Proposed Registration Decision PRD2019-03

Ammonium Salt of Fatty Acid, EMERION W 36 SL and AXXE Broad Spectrum Herbicide

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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 registration for the sale and use of EMERION W 36 SL and AXXE Broad Spectrum Herbicide, containing the technical grade active ingredient ammonium salt of fatty acid, for control or burndown of weeds and grasses on food and feed crops and pastures.

Ammonium salt of fatty acid is currently registered for the control or burndown of weeds and grasses on ornamentals, turf, landscapes, non-crop areas on farmsteads, interiorscapes and greenhouses. For details, see the Proposed Registration Decision PRD2008-12, *Ammonium Soap of Fatty Acid*, PRD2017-04 *Ammonium Salt of Fatty Acid* and the Registration Decision RD2017-09, *Ammonium Salt of Fatty Acid*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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 ammonium salt of fatty acid, EMERION W 36 SL 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 *Pest Control Products 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.

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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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on ammonium salt of fatty acid, EMERION W 36 SL and AXXE Broad Spectrum Herbicide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on ammonium salt of fatty acid, EMERION W 36 SL and AXXE Broad Spectrum Herbicide, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada'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. It is a non-selective herbicide that penetrates plant cell walls to disrupt plant growth.

Health Considerations

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

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). As such, sex and gender are taken into account in the risk assessment. 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.

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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 W 36 SL, 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.

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.

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 not expected to cause these.

Residues in Water and Food

Dietary risks from food and water are acceptable.

AXXE Broad Spectrum Herbicide is not to be applied directly on the crop. In addition, ammonium salt of fatty acid is of low toxicity, has a half-life of less than one day in both soil and water, and salts of fatty acid have a history of use as food additives, thus the dietary risk from food and drinking water is not a concern.

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.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is acceptable.

Risk from residential and non-occupational exposure to individuals coming in contact with AXXE Broad Spectrum Herbicide, containing the active ingredient ammonium salt of fatty acid, during application is acceptable when AXXE Broad Spectrum Herbicide is used according to label directions.

Occupational Risks from Handling AXXE Broad Spectrum Herbicide

Occupational risks are acceptable when AXXE Broad Spectrum Herbicide is used according to the label directions, which include protective measures.

Risk from occupational exposure to individuals handling AXXE Broad Spectrum Herbicide is acceptable 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 a potential risk due to occupational exposure.

Post-application activities, such as scouting treated areas, may result in the exposure of workers re-entering areas treated with AXXE Broad Spectrum Herbicide. The risk due to exposure is acceptable when re-entry into a treated area is restricted until dry.

Risk from bystander exposure is acceptable when the product is used according to label directions.

Environmental Considerations

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

AXXE Broad Spectrum Herbicide, containing ammonium salt of fatty acid, is not expected to pose risks of concern to the environment when used according to label instructions.

Ammonium salt of fatty acid may enter the environment when AXXE Broad Spectrum Herbicide is used to control weeds around ornamental plants, turf, landscapes, interiorscapes, greenhouses, food crops, feed crops and other non-crop areas on farmsteads. The active ingredient ammonium salt of fatty acid is soluble in water and can enter the atmosphere. In air, it would break down very quickly or would be removed by rain. Ammonium salt of fatty acid is not expected to move through soil. Fatty acids are natural components 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.

Non-target terrestrial plants may be damaged by contact with ammonium salt of fatty acid at high enough concentrations. However, the label includes requirements to prevent contact with desirable plants, including grass. When used according to label directions, ammonium salt of fatty acid is not expected to pose risks of concern to non-target terrestrial and aquatic plants.

Value Considerations

What Is the Value of AXXE Broad Spectrum Herbicide?

AXXE Broad Spectrum formulated with the active ingredient ammonium salt of fatty acid provides control or suppression of weeds and liverworts in several use sites.

Application of AXXE Broad Spectrum Herbicide at a 5% active ingredient (a.i.) concentration to the point of run-off or 325-765 L/ha based on weed height and density provides control or suppression of numerous weeds, such as crabgrass, pigweeds, amaranth, and carpetweed, and liverworts.

