of the postapplication activities typically performed (for example, scouting treated areas), dermal contact with treated plants, soil, and surfaces is possible. While the degree of exposure will be related to the time of re-entry and the duration of the activities, the potential risk due to exposure resulting from postapplication work is not expected to result in any health concerns. In addition, exposure is expected to be further reduced when re-entry into a treated area is restricted until dry.

3.2.5 Residential and Bystander Exposure and Risk

Residential and bystander exposure to AXXE Broad Spectrum Herbicide in interiorscapes and greenhouses is not of concern as individuals are not permitted to enter the treated area(s) until spray applications are dry.

3.3 Food Residue Exposure Assessment

3.3.1 Food

Due to the low toxicity of ammonium salt of fatty acid, and the history of use of salts of fatty acid as food additives, in cosmetics, and in household cleaning products, adverse effects are not a concern from the presence of residues on food.

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of ammonium salt of fatty acid from the proposed use around food crops in greenhouses, in the general population and potentially sensitive subpopulations, including infants and children.

3.3.2 Drinking Water

Although the end-use product will not be applied near or directly to water, some drinking water exposure may be possible through run-off from treated areas. Ammonium salt of fatty acid is soluble in water, dissociating into ammonium and the fatty acid ions. The fatty acid ions are biotransformed into carbon dioxide and water, with a half-life < 1 day. Exposure to ammonium salt of fatty acid and its by-products in drinking water are expected to be minimal. In addition, toxicity to ammonium salt of fatty acid and its ions is low. Consequently, the risk due to exposure from drinking water is not a concern.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculations of acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for ammonium salt of fatty acid. Based on all the available information and hazard data, the PMRA concludes that ammonium salt of fatty acid is of low toxicity. Thus there are no threshold effects of concern. As a result, there is no need to require definitive (multiple dose) testing or apply uncertainty factors to account for intra- and interspecies variability, safety factors or margins of exposure. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of ammonium salt of fatty acid, including neurological effects from pre- or post-natal exposures, and cumulative effects on infants and children of ammonium salt of fatty acid and other registered products containing ammonium salt of fatty acid, does not apply to this active ingredient. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of ammonium salt of fatty acid to human health.

3.3.4 Aggregate Exposure and Risk

Based on the relevant information in the Agency’s database, there is reasonable certainty that no harm will result from aggregate exposure of residues of ammonium salt of fatty acid to the general population in Canada, including infants and children, when AXXE Broad Spectrum Herbicide is used according to the label. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.3.5 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The dietary risks from food and drinking water are not a concern given that AXXE Broad Spectrum Herbicide is not proposed for direct application on food or feed, is of low acute toxicity, and has a half-life in water and soil of less than 1 day. Consequently, the specification of an MRL for ammonium salt of fatty acid under the PCPA is not being requested.

4.0 Impact on the Environment

Ammonium salt of fatty acid is completely miscible in water. Fatty acids can enter air and could exist in both particulate and vapour phases. Ammonium salt of fatty acid is considered highly volatile and, based on the Henry's law constant, is expected to volatilize from water and moist soil surfaces. Once in the air, however, this substance would breakdown very quickly by reaction with photochemically-produced hydroxyl radicals (for example, ozone). Particulate-phase fatty acids will be removed from the atmosphere by wet and dry deposition processes. Hydrolysis is unlikely for fatty acids due to the lack of functional groups that are readily hydrolyzed under environmental conditions. Ammonium salt of fatty acid is not expected to absorb ultra-violet radiation and therefore would not be susceptible to direct phototransformation.

Ammonium salt of higher fatty acids have carbon chain lengths of C8 to C18 saturated and C18 unsaturated, with ammonium nonanoate (C9) as the predominant species. Also known as "soap salts", these substances are simply the salts (ammonium and potassium) of the dissociated fatty acid carboxylate. Thus, the environmental fate pathways for common fatty acids (for example, nonanoic and lauric acid) are relevant for ammonium soap salts. Ammonium salt of fatty acid will be broken down quickly in soil and water by microorganisms with a half-life of less than one day and less than three days, respectively, and transformed to carbon dioxide and water. Ammonium salt of fatty acid is, therefore, not expected to be persistent in the environment and will be indistinguishable from the naturally occurring ammonium ions and fatty acids already present in the environment as a result of plant and microbial metabolism. Fatty acids are a natural component in soil and water in the environment as they are produced in the cells of both plants and animals. The ammonium ion is expected to also transform through the nitrogen cycle. Thus, build-up in the environment and long-term effects on plants and animals are not expected. Also, transformation products of environmental concern are also not expected. Ammonium salt of fatty acid is not expected to move through soil, based on the low mobility of undissociated fatty acids in soil (for example, nonanoic acid has an estimated K_{oc} of 1700).

