Proposed Registration Decision PRD2019-11

Octanoic Acid, Decanoic Acid, and BioLink Herbicide EC

(publié aussi en français)

23 September 2019

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

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ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2019-11E (print version)
H113-9/2019-11E-PDF (PDF version)

Table of Contents

Overview

Proposed Registration Decision for Octanoic Acid, Decanoic Acid, and BioLink Herbicide EC

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of BioLink FA Blend, and BioLink Herbicide EC, containing the technical grade active ingredients octanoic acid (also known as caprylic acid) and decanoic acid (also known as capric acid), for non-selective, post-emergent weed control in and around food and non-food crop areas, as well as non-agricultural and industrial sites.

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 octanoic acid, decanoic acid, and BioLink Herbicide EC.

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

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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."

Before making a final registration decision on octanoic acid, decanoic acid, and BioLink Herbicide EC, 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 octanoic acid, decanoic acid, and BioLink Herbicide EC, 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 Are Octanoic Acid and Decanoic Acid?

Octanoic acid and decanoic acid are non-conventional, non-selective contact herbicides that act by disrupting cell membranes, resulting in the leakage of cell contents followed by plant tissue death.

Health Considerations

Can Approved Uses of Octanoic Acid and Decanoic Acid Affect Human Health?

Octanoic Acid and Decanoic Acid are unlikely to affect human health when it is used according to label directions.

Potential exposure to octanoic acid and decanoic acid may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The 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.

In laboratory animals, the end-use product, BioLink Herbicide EC, was of low toxicity via the oral, dermal and inhalation routes. It was mildly irritating to the skin, moderately irritating to the eyes, and was not considered a dermal sensitizer.

Scientific rationales, as well as information from the published scientific literature, were assessed for the potential of octanoic acid and decanoic acid to cause short-term toxicity, developmental toxicity, genotoxicity, and various other effects. Octanoic acid and decanoic acid are naturally occurring fatty acids. Adverse effects in animals given repeated high doses included effects on

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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*.

the stomach, and reductions in body weights and food consumption. There was no indication that the young were more sensitive than the adult animal. There was no evidence that octanoic acid and decanoic acid induced mutagenic or genotoxic effects. The risk assessment protects against these findings noted above as well as any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are acceptable.

Although proposed for use on field and greenhouse food crops, BioLink Herbicide EC is directed to soil. Residues of octanoic acid and decanoic acid on treated food crops are possible at the time of harvest; however, toxicity to these active ingredients is low. In addition, the likelihood of residues of octanoic acid and decanoic acid in drinking water will be low. Consequently, health risks are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in Residential and Other Non-Occupational Environments

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

BioLink Herbicide EC is proposed for use on agricultural fields and residential areas. The product label will include measures to prevent bystander exposure such as reducing spray drift and restricting access to the treated area until sprays have dried. Residential and non-occupational exposure to BioLink Herbicide EC is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Occupational Risks From Handling BioLink Herbicide EC

Occupational risks are acceptable when BioLink Herbicide EC is used according to the label directions, which include protective measures.

Workers handling BioLink Herbicide EC can come into direct contact with octanoic acid and decanoic acid primarily on the skin and eyes. To protect workers from exposure to BioLink Herbicide EC, the label states that mixers, loaders, and applicators must wear chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, and socks and shoes. A restricted-entry interval of 24 hours is prescribed for treated agricultural sites, and re-entry is restricted until the sprays have dried for non-agricultural uses. If re-entry into treated agricultural sites is necessary during the restricted-entry interval, workers must wear chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, socks and shoes. If re-entry into treated non-agricultural sites is required before sprays have dried, individuals must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

Environmental Considerations

What Happens When Octanoic and Decanoic acids Are Introduced Into the Environment?

Octanoic acid and decanoic acid may enter the environment when BioLink Herbicide EC is used to control weeds around ornamental plants, turf, greenhouses and other food and non-food crops. Octanoic acid and decanoic acid are fatty acids that are soluble in water and can enter the atmosphere. In air, they are expected to breakdown very quickly or be removed by rain. Octanoic and decanoic acids are not expected to move through soil to groundwater. Fatty acids are a natural component in soil and water in the environment, and are broken down very quickly in soil and water by microorganisms. Build-up in the environment and long-term effects on plants and animals are not expected.

In general, fatty acids comprise a significant part of the normal daily diet of mammals, birds and terrestrial invertebrates. Octanoic and decanoic acids do not pose a risk of concern to bees, beneficial arthropods, birds and wild mammals.

Exposure to octanoic and decanoic acids can affect aquatic invertebrates, amphibians, and terrestrial plants. However, proposed application methods including spot treatment, directed or broadcast applications using shielded nozzles, and coarse spray will prevent drift to non-target organisms. Owing to the rapid dissipation in the environment, exposure to aquatic organisms from run-off is also not expected.

After a scientific review of the available information, the environmental risks associated with the proposed uses of BioLink FA Blend and its associated end-use product, BioLink Herbicide EC, have been determined to be acceptable when used according to the proposed label directions.

Value Considerations

What Is the Value of BioLink Herbicide EC?

BioLink Herbicide EC is a non-conventional herbicide that provides control of several annual and perennial broadleaf, grass and sedge weed species in and around food and non-food crop areas, as well as non-agricultural and industrial sites.

BioLink Herbicide EC is expected to be of benefit to users by providing access to another non-conventional product where the use of conventional herbicides is either not desirable or not permitted, such as in organic agriculture.

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 BioLink Herbicide EC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words “CAUTION – SKIN IRRITANT” and “WARNING – EYE IRRITANT” are required on the principal display panels of the labels for both BioLink FA Blend and BioLink Herbicide EC. Standard hazard and precautionary statements are also required on the end-use product labels to inform workers of the irritation potential of the active ingredient to the skin and eyes. Workers handling BioLink Herbicide EC will be required to wear standard personal protective equipment including chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, and shoes plus socks.

A restricted-entry interval of 24 hours is required for agricultural uses of BioLink Herbicide EC. Similarly, individuals are restricted from re-entering treated non-agricultural areas until the sprays have dried. If re-entry into treated agricultural sites is required during the restricted-entry interval, workers must wear chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, socks and shoes. If re-entry into treated non-agricultural sites is required before the sprays have dried, individuals must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

Environment

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

Next Steps

Before making a final registration decision on octanoic acid, decanoic acid, and BioLink Herbicide EC, 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 octanoic acid, decanoic acid, and BioLink Herbicide EC (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

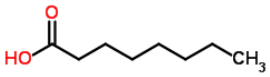
Octanoic Acid and Decanoic Acid

1.0 The Active Ingredients, Its Properties and Uses

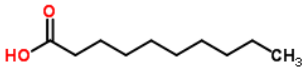
1.1 Identity of the Active Ingredients

Active substances	Octanoic Acid (Caprylic Acid) Decanoic Acid (Capric Acid)
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Octanoic Acid Decanoic Acid
2. Chemical Abstracts Service (CAS)	Octanoic Acid Decanoic Acid
CAS numbers	124-07-2 for octanoic acid 334-48-5 for decanoic acid
Molecular formula	$C_8H_{16}O_2$ $C_{10}H_{20}O_2$
Molecular weight	144.21 172.27