The registration of AXXE Broad Spectrum provides an alternative non-conventional herbicide option for weed and liverwort management in food and field crops and pastures.

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 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

A precautionary label statement indicating the phytoxicity to non-target terrestrial plants is required. A precautionary label statement to reduce the potential for runoff of ammonium salt of fatty acid to adjacent aquatic habitats, for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted, is required. In addition, label instructions will include requirements to prevent contact with desirable plants, including grass.

Next Steps

Before making a final registration decision on ammonium salt of fatty acid, EMERION W 36 SL and AXXE Broad Spectrum Herbicide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada 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). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other Information

When the Health Canada makes its registration decision, it will publish a Registration Decision on ammonium salt of fatty acid, EMERION W 36 SL and AXXE Broad Spectrum Herbicide (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, EMERION W 36 SL and AXXE Broad Spectrum Herbicide

1.0 The Active Ingredient, Its Properties and Uses

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

1.1 Directions for Use

AXXE Broad Spectrum Herbicide, 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, and carpetweed, and liverworts in a number of use sites, including food crops, field crops, pastures, ornamentals, turf, landscapes, interiorscapes, greenhouses, and non-crop areas on farmsteads. Efficacy is maximized when it is applied to young and actively growing pests, and with complete coverage.

AXXE Broad Spectrum Herbicide is recommended for application at a 5% a.i. concentration to the point of runoff or 325-765 L/ha based on weed height and density. It can be applied as (1) broadcast or spot spray using hand-held or directed (shielded) spray equipment in food and field crops, ornamentals, pastures, and turf; (2) pre-emergence spray prior to germination of seeds, regrowth of perennial plants, and sprout of tubers, bulbs, or seed pieces; and (3) post-harvest spray.

Repeat applications every two to three weeks may be necessary to achieve desired results, as well as to control newly emerged pests or re-growth of perennial weeds.

Since AXXE Broad Spectrum Herbicide 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 Herbicide.

1.2 Mode of Action

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

2.0 Methods of Analysis

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.2.2 Use Description

The end-use product, AXXE Broad Spectrum Herbicide, is currently registered for control or burndown of grass and weeds for ornamental plants, turf, landscapes, interiorscapes, greenhouses, and non-crop areas on farmsteads. AXXE Broad Spectrum Herbicide is proposed for use as a contact spray control or burndown of weeds and grasses for field crops, food crops, and pastures. AXXE Broad Spectrum Herbicide is to be applied by hand-held spray equipment, directed spray equipment, and field sprayer boom equipment. 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 2 to 3 weeks to actively growing weeds that are less than 12 cm high.

The amount of AXXE Broad Spectrum Herbicide applied by groundboom ranges from 720 to 38,160 L/day and from 20.8 to 529 L/day when applied by handheld sprayers. Applicators will handle 67.6 to 1900 kg a.i./day when spraying by groundboom and 1.04 to 26.8 kg a.i./day when using a handheld sprayer.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.2.4 Post-application Exposure and Risk

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.2.5 Residential and Bystander Exposure and Risk

The use of AXXE Broad Spectrum Herbicide outdoors may result in bystander exposure due to drift. The risk due to bystander exposure will be mitigated by the inclusion of a buffer statement on the label, requiring that consideration be given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings; prior to application to areas of human habitation and activity.

3.3 Food Residue Exposure Assessment

3.3.1 Food

AXXE Broad Spectrum Herbicide is not to be applied directly on the crop. Ammonium salt of fatty acid is of low toxicity, has a half-life of less than one day in both soil and water, and salts of fatty acid have a history of use as food additives, thus the dietary risk from food and drinking water is not a concern.

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

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.3.4 Aggregate Exposure and Risk

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

3.3.5 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. However, because of its low toxicity to mammalian systems, the PMRA does not expect any cumulative or incremental effects from exposure to residues of ammonium salts of fatty acids when used as directed on the label.

3.3.6 Maximum Residue Limits (MRLs)

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 one day in soil or water. Consequently, the specification of maximum residue limits under the *Pest Control Products Act* is not required.