Data on the fate and behaviour of ammonium salt of fatty acid are summarized inAppendix I, Table 3.

4.1 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 (for example, 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). 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.

Environmental toxicity data are summarized in Appendix 1, Table 4 (terrestrial) and Table 6 (aquatic).

4.1.1 Risks to Terrestrial Organisms

Terrestrial organisms, such as honeybees, beneficial arthropods, birds, small wild mammals and terrestrial vascular plants, may be exposed to ammonium salt of fatty acid through direct contact with spray or spray drift, contact with sprayed surfaces or from ingestion of contaminated food.

The general herbicidal mode of action for ammonium salt of fatty acid involves the disruption of photosynthesis through destruction of cell membranes resulting in plant death. Thus, ammonium salt of fatty acid is expected to be toxic to terrestrial vascular plants by contact and may damage plant parts that are contacted by the spray. Label statements will be required to inform users of the hazard to terrestrial plants and to avoid contact with non-target plants. As no plant toxicity studies were available, only low drift application equipment can be supported because an assessment to quantitatively characterise the risk to terrestrial habitats due to spray drift could not be conducted.

Ammonium salt of fatty acid is relatively non-toxic to honey bees on an acute contact basis. While the honey bee may be relatively insensitive to soap salts (including ammonium salt of fatty acid) based on an acute toxicity study, soft-bodied insects such as aphids, whiteflies, and mealy bugs are more susceptible to the toxic effects of soaps. Flightless stages of immature insects could also be susceptible to effects. Saturating bees (or other insects) with a solution of ammonium salt of fatty acid would, however, likely result in death. Other soap salts are frequently used as contact insecticides to control many pests. Vegetation control using AXXE Broad Spectrum Herbicide is by spot treatment and directed or shielded applications. Areas treated by hand are expected to be relatively small and application by tractor mounted sprayer is expected to disturb bees or other winged insects and cause them to fly away before being sprayed directly. Spray drift will also be minimized by the use of hand-held equipment and directed or shielded spraying. Risks to bees and other beneficial insects are, therefore, not expected to cause risks of concern to terrestrial invertebrates as a result of this use pattern.

Ammonium salt of fatty acid is slightly to practically non-toxic to birds and small mammals on an acute dietary basis. LOCs for mammals were not exceeded and were only minimally exceeded for small and medium-sized birds in the screening level assessment (RQs = 1.44 and 1.13, respectively; see Appendix I, Table 5). In addition, fatty acids are produced by plant and animal cells, as well as by microbial metabolism, and comprise a significant part of the normal daily diet of mammals and birds. Ammonium salt of fatty acid is not expected to pose risks of concern to birds and small mammals from its use as a herbicide in non-crop areas.

4.1.2 Risks to Aquatic Organisms

Aquatic organisms, such as fish, amphibians, invertebrates, algae and vascular plants, may be exposed to ammonium salt of fatty acid through contact with spray drift or overland runoff.

Ammonium salt of fatty acid is slightly toxic to both cold and warm water fish and aquatic invertebrates based on EC_{50}/LC_{50} values. Ammonium salt of fatty acid is not toxic to *Daphnia magna* up to a concentration of 20 mg a.i./L in water. Other salts of fatty acids may be more toxic (for example, 48-hr EC_{50}, 0.57 mg a.i./L for *Daphnia*, potassium salt of fatty acid). A risk to fish, amphibians and aquatic invertebrates was identified with the screening level risk assessment (see Appendix I, Table 7). To further characterize the risk, exposure to water, due to runoff and spray drift, are examined separately. As only hand-held or directed/shielded application is supported for the current use pattern of AXXE Broad Spectrum Herbicide, spray drift will be minimal and was not further characterised. Although overland runoff to aquatic systems may occur, data were not available to estimate this route of exposure.

Overland runoff will, however, be mitigated by the short half-life of ammonium salt of fatty acid in soil and water (< 1 to 3 days) and the potential for volatilization from moist soil surfaces. Precautionary label statements to provide guidance on how to control runoff will be required.