Structural formula



Octanoic Acid:



Decanoic Acid

Purity of the active ingredient	Octanoic Acid : 59.7 % Decanoic Acid : 40 %

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product— BioLink FA Blend

Property	Result
Colour and physical state	Transparent clear liquid
Odour	Odourless to waxy
Melting range	N/A
Boiling point or range	178.39 ºC
Specific gravity at 20 °C	0.9061
Vapour pressure at 20 °C	0.4552 Pa (20 ºC) 0.7164 Pa (25 ºC)
Ultraviolet (UV)-visible spectrum	Medium — λ_{max} (nm) Neutral — 202 Acid — 212 Basic — 204
Solubility in water at 20 °C	0.0533 g/100 mL (octanoic acid) < 0.0123 g/100 mL (decanoic acid)

Solubility in organic solvents at 20 °C	The decanoic acid is soluble in most organic solvents and in diluted nitric acid. The octanoic acid is soluble in alcohol, chloroform, ether, carbon disulfide, petroleum ether, glacial acetic acid.
n-Octanol-water partition coefficient (K_{ow})	The product dissociates in water and is partially soluble in water.
Dissociation constant (pK_a)	pKa = 4.49
Stability (temperature, metal)	The product was found to be stable when stored at 54 ºC for 14 days. It was also found to be stable when exposed to powdered elemental iron, iron (III) citrate n-hydrate, aluminum powder, and aluminum (III) phosphate at room temperature and 54 ºC for 14 days.

End-Use Product—BioLink Herbicide EC

Property	Result
Colour	Transparent
Odour	Odourless to waxy
Physical state	Liquid
Formulation type	Emulsifiable Concentrate (EC)
Label concentration	Octanoic Acid: 47.16 % Decanoic Acid: 31.6 %
Container material and description	Plastic Bottle, Jug, Pail, Drum, Tote, Bulk (3–1050 L)
Specific Gravity	0.91164
pH of 1% dispersion in water	3.26
Oxidizing or reducing action	The product does not have any oxidation or reducing actions.
Storage stability	The product was found to be stable after one year storage in HDPE container at 20 ± 2 ºC.
Corrosion characteristics	No effects were observed on the commercial container (HDPE) after one year storage of the product at 20 ± 2 ºC.
Explodability	The product does not have any explosive components.

1.3 Directions for Use

BioLink Herbicide EC is intended for application following weed emergence in and around field-grown food and feed crops, non-food crops, as well as in non-agricultural and industrial sites. Biolink Herbicide EC will control several common weed species, including annual ryegrass, annual bluegrass, barnyard grass, large crabgrass, wild oat, yellow nutsedge, black mustard, black nightshade, cleavers, curled dock, redroot pigweed, velvetleaf, wild carrot, burning nettle, hairy nightshade, common purslane, and narrowleaf plantain.

BioLink Herbicide EC may be applied as a 3%, 6% or 9% solution, depending on the type and size of weed being treated. Applications may be repeated every 14–-21 days throughout the year as required.

BioLink Herbicide EC may be applied as a spot treatment, as a broadcast application, or as a directed application in row crops provided that rows are sufficiently wide to permit the use of shielded nozzles to prevent the spray solution from contacting the crop.

1.4 Mode of Action

Octanoic acid and decanoic acid are non-conventional, non-selective contact active ingredients that penetrate green leaf and stem tissue resulting in the disruption of cell membranes and leakage of cell contents leading to tissue death.

The mode of action of octanoic acid and decanoic acid is not classified by the Weed Science Society of America or the Herbicide Resistance Action Committee.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation 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 octanoic acid and decanoic acid due to their low toxicities (see Section 3.0 for additional details).

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological information submitted in support of BioLink FA Blend and BioLink Herbicide EC was conducted by the PMRA. The data package for BioLink FA Blend and BioLink Herbicide EC is considered acceptable (Appendix I, Table 1) to assess the toxic effects that may result from exposure to octanoic acid and decanoic acid. The data package consisted of acute toxicity studies for BioLink Herbicide EC (acute oral, dermal, and inhalation toxicity, skin and eye irritation, and dermal sensitization), publicly available information on structurally similar medium chain fatty acids, and scientific rationales to waive acute toxicity, short-term toxicity, prenatal developmental toxicity, and genotoxicity testing for BioLink FA Blend.

BioLink Herbicide EC is of low acute oral, dermal, and inhalation toxicity, moderately irritating to the eyes, mildly irritating to the skin, and is not a dermal sensitizer. No studies were submitted to address the acute toxicity requirements for BioLink FA Blend. Since the active ingredients in BioLink Herbicide EC are present at comparable levels in BioLink FA Blend (47.16% octanoic acid and 31.6% decanoic acid vs 59.7% octanoic acid and 39.8% decanoic acid) and the formulants present in the end-use product are not expected to adversely affect the toxicology findings, the studies submitted for BioLink Herbicide EC are acceptable as bridging data for BioLink FA Blend. Consequently, BioLink FA Blend is considered of low acute oral, dermal, and inhalation toxicity, moderately irritating to the eyes, mildly irritating to the skin, and is not a dermal sensitizer.

Requests to waive testing were granted for the acute toxicity, short-term toxicity, prenatal developmental toxicity, and genotoxicity of BioLink FA Blend based on the rationale that the proposed use of BioLink Herbicide EC on greenhouse and field crops would result in minimal dietary exposure; that its active ingredients, octanoic acid and decanoic acid, are medium chain fatty acids that are naturally present in foods; and that the European Food Safety Authority has thoroughly reviewed the safety of fatty acids as food additives and has not found any concerns in their assessment of octanoic and decanoic acids. Fatty acids are an important component of fats. In food, fatty acids naturally occur as triglycerides with three, often different, fatty acids that are esterified to a glycerin backbone. Triglycerides are variable in length and saturation, and somewhat species specific, but the majority of fatty acids have carbon chain lengths that are even-numbered.

The available literature on triglycerides containing octanoic acid and decanoic acid and medium chain fatty acids indicate that triglycerides are hydrolyzed by the lingual lipase enzyme in the stomach and the resulting fatty acids are absorbed directly into the bloodstream. Medium chain fatty acids such as octanoic acid and decanoic acid are quickly absorbed into the blood stream from the intestinal lumen and transported to the liver via the portal vein. Afterwards, medium chain fatty acids are catabolized two carbons at a time by a cellular process called beta-oxidation. The resulting 2-carbon units can be further catabolized to carbon dioxide via the citric acid cycle or used to synthesize longer chain fatty acids. Medium chain fatty acids are not typically stored in adipose tissues.