Incident Reports

As of 26 October 2018, the PMRA has received 13 human incidents and 5 domestic animal incidents involving products containing ammonium salts of fatty acids. In humans, minor skin effects were frequently reported following exposure to diluted products, mostly during application around the home. In a few cases, individuals experienced minor eye, nose or throat irritation, headache, or pain. In domestic animal incidents, dogs had transient gastrointestinal effects, while one cat experienced ataxia and diluted pupils. No incidents were reported for the products Axxe Broad Spectrum Herbicide or EMERION W 36 SL.

Overall, the assessment of incident reports involving ammonium salts of fatty acids did not identify any concerns for human or domestic animal health. Based on the low number and minor severity of human and domestic animal incidents reported, no additional mitigation measures are proposed based on the review of incidents.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

4.2 Environmental Risk Characterization

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

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g., direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). 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.

The environmental toxicity and risk assessment of ammonium salt of fatty acid had been previously characterized for foliar application on ornamentals, turf, landscape, interiorscapes, greenhouses, non-crop areas on farmsteads and around buildings and industrial sites using hand-held equipment (PRD2017-04, *Ammonium Salt of Fatty Acid*). This assessment takes into account two new proposed methods of application, broadcast application with boom-equipped field sprayer and directed spray equipment on terrestrial food and feed crops, for which a potential for exposure to non-target plants through spray drift is considered to be greater than for hand-held methods.

As the proposed label for AXXE Broad Spectrum Herbicide indicates the same application rate as previously registered, only the risk to non-target terrestrial and aquatic plants as a result of broadcast application by boom sprayer equipment was assessed.

4.2.1 Risks to Terrestrial Plants

A summary of terrestrial plant toxicity data is presented in Appendix I, Table 1. The accompanying risk assessment is presented in Appendix I, Table 2.

Ammonium salt of fatty acid is toxic to terrestrial vascular plants. Based on an EEC equal to the maximum application rate for the proposed uses (38.25 kg a.i./ha), and a toxicity endpoint for effects on vegetative vigour (ER_{25} values = 3.55 kg a.i./ha), the calculated risk quotient exceeds the level of concern at the screening level (RQ=10.8). The risk to terrestrial vascular plants was further characterized by looking at off-field exposure from drift.

For an ASAE 'coarse' droplet size, the maximum spray drift deposition at one meter downwind from the point of application is 3% for ground application. The maximum percent deposition on non-target plants located 1 metre downwind from the point of application would therefore be 1.15 Kg a.i./ha (38.25 kg a.i./ha x 0.03). Based on the risk quotients using the off-field EECs from drift, the level of concern for terrestrial vascular plants off-field does not exceeded the level of concern (RQ = 0.32). The precautionary measures on the proposed label include directed and shielded sprays coupled with a coarse nozzle setting to prevent spray contact on desired terrestrial plants, therefore, no risks of concern are expected and terrestrial buffer zones are not required. In addition, for on-field non-target plants, label instructions will include requirements to prevent contact with desirable plants, including grass.

4.2.2 Risks to Aquatic Plants

A summary of aquatic toxicity data is presented in Appendix I, Table 1. The accompanying risk assessment is presented in Appendix I, Table 2.

Freshwater vascular plants: Ammonium salt of fatty acid showed no adverse effects to the vascular plant, duckweed, *Lemna gibba*. The risk quotients calculated at the screening level did not exceed the level of concern (RQ <0.026) therefore, aquatic buffer zones are not required.

4.2.3 Incident Reports

As of 26 October 2018, the PMRA has received four minor environment incidents involving ammonium salt of fatty acid. Damage to home lawns and vegetables were reported when the active ingredient contacted these plants. No incidents were found in the EIIS database for ammonium salt of fatty acid.

5.0 Value

There are many conventional herbicides registered for weed control in food and field crops as well as pastures. However, very few non-conventional herbicides are registered for such uses. The registration of AXXE Broad Spectrum Herbicide provides farmers with an alternative non-conventional herbicide option for weed management in these sites.