Information regarding the toxicity of ammonium salt of fatty acid to aquatic plants was not available and a quantitative risk assessment for these organisms could not be conducted. Due to its herbicidal properties, and known use as an algicide, ammonium salt of fatty acids is expected to be toxic to algae and aquatic vascular plants if they are exposed to high enough concentrations. To reduce the potential for harmful effects to aquatic plants, only application methods that minimize spray drift (hand-held or directed / shielded application) will be used and precautionary label statements to provide guidance on how to control runoff will be required.

Environmental Incident reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

As of December 6, 2016, the PMRA has received four minor environment incidents involving ammonium salts of fatty acids. Damage to home lawns and vegetables were reported when the active ingredient contacted these plants.

5.0 Value

There are many conventional herbicides registered for weed management on interiorscapes and greenhouses. However, very few non-conventional herbicides are registered for such uses. The registration of AXXE Broad Spectrum provides an alternative herbicide option for weed management in these sites, especially in situations where the use of conventional herbicides is not desirable.

Given the mode of action of ammonium salt of fatty acid, the development of weed resistance to AXXE Broad Spectrum is unlikely. The use of AXXE Broad Spectrum may reduce the potential for the development of weed resistance to other herbicide modes of action.

Efficacy information submitted for review included data from two field trials conducted in Oklahoma in 2006 and 2007, three greenhouse experiments conducted in Ohio and New York in 2010 and 2011, and rationales.

The information was sufficient to support the efficacy claims of control or suppression of weeds, such as crabgrass, pigweeds, amaranth, carpetweed, and liverworts with the application of AXXE Broad Spectrum at the 5% a.i. concentration. The efficacy of AXXE Broad Spectrum is maximized when it is applied to young and actively growing weeds, and with complete coverage.

Repeat applications every two to three weeks may be necessary to achieve desired weed control results, as well as to control new weeds emerging from seeds or re-growth of biennial and perennial weeds.

Since AXXE Broad Spectrum is a non-selective contact herbicide, care must be taken to avoid spraying desirable plants. Injury will occur to any plant part contacted with AXXE Broad Spectrum.

AXXE Broad Spectrum is supported for use in the listed sites when it is applied as a vegetative burndown treatment, a directed or shielded spray, and a pre-emergent spray before seeds germinate and emerge and before perennial plants, tubers, bulbs or seed pieces sprout and emerge.

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, ammonium salt of fatty acids was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Ammonium salt of fatty acids does not meet the Track1 criteria because it is not persistent in the environment and is, therefore, not considered a Track 1 substance.
- A previous assessment (Proposed Acceptability for Continuing Registration, PACR2004-04, *Re-evaluation of Soap Salts*) also concluded that soap salts are not a TSMP Track 1 substance.

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*

[5] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

Contaminants of Health or Environmental Concern maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03[8]; and DIR2006-02[9]; 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 ammonium salt of fatty acids, Emerion 7005 Concentrate, and the end-use product, AXXE Broad Spectrum Herbicide, 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[10].

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for the ammonium salt of fatty acid is adequate to define the toxic effects that may result from exposure to the ammonium salt of fatty acid. Both the technical grade active ingredient, Emerion 7005 Concentrate, and the end-use product, AXXE Broad Spectrum Herbicide, are of low acute toxicity by the oral, dermal, and inhalation routes. Emerion 7005 Concentrate and AXXE Broad Spectrum Herbicide are mildly to moderately irritating to the skin and moderately irritating to the eyes. Neither the TGAI nor the EP are dermal sensitizers.

Loaders, mixers, applicators, and workers are not expected to be exposed to levels of the ammonium salt of fatty acid that will result in an unacceptable risk due to exposure when AXXE Broad Spectrum Herbicide is used according to label directions.

Residential and bystander exposure is not a concern when AXXE Broad Spectrum Herbicide is used according to the label and individuals do not enter treated area(s) until sprays are dry.

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6 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.

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

8 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic SubstancesManagement Policy

9 DIR2006-02, PMRA Formulants Policy.

10 DIR2006-02, PMRA Formulants Policy.

The dietary risks from food and drinking water are not a concern given the low toxicity of AXXE Broad Spectrum Herbicide, the long history of non-pesticidal use of ammonium salt of fatty acid as a food additive, in cosmetics, and in household cleaning products, as well as the limited half-life of less than 1 day in soil or water. Consequently, the specification of an MRL under the PCPA is not required.