In addition to the above rationale, the applicant also provided toxicological summaries obtained primarily from United States Environmental Protection Agency (USEPA) Final Registration Review Decision documents for octanoic (octanoic) acid and decanoic (decanoic) acid, but also from published scientific literature and from information databases such as International Uniform Chemical Information Database, Hazardous Substances Databank and the USEPA High Production Volume Information System. These toxicological summaries were derived from various sources of octanoic acid and decanoic acid and also included surrogate data for two other medium chain fatty acids, namely heptanoic acid and nonanoic acid. The data indicated that octanoic acid and decanoic acid were generally of low acute toxicity via the oral and dermal routes, from low to slightly acutely toxic via the inhalation route, and moderately to severely irritating to the skin and eyes. The toxicological information also included various summaries of oral, dermal, and inhalation subchronic and chronic toxicity studies, and of developmental toxicity studies. Few effects were observed in these longer studies despite the large daily doses

(up to 3500 mg/kg bw/day by gavage). In subchronic and chronic studies, systemic effects most often included significant decreases in body weight and food consumption but also included signs such as hyperkeratosis of the non-glandular stomach, languid behavior, dyspnea, polypnea, tremors, wheezing, ataxia and excess salivation at the highest doses tested. In developmental toxicity studies, no developmental toxicity was reported even at doses up to 1500 mg/kg bw/day. In some of these studies, the high dose treatments did cause maternal toxicity and a significant decrease in the number of live pups. Lastly, no evidence of mutagenic activity in bacterial reverse mutation assays or unscheduled mammalian DNA synthesis was reported for octanoic acid and decanoic acid.

Health Incident Reports

As of 1 March 2019, no human, animal, or packaging failure incident reports involving decanoic acid or octanoic acid had been submitted to the PMRA. As well, no scientific study reports involving decanoic acid or octanoic acid had been submitted through the Incident Reporting Program. No human or domestic health concerns were identified from the incident report review.

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

No information on dermal absorption of octanoic acid and decanoic acid from BioLink Herbicide EC was provided, however, dermal absorption is expected to be limited when the precautionary statements on the label are observed.

3.2.2 Use Description

BioLink Herbicide EC is proposed for use in food and non-food agricultural crops (field and greenhouse), as well as in non-agricultural sites. BioLink Herbicide EC is applied with hand-held equipment, boom sprayers, and pressure sprayers. When applying this product in a broadcast application, workers should use a hooded sprayer, shield, or other spray equipment that prevents the movement of spray away from the target weeds. Also, nozzles that are designed to produce large spray droplets to prevent drift onto crops should be used. BioLink Herbicide EC is most effective when applied to newly emerged, actively growing weeds.

When applying BioLink Herbicide EC to more mature weeds, the higher concentrations (6% and 9%), with up to 945 L of water per hectare, should be used. A 3% solution should be used to control small annual broadleaved weeds (less than 15 cm in height), and a 6% solution for the control of annual grass weeds and burndown of perennial herbaceous plants (less than 15 cm in height) and annual broadleaved weeds (greater than 15 cm in height). A 9% solution is required to control large annual grasses and perennial weeds, or for maximum vegetative burndown, edging, or when foliar trimming is desired. BioLink Herbicide EC is applied such that the weeds are thoroughly covered and is to be applied as required throughout the growing season. There is no limit to the number of applications per year.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

When BioLink Herbicide EC is used according to label directions, occupational exposure is characterized as short- to intermediate-term in duration and is primarily by the dermal route, but incidental inhalation and ocular exposure is also possible while mixing, loading, and applying the product, as well as during clean-up, and equipment maintenance or repair. To protect workers from exposure to BioLink Herbicide EC, the label states to wear goggles or face shield, long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. Adequate ventilation is also required when spraying in enclosed areas, such as greenhouses.

Precautionary statements such as the wearing of PPE on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the label are followed which include PPE.

3.2.4 Postapplication Exposure and Risk

There is the potential for postapplication exposure to workers re-entering areas treated with BioLink Herbicide EC. Given the nature of the post-application activities typically performed (for example, scouting treated areas), dermal contact with treated plants, soil, and surfaces is possible. A restricted-entry interval (REI) of 24 hours must be observed for agricultural uses of the end-use product, as well as instructions for individuals to remain out of the treated area until the sprays have dried for non-agricultural uses. If re-entry is necessary during the REI for agricultural uses, dermal exposure is likely and individuals will be required to wear goggles, long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. If re-entry before sprays have dried is required for non-agricultural uses, individuals must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

Precautionary (for example, wearing of PPE) statements on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from risk due to post-application exposure.

3.2.5 Residential and Bystander Exposure and Risk

The use of BioLink Herbicide EC outdoors may result in bystander exposure due to drift. Bystander exposure will be mitigated by the inclusion of a spray drift statement on the label, advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings. Consequently, the health risks to bystanders are considered acceptable.

BioLink Herbicide EC is proposed for use in residential areas, such as in and around parks. Observing the label instructions that prohibit entry in treated areas until the sprays have dried will ensure that exposure to humans and companion animals in residential areas is negligible. Consequently, the health risks to individuals in residential areas are considered acceptable.

3.3 Food Residue Exposure Assessment

3.3.1 Food

While dietary exposure to octanoic acid and decanoic acid may occur through consumption of treated crops, the risk from consuming food crops treated with BioLink Herbicide EC is acceptable due to their low toxicity profiles, the history of their use as food additives, and the fact that direct application of BioLink Herbicide EC on food crops is to be avoided.

3.3.2 Drinking Water

Dietary exposure from drinking water is expected to be negligible as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of octanoic acid and decanoic acid. Health risks from residues of octanoic acid and decanoic acid in drinking water are acceptable due to their low toxicity profiles and limited exposure following application of BioLink Herbicide EC.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for octanoic acid and decanoic acid. Based on all the available information and hazard data, these active ingredients are considered to be of low toxicity. Thus, there are no threshold effects of concern. As a result, there is no need to apply uncertainty factors to account for intra- and interspecies variability, or have a margin of exposure required. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of octanoic acid and decanoic acid including developmental effects from pre- or postnatal exposures, and cumulative effects on infants and children of this active ingredient and other registered products containing it, does not apply to this active ingredient. As a result, the PMRA has not used a margin of exposure (safety) approach to account for intra- and interspecies variability or have a margin of exposure given that a threshold for potential effects is not required.

3.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of octanoic acid and decanoic acid to the general population in Canada, including infants and children, when BioLink Herbicide EC is used as labelled. 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 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, a cumulative health assessment was undertaken.

While octanoic acid and decanoic acid may share a common moiety with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to octanoic acid, decanoic acid, and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of octanoic acid and decanoic acid.