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

Refer to PRD2017-04, *Ammonium Salt of Fatty Acid*, for details.

Crop tolerance is not of concern for use of AXXE Broad Spectrum Herbicide in food and field crops and pastures as long as it is applied in accordance with label instructions, e.g., "*do not allow to spray or contact any green plant parts of desirable plants*" and "*contact with the desirable vegetation is avoided*".

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 acid 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 acid does not meet all Track 1 criteria and it is not expected to form any transformation products that are Track 1 substances. Ammonium salt of fatty acid is not expected to persist or bioaccumulate in the environment.

6.2 Formulants and 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*

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

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; and DIR2006-02,[8] and takes 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 EMERION W 36 SL containing ammonium salt of fatty acid 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 the PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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 W 36 SL, and the end-use product, AXXE Broad Spectrum Herbicide, are of low acute toxicity by the oral, dermal, and inhalation routes. EMERION W 36 SL 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.

Bystander exposure is mitigated by observing the standard buffer statement on the label, advising against application to areas of human habitation and activity unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

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

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 MRLs under the *Pest Control Products Act* is not required.

7.2 Environmental Risk

The use of ammonium salt of fatty acid is not expected to pose risks of concern to aquatic vascular plants. Risks to non-target terrestrial plants as a result of spray drift have been identified in areas adjacent to the treatment area. Precautionary measures to protect desirable plants from drift are required on the product label. Ammonium salt of fatty acid is not expected to persist in the environment; when used according to the label directions of the proposed end-use product, this compound is not expected to pose risks of concern to the environment.

7.3 Value

AXXE Broad Spectrum Herbicide is a non-conventional herbicide that provides an alternative non-conventional herbicide option for weed management in food crops, field crops, and pastures.

Crop tolerance is not of concern for use of AXXE Broad Spectrum Herbicide in food and field crops and pastures as long as it is applied as per label instructions, e.g., "*do not allow to spray or contact any green plant parts of desirable plants*" and "*contact with the desirable vegetation is avoided*.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of EMERION W 36 SL and AXXE Broad Spectrum Herbicide, containing the technical grade active ingredient ammonium salt of fatty acid, for control or burndown of weeds and grasses on food and feed crops and pastures.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

Additional Information Being Requested

No additional scientific information is required at this time.

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DF	dry flowable
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ER_{25}	effective rate for 25% of the population
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Toxicity to Non-Target Terrestrial and Aquatic Vascular Plants

Organism	Exposure	Test substance	Endpoint value
Terrestrial plants			
Ten species	21d-vegetative vigour	EMERION W 36 SL	EC_{25}: 1.3% at 3.55 kg a.i./ha
Aquatic plants			
Duckweed (*Lemna gibba)*	7d-dissolved	EMERION W 36 SL (purity 36%)	IC_{50} >360 mg a.i./L

Table 2 Risks to Non-Target Terrestrial and Aquatic Vascular Plants

Organism	Exposure	Endpoint value	EEC	RQ	Risk
Terrestrial plants					
Ten species	Vegetative vigour	EC_{25}: 3.55 kg a.i./ha	In-field ground: 38.25 kg a.i./ha	10.8	Yes
			Off-field ground, 3% drift: 1.15 kg a.i./ha	0.32	No
Aquatic plants					
Duckweed (*Lemna gibba)*	Dissolved	IC_{50} >360 mg a.i./L÷2	4.78 mg a.i./L	<0.026	No

Table 3 List of Supported Uses

Item	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 labelled weeds and liverworts.
Hosts and use sites	Food and field crops and pastures
Use methods	(1) Broadcast or spot spray using hand-held or directed (shielded) spray equipment. (2) Pre-emergence spray to the crop. (3) Prior to regrowth of perennial plants and sprout of tubers, bulbs, or seed pieces. (4) Post-harvest broadcast spray.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

None

2.0 Human and Animal Health

None

3.0 Environment

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4.0 Value

2545933 2007, Value of Emery AE7005 Concentrate, OK State USDA study, DACO: 10.2.3.3(B) and 10.3.2.

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