7.2 Environmental Risk

Ammonium salt of fatty acid is readily transformed in the environment and transformation products of environmental concern are not expected. Ammonium salt of fatty acid is not expected to pose a risk to beneficial insects, birds and small mammals. Ammonium salt of fatty acid is toxic to terrestrial and aquatic plants, and may pose a risk to fish, amphibians and aquatic invertebrates if exposed at high enough concentrations. Label directions specify that only hand-held and directed/shielded application methods are to be used, which will minimize drift to non-target terrestrial and aquatic habitats. Exposure to aquatic habitats due to runoff will be mitigated by the volatility and short transformation half-lives of ammonium salt of fatty acid in soil and water. Precautionary label statements to provide guidance on how to control runoff will, however, be required. Hazard label statements to inform users of the toxicity to terrestrial and aquatic plants, and other aquatic organisms, will also be required. When used according to label directions, the risks to non-target organisms from the use of this product are not of concern.

7.3 Value

AXXE Broad Spectrum is a non-conventional herbicide that provides an alternative herbicide option for weed management in interiorscapes and greenhouses. AXXE Broad Spectrum may be particularly useful in situations where the use of conventional herbicides is not desirable.

Value information submitted for review demonstrated that the control or suppression of weeds, such as crabgrass, pigweeds, amaranth, carpetweed, and liverworts can be achieved with applications of AXXE Broad Spectrum at the 5% a.i. concentration. Crop tolerance is not of concern when the products are applied as a vegetative burndown treatment, a directed or shielded spray, and a pre-emergent spray before seeds germinate and emerge and before perennial plants, tubers, bulbs or seed pieces sprout and emerge.

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 Emerion 7005 Concentrate and AXXE Broad Spectrum Herbicide containing the technical grade active ingredient ammonium salt of fatty acid, for contact spray control or burndown of weeds and grasses for interiorscapes and greenhouses.

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	microgram
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DACO	data code
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	environmental exposure concentrations
EP	end-use product
FDA	Food and Drugs Act
FIR	food ingestion rate
g	gram
ha	hectare(s)
hr(s)	hour(s)
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_{50}	lethal concentration 50%
LOC	level of concern
LD_{50}	lethal dose 50%
NOEC	no observed effect concentration
MAS	maximum average score
mg	milligram
MIS	maximum irritation score
mL	millilitre
MRL	maximum residue limit
NA	not applicable
PCPA	Pest Control Products Act
pH	measure of the acidity or basicity of an aqueous solution
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
RED	Reregistration Eligibility Decision (USEPA)
RQ	risk quotient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor

USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight per weight dilution

Appendix I Tables and Figures

Table 1 Toxicity Profile of AXXE Broad Spectrum Herbicide Containing Ammonium Salt of Fatty Acid

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Acute dermal toxicity Acute inhalation toxicity Dermal irritation Dermal sensitization PMRA # 2100556	Based on previously submitted and reviewed publicly available information, ammonium salt of fatty acid is of low acute oral, dermal, and inhalation toxicity, is a mild to moderate skin irritant, but is not a dermal sensitizer.
Eye irritation Rabbit, New Zealand White PMRA # 2100558	A study was previously submitted, reviewed by the PMRA, and found to be acceptable. MAS [a] = 35/110 MIS [b] = 39/110 (24 hrs) Moderately irritating.

[a] MAS = Maximum Average Score for 24, 48, and 72 hrs
[b] MIS = Maximum Irritation Score (average)