3.3.6 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 is 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* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Dietary risk to humans from the proposed use of octanoic acid and decanoic acid on agricultural and non-agricultural crops is acceptable due to the low toxicity profile of octanoic acid and decanoic acid and because BioLink Herbicide EC is not proposed for direct use on food or feed. Therefore, the specification of MRLs, under the *Pest Control Products Act*, will not be required for octanoic acid and decanoic acid.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Octanoic and decanoic acids can enter the environment when BioLink Herbicide EC is used as pre-plant, pre-emergent (broadcast) or postemergent foliar spray on food and non-food crops to control undesired vegetation (in other words, weeds and grasses), unwanted basal sucker growth on woody trees, foliage growth on vines and excessive cane growth in the brambles. The active ingredients octanoic and decanoic acids are very weak and semi-volatile fatty acids. Octanoic and decanoic acids partially dissociate in aqueous solution under environmental conditions. Abiotic processes such as hydrolysis and phototransformation are not important routes of dissipation in the environment. Under aerobic conditions, octanoic and decanoic acids undergo rapid microbial β-oxidation into CO_2 and water. Dissipation of octanoic and decanoic acids from soil and water is similar to that for nonanoic acid, another saturated fatty acid intermediate in length with octanoic and decanoic acids, with a DT_{50} value of approximately 1.1 days at 20 °C. Thus, octanoic and decanoic acids are not expected to persist in terrestrial and aquatic environments.

Octanoic and decanoic acids have moderate to very high mobility in soil based on estimated K_{oc} values of 29–70 L/kg (octanoic acid) and 96–262 L/kg (decanoic acid). Although QSAR modeling indicates mobility, because of rapid degradation in soil, octanoic and decanoic acids are not expected to leach to groundwater. In water, the estimated K_{oc} indicates that adsorption to suspended solids and sediments may occur.

Although the estimated log K_{ow} of 3.05 and 4.09 for octanoic and decanoic acids, respectively, suggest a potential for bioconcentration, the estimated bioconcentration factor (BCF) values less than 100 indicate a low potential for bioaccumulation. There is also limited potential for uptake given its rapid breakdown in the environment and fatty acids are consumed as part of the normal diet of animals.

Octanoic and decanoic acids have solubility in water, high vapour pressure and, based on Henry's law constant of 1.91×10^{-3} atm m^3/mole, they readily volatilize from moist soil or water surfaces. Although volatilisation is expected to be a route of dissipation, octanoic and decanoic acids are not expected to undergo long-range transport in the atmosphere because they are subject to photo-oxidation in air through reactions with hydroxyl radicals. The estimated half-lives are 15.4 and 11.5 hours for octanoic and decanoic acids, respectively. Level III fugacity modelling using EPI Suite v4.11 indicates that the octanoic and decanoic acids will distribute primarily to soil (68.3–64.9%) and water (28.8–31.6%) with lesser amounts to air (2.78–3.39%) and sediment (0.14–0.09%).

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 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 (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (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 = 1 for most species, 0.4 for acute risk to pollinators). If the screening level risk quotient (RQ) 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.

Data for octanoic and decanoic acids were considered in the environmental assessment. For birds, aquatic invertebrates and fish, toxicity data for octanoic and decanoic acids were not available. Toxicity data was available for potassium salt of fatty acid (nonanoic acid), which is similar in structure and intermediate in length as compared to octanoic and decanoic acid. Toxicity data on potassium salt of fatty acid (nonanoic acid) are considered in the environmental assessment where data gaps existed for octanoic and decanoic acids. Environmental toxicity data are summarized in Appendix I, Table 2.

4.2.1 Risks to Terrestrial Organisms

Terrestrial organisms, such as honeybees, beneficial arthropods, birds, small wild mammals and terrestrial vascular plants, could be exposed to octanoic and decanoic acids through direct contact with spray or spray drift, contact with sprayed surfaces or from ingestion of contaminated food.

BioLink FA Blend is practically non-toxic to honey bees on an acute basis (oral 48 hour LD_{50} >164 µg a.i./bee and contact 48 hour LD_{50} >159.3 µg a.i./bee). However, potential acute risks were identified for bees exposed to the proposed maximum application rate of 61.25 kg a.i/ha (oral RQ <10.8 and contact RQ <0.9) (see Appendix I, Table 3). Vegetation control using BioLink Herbicide EC is by spot treatment and directed or shielded applications, and other methods to reduce drift, such as application with coarse spray. 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 be minimized by the use of hand-held equipment, coarse spray, and directed or shielded spraying. Risks to bees and other beneficial insects are, therefore, not expected as a result of this use pattern.

BioLink FA Blend is practically non-toxic to small mammals on an acute oral basis (LD_{50} >3950 mg a.i./kg bw) and no adverse effects were observed in birds exposed to potassium salt of fatty acid on an acute oral and dietary basis (acute oral LD_{50} >2000 mg/day and dietary LC_{50} >5620 mg/day). The LOCs were potentially exceeded for birds and mammals feeding in field based on high rates of application (RQ <2.5). However, risk is expected to be negligible given that no effects were observed at the highest dose tested in the studies. In addition, octanoic and decanoic acids are naturally produced by plant and animal cells, as well as by microbial metabolism and comprise a part of the normal daily diet of mammals and birds. LOCs were not exceeded for birds and mammals feeding off field (see Appendix I, Table 4).

The general herbicidal mode of action for BioLink FA Blend involves the disruption of photosynthesis through destruction of cell membranes resulting in plant death. Thus, BioLink FA Blend 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. Low drift application equipment including shrouded sprayers or hand held equipment and coarse spray will prevent drift to non-target terrestrial plants.

Overall conclusion about potential risks to terrestrial organisms

Overall, there is no risk of concern to bees and other beneficial arthropods from exposure to BioLink FA Blend, given that the proposed methods of application will minimize spray drift and the active ingredients are not toxic to these organisms. Fatty acids comprise part of the normal daily diet of mammals and birds and are considered non-toxic to these organisms. As such, there is also no risk of concern for birds and small mammals. Octanoic and decanoic acids are toxic to plants. However, low drift application equipment including shrouded sprayers or hand held equipment and coarse spray applications will prevent drift to non-target terrestrial plants. A label statement is required to inform the user of the potential hazard.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms, such as fish, amphibians, invertebrates, algae and vascular plants, could be exposed to octanoic and decanoic acids through contact with spray drift or overland runoff.

Owing to its herbicidal properties and known use as an algicide, BioLink FA Blend is expected to be toxic to algae and vascular plants if they are exposed to high enough concentrations. Potassium salt of fatty acid is highly toxic to the aquatic invertebrate *Daphnia magna* with a 48-hr EC_{50} of 0.57 mg/L in water. Potassium salt of fatty acid was slightly toxic to both cold and warm water fish. The 96-h LC_{50s} were 18.06 and 35.35 mg/L for rainbow trout and bluegill sunfish, respectively. The level of concern was exceeded for freshwater invertebrates, fish and amphibians using the screening level risk assessment which considers direct application to a shallow water body (RQ = 4.24–26.8; see Appendix I, Table 5). As handheld or directed/shielded application and coarse spray are supported for the current use pattern of BioLink Herbicide EC, spray drift will be minimal. After further characterization of the risk to aquatic organisms from spray drift (>70% reduction in drift using shrouded boom and/or coarse spray), the LOC (level of concern) was not exceeded for any aquatic organisms. Overland runoff is expected to be minimal due to the short half-life of fatty acids in soil and water and the potential for volatilization from moist soil surfaces. Precautionary label statements to provide guidance on how to control runoff will be required on the label.