Table 2 Toxicity Profile of Technical Ammonium Salt of Fatty Acid

(Effects are known or assumed to occur in both sexes unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Acute dermal toxicity Acute inhalation toxicity Dermal irritation Dermal sensitization PMRA # 2100556	Based on previously submitted and reviewed publicly available information, ammonium salt of fatty acid is of low acute oral, dermal, and inhalation toxicity, is a mild to moderate skin irritant, but is not a dermal sensitizer.
Eye irritation Rabbit, New Zealand White PMRA # 2100558	A study was previously submitted, reviewed by the PMRA, and found to be acceptable. MAS [a] = 35/110 MIS [b] = 39/110 (24 hrs) Moderately irritating
Short-term oral toxicity Short-term dermal toxicity Short-term inhalation toxicity PMRA # 2100557	Waiver requests based on a low acute toxicity and minimal exposure were previously submitted, reviewed by the PMRA, and found to be acceptable.
Prenatal developmental toxicity PMRA # 2100557	Waiver requests based on minimal exposure were previously submitted, reviewed by the PMRA, and found to be acceptable.
Genotoxicity: bacterial reverse mutation assay Genotoxicity: in vitro mammalian cell assay PMRA # 2100557	Waiver requests based on minimal exposure were previously submitted, reviewed by the PMRA, and found to be acceptable.

[a] MAS = Maximum Average Score for 24, 48, and 72 hrs
[b] MIS = Maximum Irritation Score (average)

Table 3 Fate and behaviour of ammonium salt of fatty acid in the terrestrial environment

Property	Value	Comments	PMRA#
Abiotic transformation			
Hydrolysis	NA	Not expected; lack of functional groups that are readily hydrolysed.	2704946
Photochemical reactions in air	Half-life: several hours to 1.6 days (estimated)	Vapour phase fatty acids are degraded in the atmosphere by reaction with photochemically produced hydroxyl radicals; estimated half-life.	2704946
	Half-lives: 1.4–2.1 hours (estimated)	Unsaturated fatty acids, reaction with ozone; estimated half-life.	
Biotransformation			
Biotransformation in soil	Half-life: < 1 day	No transformation products of concern are expected.	2100550
Biotransformation in water	Half-life: 13 to 70 hours	Natural water sample; no transformation products of concern are expected.	2704942
Mobility			
Adsorption / desorption in soil	Koc of 1700 to 340,000 mL/g	Undissociated fatty acids should have low to practically no mobility in soils.	2704946

NA = not applicable

Table 4 Toxicity of ammonium salt of fatty acid to terrestrial non-target species

Organism	Exposure	Toxicity Value	Toxicity Classification	Reference (PMRA#)
Terrestrial Invertebrates				
Honey bee	Acute contact, 48 hr LD_{50}	>13 µg/bee[1]	Practically non-toxic	2100556 2100550
		>100 µg/bee	Practically non-toxic	2704946 2705282
Birds				
Bobwhite quail	Acute oral, LD_{50}	> 2150 mg/kg[2]	Slightly toxic	2100556 2704946 2558259 2100550
Bobwhite quail and mallard duck	Acute dietary, LD_{50}	> 5000 mg/kg[2]	Practically non-toxic	2100556 2704946 2558259 2100550
Mammals				
Rat	Acute oral, LD_{50}	> 74000 mg/kg (oleic acid soap salt)	Practically non-toxic	2100556 2558259 2100550
Terrestrial Vascular Plants – Toxicity data were not available and an ER_{25} was not determined. However, ammonium salt of fatty acid is a herbicide which disrupts cell membranes resulting in plant death.				

[1] Potassium soap salt used; considered by USEPA to be equivalent to ammonium soap salts for ecological risk assessment purposes. This was accepted for PMRA re-evaluation of soap salts (PACR2004-04).
[2] Test substance is a technical grade active ingredient, 14.65% a.i., ammonium salt of fatty acid. Study details were not available; for the purposes of the risk assessment, it was assumed that no mortality was observed at the highest test concentration.

Table 5 Screening level risk assessment of ammonium salt of fatty acid to birds and small mammals

Organism	Toxicity Value (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE[1] (mg a.i./kg bw)	RQ	LOC exceeded?
Small Bird (0.02 kg)					
Acute Oral	2150.00[2]	Insectivore	3106.07	1.44	Yes[3]
Medium Sized Bird (0.1 kg)					
Acute Oral	2150.00	Insectivore	2423.95	1.13	Yes[3]
Large Sized Bird (1 kg)					
Acute Oral	2150.00	Herbivore (short grass)	1565.75	0.73	No
Small Mammal (0.015 g)					
Acute	74000	Insectivore	1786.5	0.02	No
Medium Sized Mammal (0.035 kg)					
Acute	74000	Herbivore (short grass)	3464.89	0.05	No
Large Sized Mammal (1 kg)					
Acute	74000	Herbivore (short grass)	1851.41	0.03	No