Overall conclusion about potential risks to aquatic organisms

The overall potential risk as a result of spray drift and runoff to aquatic organisms is minimal. Although the risks are considered to be acceptable, a label statement is required to inform the user of the potential hazard. In addition, a precautionary label statement to provide guidance on how to control runoff will be required on the label.

4.3 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. Information on the reporting of incidents can be found on the PMRA website.

As of 12 March 2019, there were no incident reports involving these active ingredients in the PMRA database. A review of incident reports in the United States in the Ecological Incident Information System database was also conducted. There were no environmental incidents involving decanoic acid and octanoic acid blend in the database.

5.0 Value

BioLink Herbicide EC reduces weed competition with field-grown crops and may be used for control of vegetation in other areas where weed growth is undesirable, such as industrial sites and around building structures. Non-conventional herbicides, such as BioLink Herbicide EC, are of particular benefit where the use of conventional herbicides is either not desirable or not permitted, such as in organic agriculture.

BioLink Herbicide EC can be included as a component of a weed management program that utilizes tillage and pre-plant, pre-emergent and/or postemergent herbicides for control or suppression of additional weeds and to extend weed control throughout the season.

Due to the nature of the mode of action for octanoic and decanoic acid, the development of weed resistance is unlikely. Furthermore, the use of BioLink Herbicide EC may reduce reliance on conventional alternatives.

Value information was submitted as efficacy and crop tolerance data generated in small-scale replicated research trials. Greenhouse and field trials were conducted on a variety of annual and perennial broadleaf, grassy and sedge weeds that were growing either in the absence of or presence of a crop.

The trial data demonstrated that an application of BioLink Herbicide EC as a 3%, 6% or 9% solution after weed emergence can be expected to provide control of several common weed species, including annual ryegrass, annual bluegrass, barnyard grass, large crabgrass, wild oat, yellow nutsedge, black mustard, black nightshade, cleavers, curled dock, redroot pigweed, velvetleaf, wild carrot, burning nettle, hairy nightshade, common purslane and narrowleaf plantain.

Crop tolerance evaluations demonstrated that broadcast applications prior to planting or prior to crop emergence or as directed and shielded applications between crop rows would not be expected to result in crop injury. Furthermore, as BioLink Herbicide EC is a contact herbicide with no residual soil activity, injury to emerging crop plants would not be expected.

Supported uses are summarized in Appendix I, Table 6.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Assessment of the Active Ingredient under the Toxic Substances Management Policy

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the Canadian *Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, octanoic and decanoic acids and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[1] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that octanoic and decanoic acids and their transformation products do not meet all of the TSMP Track 1 criteria.

BioLink FA Blend is a naturally occurring substance that has a non-toxic mode of action and is not expected to be persistent or bioaccumulative in the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical as well as 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.*[5] The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including DIR99-03; and DIR2006-02,[7] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade BioLink FA Blend and its end-use product, BioLink Herbicide EC do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

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

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5 SI/2005-114

6 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concernt.*

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

7.0 Summary

7.1 Human Health and Safety

The available information for BioLink FA Blend and BioLink Herbicide EC is adequate to qualitatively identify the toxicological hazards that may result from human exposure to octanoic and decanoic acids. The end-use product, BioLink Herbicide EC, is of low acute toxicity by oral, dermal, and inhalation routes. However, there was evidence of mild to moderate irritation to the skin and eyes, respectively, of rabbits after acute dosing. BioLink Herbicide EC is not a dermal sensitizer. Waivers were granted for short-term toxicity, prenatal developmental toxicity, and genotoxicity on the basis that medium chain fatty acids have low toxicity, are naturally present and used as food additives.

Workers can be exposed to octanoic acid and decanoic acid while mixing, loading, and applying BioLink Herbicide EC, as well as during clean-up, and equipment maintenance or repair. Consequently, the label states to wear goggles or face shield, long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves. Adequate ventilation is also required when spraying in enclosed areas, such as greenhouses. Postapplication exposure will occur mainly by the dermal route. An REI of 24 hours must be observed for agricultural uses of the end-use product, as well as instructions for individuals to remain out of the treated area until the sprays have dried for non-agricultural uses. If re-entry into treated areas is required during the REI for agricultural uses, individuals will be required to wear goggles or face shield, long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. If re-entry into treated non-agricultural areas is required before sprays have dried, individuals will be required to wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Precautionary statements (for example, wearing of personal protective equipment) on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from risk due to occupational exposure.

Exposure to bystanders during the application of BioLink Herbicide EC may be minimized when the end-use product is only applied when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal. Applicators should take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

BioLink Herbicide EC is proposed for use in residential areas, such as in and around parks. Observing the label instructions that prohibit entry in treated areas until the sprays have dried will ensure minimal exposure to humans and companion animals. Consequently, the risks to individuals in residential areas are considered acceptable.

While dietary exposure to octanoic acid and decanoic acid may occur through consumption of treated crops, the dietary risks to humans are acceptable due to their low toxicity profiles, the history of their use as food additives, and that direct application of BioLink Herbicide EC on food crops is to be avoided. The specification of an MRL under the *Pest Control Products Act* is not being recommended as octanoic acid and decanoic acid are naturally occurring fatty acids.

7.2 Environmental Risk

Octanoic and decanoic acids are readily transformed in the environment and transformation products of environmental concern are not expected. Octanoic and decanoic acids and BioLink FA Blend are practically non-toxic to honey bees and small mammals. Potassium salt of fatty acid is practically non-toxic to birds, but is slightly toxic to fish and highly toxic to *Daphnia*. Adverse developmental effects were observed in amphibian embryos exposed to octanoic acid in laboratory studies. Fatty acids are short-lived in the environment and are natural components of diets for all living organisms, consequently risks to terrestrial and aquatic organisms are expected to be minimal when label directions are followed. Exposure to aquatic habitats due to runoff is mitigated by the volatility and short transformation half-lives of octanoic and decanoic acids in soil and water. Precautionary label statements to provide guidance on how to control runoff along with hazard label statements to inform users of the toxicity to terrestrial plants and aquatic organisms are required. When used according to label instructions, risks to non-target organisms are acceptable.

7.3 Value

The information submitted to register BioLink Herbicide EC is adequate to demonstrate the value of its use for general weed control in an array of use sites. The availability of BioLink Herbicide EC will provide users with access to a non-conventional product that is currently available in other countries and it can be an additional option where the use of conventional herbicides is either not desirable or not permitted, such as in organic agriculture.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Biolink FA Blend, and BioLink Herbicide EC, containing the technical grade active ingredients octanoic acid and decanoic acid, to control for non-selective, postemergent weed control in and around food and non-food crop areas, as well as non-agricultural and industrial sites.

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.

List of Abbreviations

° C	degrees Centigrade
µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
atm	atmosphere
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
d	day
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
FIR	food ingestion rate
g	gram
ha	hectare(s)
HDPE	high density polyethylene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
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%
LOC	level of concern
m	metre
mg	milligram
mL	millilitre
MAS	maximum average score
MIS	maximum irritation score
MRL	maximum residue limit
n/a	not applicable
nm	nanometre
OCA	octanoic acid
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
REI	restricted-entry interval
RQ	risk quotient
TSMP	Toxic Substances Management Policy

USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Toxicity Profile of BioLink Herbicide EC Containing Octanoic Acid and Decanoic 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 Rat, Sprague Dawley (♀) PMRA #2803952	LD_{50} ♀ > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Rat, Sprague Dawley PMRA #2803953	LD_{50} ♂♀ > 5050 mg/kg bw Low toxicity
Acute inhalation toxicity Rat, Sprague Dawley PMRA #2803954	LC_{50} ♂♀ > 2.11 mg/L Low toxicity
Eye irritation Rabbit, New Zealand White PMRA #2803955	MAS [a] = 15.3/110 (at 24, 48 and 72 hours) MIS [b] = 15.3/110 (at 24, 48 and 72 hours) MAS was not 0/110 by 24 hours. MIS was 0/110 by Day 17. Moderately irritating
Skin Irritation Rabbit, New Zealand White PMRA #2803956	MAS [a] = 2.11/8 (at 24, 48 and 72 hours) MIS [b] = 2.67/8 (at 72 hours) Mildly irritating
Dermal sensitization (Buehler) Guinea Pig, Hartley-Albino PMRA #2803957	Negative Not a dermal sensitizer

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

Table 2 Toxicity of fatty acids to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Invertebrates					
Bee *Apis mellifera*	48h-Oral	BioLink Herbicide EC	48-h LD_{50} >164 µg a.i./bee	Practically non toxic	2808129
	48h-Contact	BioLink Herbicide EC	48-h LD_{50} >159.3 µg a.i./bee	Practically non toxic	2808128
Birds					
Bobwhite quail *Cortunix cortunix japonicaColinus virginianus*	Acute oral	Potassium salt of fatty acid	LD_{50} >2000 ppm	Practically non-toxic	USEPA RED, 1992
Bobwhite quail *Colinus virginianus*	Dietary		LC_{50} >5620 ppm	Practically non-toxic	
Mallard duck Anas platyrhynchos	Dietary		LC_{50} >5620 ppm	Practically non-toxic	
Mammals					
Rat, Sprague Dawley	Acute oral	Biolink Herbicide (79% fatty acids)	LD_{50} >5000 mg product/kg bw (or LD_{50} >3950 mg a.i./kg bw)	Practically non-toxic	2803952
Vascular plants	No data were submitted				
Freshwater species					
Daphnia magna	48h-Acute	Potassium salt of fatty acid	EC_{50}: 0.57 mg/L	Highly toxic	USEPA RED, 1992
Rainbow trout *Oncorhynchus mykiss*	96-Acute	Potassium salt of fatty acid	LC_{50}: 18.06 mg/L	Slightly toxic	
Bluegill sunfish *Lepomis macrochirus*	96-Acute	Potassium salt of fatty acid	LC_{50}: 35.35 mg/L	Slightly toxic	
African clawed frog *Xenopus laevis*	96h-FETAX	Octanoic acid	EC_{50}: 27.9 mg/L	NA	Dawson, 1991
Marine diatom *Nitzchia closterium*	72 h	Octanoic acid	EC_{50}: 144 mg/L	NA	2808130 Pg. 137
Vascular plant	No data were submitted				

[a]Atkins et al.(1981) for bees and USEPA classification, where applicable.

Table 3 Risk to terrestrial organisms other than birds and mammals

Organism	Exposure	Endpoint value	EEC[a]	RQ	LOC exceeded?
Invertebrates					
Honeybee *Apis mellifera*	Oral	LD_{50} >164 µg a.i./bee	61.25 kg a.i./ha × 29 µg a.i./bee per kg/ha = 1776.25 µg a.i./bee	<10.8	Potentially
	Contact	LD_{50} >159.3 µg a.i./bee	61.25 kg a.i/ha × 2.4 µg a.i./bee per kg/ha = 147 µg a.i./bee	<0.9	Potentially
[a]For contact exposure, the exposure estimate = (2.4 µg a.i./bee)*(application rate in kg a.i./ha) and dietary					

factors are 29 µg a.i./bee (adult). LOC of 0.4 for acute pollinator risk assessment.

Table 4 Screening and extended avian and mammalian risk assessment using maximum and mean BioLink FA Blend residue values on the highest crop application rate

			Maximum nomogram residues				Mean nomogram residues			
			On field		Off field		On field		Off field	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Bird (0.02 kg)										
Acute	2000.00	Insectivore	4986.24	<2.5	149.59	<0.1	3442.88	<1.72	103.29	<0.05
	2000.00	Granivore (grain and seeds)	771.68	<0.4	23.15	0.0	368.03	<0.18	11.04	<0.01
	2000.00	Frugivore (fruit)	1543.37	<0.8	46.30	0.0	736.07	<0.37	22.08	<0.01
Medium-sized Bird (0.1 kg)										
Acute	2000.00	Insectivore	3891.22	<1.9	116.74	<0.1	2686.80	<1.34	80.60	<0.04
	2000.00	Granivore (grain and seeds)	602.22	<0.3	18.07	0.0	287.21	<0.14	8.62	<0.00
	2000.00	Frugivore (fruit)	1204.43	<0.6	36.13	0.0	574.42	<0.29	17.23	<0.01
Large-sized Bird (1 kg)										
Acute	2000.00	Insectivore	1136.08	<0.6	34.08	0.0	784.44	<0.39	23.53	<0.01
	2000.00	Granivore (grain and seeds)	175.82	<0.1	5.27	0.0	83.85	<0.04	2.52	0.00
	2000.00	Frugivore (fruit)	351.65	<0.2	10.55	0.0	167.71	<0.08	5.03	0.00
	2000.00	Herbivore (short grass)	2513.52	<1.3	75.41	0.0	892.66	<0.45	26.78	<0.01
	2000.00	Herbivore (long grass)	1534.70	<0.8	46.04	0.0	501.13	<0.25	15.03	<0.01
	2000.00	Herbivore (Broadleaf plants)	2325.55	<1.2	69.77	0.0	768.78	<0.38	23.06	<0.01
Small Mammal (0.015 kg)										
Acute	3950.00	Insectivore	2867.90	<0.72	86.04	<0.02	1980.22	<0.50	59.41	<0.01
	3950.00	Granivore (grain and seeds)	443.84	<0.11	13.32	0.00	211.68	<0.05	6.35	0.00
	3950.00	Frugivore (fruit)	887.69	<0.22	26.63	0.00	423.36	<0.10	12.70	0.00
Medium-sized Mammal (0.035 kg)										
Acute	3950.00	Insectivore	2514.07	<0.63	75.42	<0.01	1735.91	<0.43	52.08	<0.01
	3950.00	Granivore (grain and seeds)	389.08	<0.09	11.67	0.00	185.56	<0.04	5.57	0.00
	3950.00	Frugivore (fruit)	778.17	<0.19	23.35	0.00	371.13	<0.09	11.13	0.00
	3950.00	Herbivore (short grass)	5562.26	<1.40	166.87	<0.04	1975.39	<0.50	59.26	<0.01
	3950.00	Herbivore (long grass)	3396.20	<0.85	101.89	<0.02	1108.96	<0.28	33.27	0.00
	3950.00	Herbivore (forage crops)	5146.29	<1.30	154.39	<0.03	1701.25	<0.43	51.04	<0.01