[1] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/bw) × EEC, where
FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight ≤200 g): FIR (g dry weight/day) = $0.398(\text{bw in g})^{0.850}$
All birds Equation (body weight >200 g): FIR (g dry weight/day) = $0.648\ (\text{bw in g})^{0.651}$
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{bw in g})^{0.822}$
bw: Generic Body Weight
EEC: Concentration of pesticide on food item. At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used. A cumulative application rate of approximately 38 kg a.i./ha was used based on 8 applications, 14-day application interval, and a 1-day foliar half-life (in general, ammonium salt of fatty acids are readily transformed in the environment). In addition, higher rates will likely kill small insects and plant food items will be killed if exposed to higher rates of ammonium salt of fatty acid.
[2] Assumed no mortality at highest test concentration; therefore, an uncertainty factor was not used for the toxicity value.
[3] The LOC was only slightly exceeded. It is not expected that wild birds will exclusively eat insects and plant matter that have been treated with the active ingredient. Therefore, no risks of concern are expected for the proposed uses.

Table 6 Toxicity of Ammonium Salt of Fatty Acid to Aquatic Non-Target Species

Organism	Exposure	Toxicity Value	Toxicity Classification[1]	Reference (PMRA#)
Daphnia magna	Acute, 48 hr EC_{50}	0.57 mg a.i./L[2] (lethargy or mortality)	Highly toxic	2558259 2100550 740807
		27.1 mg a.i./L[3] (estimated EC_{50}) NOEC = 20 mg a.i./L, 100% lethargy or mortality at 33 mg a.i./L and all greater test concentrations.	Slightly toxic	2705282
Rainbow trout *Onchorhynchus mykiss*	Acute, 96 hr LC_{50}	18.06 mg a.i./L[2]	Slightly toxic	2558259 2100550 740807
		12 mg a.i./L[3] (visually observed NOEC is 8 mg a.i./L)	Slightly toxic	2705282
Bluegill sunfish *Lepomis macrochirus*	Acute, 96 hr LC_{50}	35.35 mg a.i./L	Slightly toxic	2558259 2100550 740807

[1] USEPA toxicity classification scheme

[2] Test substance is potassium salt of fatty acid which the USEPA considered to be equivalent to ammonium salt of fatty acid. This was accepted for PMRA re-evaluation of soap salts (PACR2004-04). However, other data indicate that ammonium salt of fatty acid would have a lower toxicity to *Daphnia magna* than the potassium salt.

[3] Test substance 13.1% formulation of ammonium salt of fatty acid.

NA = not applicable

Table 7 Screening level risk assessment of ammonium salt of fatty acid for aquatic organisms

Organism	Exposure	Toxicity Value (mg a.i./L)		EEC[2] (mg a.i./L)	RQ[3]	LOC exceeded?
		Study	Uncertainty factor applied[1]			
Freshwater invertebrates						
Daphnia magna	Acute	48 hr EC_{50}: 0.57[A]	0.29	4.77	16.5	Yes
		48 hr EC_{50}: 27.1[B] 48 hr NOEC: 20.0[C]	2.71 20	4.77 4.77	1.8 0.24	Yes No
Freshwater fish						
Oncorhynchus mykiss	Acute	96 hr LC_{50}: 18.06	1.8	4.77	2.7	Yes
		96 hr LC_{50}: 12.0	1.2	4.77	4.0	Yes
Amphibians (surrogate: *Oncorhynchus mykiss*)	Acute	96 hr LC_{50}: 18.06	1.8	25.44	14.1	Yes
		96 hr LC_{50}: 12.0	1.2	25.44	21.2	Yes

[1] Uncertainty factors (UF) are 0.5 (aquatic invertebrates) and 0.1 (fish).
[2] Estimated environmental concentration (EEC) was estimated in 80 cm depth of water for fish and a 15 cm depth of water for amphibians at a cumulative application rate of approximately 38 kg a.i./ha (considering 8 applications, 14 day application interval, half-life in water of 1 day). A half-life of 1 day was used for water as the range of half-life in water was reported as 13 to 70 hours, and a half-life in soil of 1 day was also used.
[3] RQ = [EEC / (toxicity value x UF)]
[A] Test substance is potassium salt of fatty acid.
[B] EC_{50} estimated based on no effects at 20 mg a.i./L and 100% effects at 33 mg a.i./L.
[C] Uncertainty factors are not applied to no-effect endpoints.