Large-sized Mammal (1 kg)										
Acute	3950.00	Insectivore	1343.35	<0.34	40.30	<0.01	927.55	<0.23	27.83	0.00
	3950.00	Granivore (grain and seeds)	207.90	<0.05	6.24	0.00	99.15	<0.02	2.97	0.00
	3950.00	Frugivore (fruit)	415.80	<0.10	12.47	0.00	198.31	<0.05	5.95	0.00
	3950.00	Herbivore (short grass)	2972.10	<0.75	89.16	<0.02	1055.51	<0.26	31.67	0.00
	3950.00	Herbivore (long grass)	1814.70	<0.45	54.44	<0.01	592.56	<0.15	17.78	0.00
	3950.00	Herbivore (Broadleaf plants)	2749.83	<0.69	82.49	<0.02	909.04	<0.23	27.27	0.00

*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 <or = 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.
DT_{50} of 1.1 days was used in calculation of EDE.

Table 5 Risk to aquatic organisms

Organism	**Exposure**	**Adjusted Endpoint value**	**EEC (mg/L)**	**RQ**	**Risk**
Freshwater species					
Daphnia magna	Acute	EC_{50}/2: 0.285 mg/L	7.65 3% drift ; 0.23	26.8 Drift: 0.80	Yes No
Rainbow trout *Oncorhynchus mykiss*	96h-Acute	LC_{50}/10: 1.806 mg/L	7.65 3% drift ; 0.23	4.24 0.12	Yes No
African clawed frog *Xenopus laevis*	96h-Acute - FETAX	EC_{50}/10: 2.79 mg/L (OCA)	24.27 3% drift: 0.74	8.7 Drift: 0. 3	Yes No
Marine diatom *Nitzchia closterium*	72h-Acute	EC_{50}/2: 72 mg/L (OCA)	4.55 (OCA) 7.65	0.06 (OCA) 0.10	No No

OCA: octanoic acid

Table 6 List of Supported Uses

Items	**Label claims that are supported**
Application rates and weed timing	Postemergent (to weed) application as follows: Use a 3% solution for control of small annual broadleaved weeds less than 15 cm in height. Use a 6% solution for control of annual grass weeds and burndown of

	perennial herbaceous broadleaved plants less than 15 cm in height and annual broadleaved weeds larger than 15 cm in height. Use a 9% solution for control of larger annual grass and perennial weeds, such as sedges, or for maximum vegetative burndown, edging, or when foliar trimming is desired.
Efficacy claims	Control of weeds such as: grasses, such as annual ryegrass, annual bluegrass, barnyard grass, large crabgrass and wild oat; sedges, such as yellow nutsedge; and broadleaf weeds, such as black mustard, black nightshade, cleavers, curled dock, redroot pigweed, velvetleaf, wild carrot, burning nettle, hairy nightshade, common purslane and narrowleaf plantain.
Hosts and use sites	For use in and around food and non-food crops and non-agricultural and industrial sites, including: Berries: Strawberries, Blackberries, Blueberries (including lowbush), Gooseberries, Cranberries, Red Raspberries, Red and Black Currants Brassicas (Cole): Broccoli, Brussels Sprouts, Cabbage, Cauliflower, Collards, Kale, Mustard Greens Bulb Vegetables: Garlic, Leaks, Onions, Shallots Cucurbit Vegetables: Cucumbers, Gourds, Pumpkins, Squash Field Crops: Alfalfa*, Canola*, Cereal Grains*, Corn, Sorghum*, Soybeans, Sweet Corn Fruiting Vegetables: Eggplant, Peppers (All Varieties), Tomatillos, Tomatoes Herbs and Spices: Anise, Basil, Chive, Dill, Fennel, Oregano Grapes: Wine Grapes, French Hybrids, native Lambrusca types Leafy Greens: Arugula, Celery, Lettuce, Spinach Legumes: Beans, Garbanzo, Lentils, Peas Tree Nuts: Hazelnuts (Filberts), Walnuts Pome Fruit: Apples, Crabapples, Pears, Quince Stone Fruit: Apricots, Cherries, Nectarines, Peaches, Plums, Prunes Root and Tuber Vegetables: Beets, Sugar Beets, Carrots, Potatoes, Seed Potato, Radishes, Sweet Potatoes Miscellaneous Crops: Asparagus Turf, Flowers, Bedding and Landscape: Bedding Plants, Flowers and Ornamentals, Turf Grass (Maintenance, Sod or Seed Prod) Trees and Shrubs: Christmas Trees, Forest and Commercial Trees, Landscape Trees, Nursery Trees or Shrubs Greenhouse and Nurseries: All Crops, Plants Fallow Land, Forages and Pastures, Uncultivated Land Parks, golf courses, turf, ornamentals, landscapes, non-crop areas, right-of-ways, and around building structures.

	*Pre-plant or pre-emergent applications only
Application methods	Spot application, broadcast application and directed application. Directed application is for use only in row crops in which spacing in between rows is sufficient for use of shielded nozzles to prevent spray from contacting the crop.
Application timing (relative to the crop)	Pre-plant or pre-emergent (broadcast); and Postemergent (directed such that crop is not contacted with the spray solution).
Repeat applications	Every 14 to 21 days, as required (no maximum seasonal limit).
Application equipment	Conventional ground application equipment, including but not limited to: boom sprayers, ATV-mounted tractor sprayers, handheld and backpack sprayers.
Utility Modifier	Use an acidifier (such as BioLink Acidifier) to maintain spray water pH below 6.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2808118	2017, Chemical Abstracts Registry Number, DACO: 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2808121	2016, Confirmation of Identity, DACO: 2.13.1, 2.13.2, 2.13.3 CBI
2808123	2013, Octanol/Water Partition Coefficient, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.9,830.7000 CBI
2808124	2013, UV/Visible Absorption Spectra, DACO: 2.14.1, 2.14.10, 2.14.12, 2.14.13, 2.14.15, 2.14.2, 2.14.3, 2.14.5, 2.14.6, 2.14.7, 2.14.9,830.7000 CBI
2808125	2017, Solvent Solubility (mg/L), DACO: 2.14.8 CBI
2845349	2018, Other Studies/Data/Reports, DACO: 2.16 CBI
2846103	2018, Other Studies/Data/Reports, DACO: 2.16 CBI
2846104	2015, Other Studies/Data/Reports, DACO: 2.16 CBI
2870050	2018, Description of Starting Materials, DACO: 2.11.2 CBI
2870053	2018, Other Studies/Data/Reports, DACO: 2.16 CBI
2803943	2013, Description Of Starting Materials, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI
2803944	2013, Corrosion Characteristics, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9 CBI
2803947	2017, Container Material And Description, DACO: 3.5.5 CBI
2803949	2015, Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
2803950	2017, Explodability, DACO: 3.5.12, 3.5.15, 3.5.4, 3.5.8 CBI
2876201	2018, Description of Starting Materials, DACO: 3.2.1 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2803952	2012, Biolink Herbicide Acute Oral toxicity (UDP) in Rats, DACO: 4.6.1
2803953	2012, Biolink Herbicide Acute Dermal Toxicity in Rats, DACO: 4.6.2
2803954	2012, Biolink Herbicide Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2803955	2013, Biolink Herbicide Acute Eye Irritation in Rabbits, DACO: 4.6.4
2803956	2013, Biolink Herbicide Acute Dermal Irritation in Rabbits, DACO: 4.6.5
2803957	2012, Biolink Herbicide Skin Sensitization in Guinea Pigs, DACO: 4.6.6
2803958	2017, Use Description Scenario-BioLink Herbicide EC, Data Numbering Code: 5.2
2808126	2013, Summary of the OPPTS 870 Series Human Health Data Requirements: Caprylic Acid (Octanoic Acid), DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.3.4, 4.3.6, 4.5.2, 4.5.4, 4.5.5
2808127	2013, Summary of the OPPTS 870 Series Human Health Data Requirements: Capric Acid (Decanoic Acid), DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.3.4, 4.3.6, 4.5.2, 4.5.4, 4.5.5
2893797	2018, Scientific Rationale: BioLink¿¿ Herbicide TGAI: PMRA Submission Number 2017-5389 TGAI Submission Deficiencies: DACO: 4.2.1, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.5.2, 4.5.4, 4.5.5
2893802	2017, Re-Evaluation of fatty acids (E 570) as a food additive, DACO: 4.2.1, 4.3.1, 4.4.4, 4.5.5

3.0 Environment

PMRA Document Number	Reference
2803952	2012, Biolink Herbicide Acute Oral toxicity (UDP) in Rats, DACO: 4.6.1
2808128	2017, BioLink Herbicide: Effects (Acute Contact Test) on Honey Bees (*Apis mellifera* L.) in the Laboratory, DACO: 9.2.4.1
2808129	2016, BioLink Herbicide: Effects (Acute Oral Test) on Honey Bees (*Apis mellifera* L.) in the Laboratory, DACO: 9.2.4.2
2808130	2013, Waiver Request - Nontarget Organisms: Caprylic Acid, DACO: 9.3.2,9.5.2.1,9.6.2.1,9.6.2.4,9.6.2.5
2808131	2013, Waiver Request - Nontarget Organisms: Capric Acid, DACO: 9.3.2,9.5.2.1,9.6.2.1,9.6.2.4,9.6.2.5
2808133	2017, Non-Target Plants-Caprylic and Capric Acids, DACO: 9.8,9.8.2,9.8.3

4.0 Value

PMRA Document Number	Reference
2803967	2014, Dickinson Natural Products Weed Control Efficacy Study - Report, DACO: 10.2.3.3(B).
2803968	2014, Dickinson Natural Products Weed Control Efficacy Study - Slides, DACO: 10.2.3.3(B).
2895525	2010, 2010 Organic Herbicide Trial, DACO: 10.2.3.3(B), 10.3.2(A).
2895526	2010, 2010 Onion Weed Control Trials, DACO: 10.2.3.3(B), 10.3.2(A).
2895527	2018, Orchard Floor Management in North Coast Organic Pear Orchards., DACO: 10.2.3.3(B), 10.3.2(A).
2895528	2018, Woolly Distaff Thistle Control, DACO: 10.2.3.3(B), 10.3.2(A)
2895529	2013, 2013 Evaluation of Spray Materials for Thinning/Weeding Lettuce, DACO: 10.2.3.3(B), 10.3.2(A).
2895531	2018, Weed control in establishing dune sedge (Carex pansa), DACO: 10.2.3.3(B), 10.3.2(A).
2895532	2018, Weed Control Evaluation with Biolink Formulations, DACO: 10.2.3.3(B), 10.3.2(A).
2895533	2018, Enhanced Weed Management for Organic Vegetable Crop Production, DACO: 10.2.3.3(B), 10.3.2(A).
2895534	2012, Biolink spreader/sticker - 1% v/v used in each treatment, DACO: 10.2.3.3(B), 10.3.2(A).
2895535	2012, Evaluation of Biolink for Weed Control, DACO: 10.2.3.3(B), 10.3.2(A).
2895536	2011, Optimizing Organic Herbicide Activity, DACO: 10.2.3.3(B), 10.3.2(A).
2895538	2018, high-density apple orchard was battling a Canada thistle, DACO: 10.2.3.3(B), 10.3.2(A).

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA Document Number	Reference
2978334	K. A. Traul, A. Driedger, D. L. Ingle and D. Nakhasi, 2000, Review of the Toxicologic Properties of Medium-chain Triglycerides, Food and Chemical Toxicology 38:79-98, DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.3.1, 4.5.2, 4.5.4, 4.5.5

2.0 Environment

PMRA Document Number	Reference
2558259	1992, US-EPA Soap Salts Reregistration Eligibility Document (RED), DACO: 12.5
1573066	Atkins, E.L., Kellum, D. and Atkins, K.W. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management strategies. University of California Division of Agricultural Sciences Leaflet No. 2883. 22 pp., DACO: 9.2.4.1
	IUCLID (2000) IUCLID Dataset on Decanoic acid. Creation Date 18 February 2000. European Chemical Bureau, Ispra, Italy.
	Dawson D A. 1991. Additive incidence of developmental malformation for *Xenopus* embryos exposed to a mixture of Ten aliphatic carboxylic acids. Teratol 44:531-546.
	EFSA 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance Fatty acids C7 to C18 (approved under Regulation (EC) No 1107/2009 as Fatty acids (C7 to C20). EFSA Journal 11(1):3023.
	ECHA 2010. Nonanoic acid Product-type 19 (repellents and attractants). Directive 98/8/EC concerning the placing biocidal products on the market. Assessment Report. https://echa.europa.eu/documents/10162/7e06caf7-5255-6fb8-f72b-c9bdb5c4c625
	ECHA, 2013: Annex 1. Background Document to RAC Opinion on octanoic acid https://echa.europa.eu/documents/10162/24c6f0f9-6d38-69f6-38d7-37b9fce0594a
	EFSA 2017. Re-evaluation of fatty acids (E 570) as a food additive. EFSA Journal 15 (5): 4785.