Table 8 List of supported uses

Items	Label claims that are supported
Application rate	Apply at 5% a.i. to the point of run-off or 325-765 L/ha based on weed height and density.
Efficacy claims	Control or suppression of grass and broadleaf weeds, such as crabgrass, pigweeds, amaranth, and carpetweed, and liverworts.
Hosts and use sites	Turf, ornamentals, landscapes, interiorscapes, greenhouses, and non-crop areas on farmstead, if desirable plants are protected from contact with the spray solution.
Use methods	(1)Vegetative burndown: Broadcast spray for no-till planting or seedbed preparation prior to seeding or transplanting. (2)Directed and shield spray: Apply to area between mulch strips and staked crops. (3)Pre-emergent spray: Broadcast spray before seeds germinate and emerge and before perennial plants, tubers, bulbs or seed pieces sprout and emerge. (4)Industrial and building uses: Broadcast or spot sprays to open field areas and right-of-ways.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	References
	1.0 Chemistry
2100552	Emery Agro 7001 Concentrate Chemistry Information DACO Sections 2.0 - 2.16, DACO: 2.0 CBI
2100554	Emery Agro 7001 Concentrate Batch Analysis Waiver, DACO: 2.13.3 CBI
2153481	2012, Emery Agro 7005 Concentrate Pilot scale batch Analysis, DACO: 2.13.3 CBI
2288731	2013, Emerion 7005 Concentrate Raw material Supply, DACO: 2.11.2 CBI
2288732	2010, [CBI Removed] Specifications, DACO: 2.11.2 CBI
2288733	[CBI Removed] Certificate of Analysis, DACO: 2.11.2 CBI
2288734	2012, [CBI Removed] Certificate of Analysis, DACO: 2.11.2 CBI
2288738	2012, [CBI Removed] Specifications, DACO: 2.11.2 CBI
2288739	2013, [CBI Removed] Compositional profile, DACO: 2.11.2 CBI
2288741	2013, Emery Agro 7005 Concentrate Preliminary Analysis, DACO: 2.13 CBI
	2.0 Human and Animal Health
2100226	2010, Emery Agro 7001 Concentrate Attachment 1: USEPA Regulatory Review, DACO: 4.2.1, 4.2.2. 4.2.3, 4.2.5, and 4.2.6
2100557	2010, Emery Agro 7001 Concentrate Attachment 2: USEPA Regulatory Review, DACO: 4.3.1, 4.3.4, 4.3.6, 4.5.2, 4.5.3, 4.5.4, 4.5.5, and 4.8
2558242	2015, PART 5 - Exposure 5.2-AXXE, DACO: 5.2
	3.0 Environment
2558259	1992, US-EPA Soap Salts Reregistration Eligibility Document (RED), DACO: 12.5
2100550	2008, US-EPA Biopesticides Registration Action Document (BRAD), Ammonium Nonanoate (PC code 031802), DACO: 12.5.4
2100556	EA_7001_Concentrate_Attachment_1_USEPA_Regulatory_Review, DACO: 4.2.1,4.2.2,4.2.3,4.2.5,4.2.6,4.2.9
	4.0 Value
2545933	2007, Value of Emery AE7005 Concentrate, OK State USDA study, DACO: 10.2.3.3(B) and 10.3.2.
2575946	2010, Outside study, AXXE (Racer) for liverwort control, IR-4, DACO: 10.2.3.3(B) and 10.3.2.
2575947	2011, Outside study, AXXE (Racer) for liverwort control, IR-4, DACO: 10.2.3.3(B) and 10.3.2.
2575948	2011, Outside study-AXXE (Racer) for liverwort control, IR-4, DACO: 10.2.3.3(B) and10.3.2.

B. Additional Information Considered

i) Published Information

1.0 Environment

2704946 2015, Soap-Based Algicide / Demossers, Technical Evaluation Report, Compiled by Pesticide Research Institute for the USDA National Organic Program, 17 pages

2705282 2013, US-EPA Environmental Fate and Ecological Risk Assessment for the Registration of Soap Salts, 113 pages

2704942 Koichi Yoshimura, Katsutoshi Ara, Katsumi Hayashi, Jiro Kawase and Kazuro Tsuji, Biodegradation of linear alkylbenzene sulfonates and soap in river water. Japanese Journal of Limnology, 1984, 45(3): 204-212.