Proposed Registration Decision PRD2019-15

Pelargonic Acid Beloukha Herbicide and Beloukha Agricultural Herbicide

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Overview

Proposed Registration Decision for Pelargonic Acid

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 Pelargonic Acid Technical, Beloukha Herbicide and Beloukha Agricultural Herbicide, containing the technical grade active ingredient pelargonic acid, to provide burndown, spot, and inter-row weed control in fruit, vegetable and field crops, desiccant and pre-harvest weed management in potato and cereal crops, sucker control in grapes and tree fruits, and control of unwanted weeds and mosses in non-crop areas.

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 pelargonic acid, Beloukha Herbicide and Beloukha Agricultural Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the 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 pelargonic acid, Beloukha Herbicide and Beloukha Agricultural 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 pelargonic acid, Beloukha Herbicide and Beloukha Agricultural 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 Pelargonic Acid?

Pelargonic acid is a non-selective contact herbicide that inhibits plant growth by disrupting cell membranes resulting in leakage of cell contents, which leads to plant death. Pelargonic acid does not translocate in the plant nor does it have any residual activity in the soil.

Health Considerations

Can Approved Uses of Pelargonic Acid Affect Human Health?

Pelargonic acid is unlikely to affect human health when it is used according to label directions.

Potential exposure to pelargonic 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 animal studies, the technical grade active ingredient, pelargonic acid was of low toxicity via the oral and dermal routes and slightly acutely toxic by the inhalation route. It was severely irritating to the skin and eyes, and was a dermal sensitizer.

In laboratory animals, the end-use products, Beloukha Herbicide and Beloukha Agricultural Herbicide, were of low toxicity via the oral and dermal routes. They were mildly irritating to the skin, moderately irritating to the eyes, and were not considered dermal sensitizers. Both products are considered to be slightly acutely toxic by the inhalation route.

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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*.

Animal toxicity tests as well as information from the published scientific literature were assessed for the potential of pelargonic acid to cause short-term toxicity, developmental toxicity, genotoxicity and various other effects. Pelargonic acid is a medium chain fatty acid. Fatty acids are used by the body as a primary nutrient, following a metabolic pathway that is well described. The short-term toxicity for pelargonic acid was characterized as low, and there is a low level of concern for sensitivity of the young animal. The mutagenic potential of pelargonic acid was considered to be of no concern based on a weight of evidence of the data. The risk assessment further 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.

Applications of Beloukha Herbicide and Beloukha Agricultural Herbicide are directed to weeds in and around food and non-food crops or directly to cereal crops before harvest. Therefore, residues of pelargonic acid on food crops are possible at the time of harvest; however, toxicity to this active ingredient is low. In addition, the likelihood of residues of pelargonic 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.

Beloukha Herbicide and Beloukha Agricultural Herbicide are proposed for use on agricultural fields and non-crop land areas. The product labels 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 Beloukha Herbicide and Beloukha Agricultural Herbicide 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 Beloukha Herbicide and Beloukha Agricultural Herbicide

Occupational risks are acceptable when Beloukha Herbicide and Beloukha Agricultural Herbicide are used according to the label directions, which include protective measures.

Workers handling Beloukha Herbicide and Beloukha Agricultural Herbicide can come into direct contact with pelargonic acid primarily on the skin and eyes. To protect workers from exposure to Beloukha Herbicide and Beloukha Agricultural Herbicide, the label states that mixers, loaders, and applicators must wear chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, socks and shoes. Individuals must remain out of the treated area until the sprays have dried. If re-entry is necessary before the sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks, shoes, and protective eyewear (goggles or face shield).

Environmental Considerations

What Happens When Pelargonic Acid Is Introduced Into the Environment?

After a scientific review of the available information, PMRA has concluded that environmental risks associated with the proposed uses of pelargonic acid and associated end-use products are acceptable when used according to the proposed label directions.

Pelargonic acid can enter the environment when Beloukha Herbicide or Beloukha Agricultural Herbicide are used to control weeds in fruit, vegetable, and non-crop land, for cereal and potato desiccation, and for grape and fruit tree sucker control. Fatty acids, including pelargonic acid, are natural components in the environment and are produced by both plants and animals. Pelargonic acid is not persistent and is quickly broken down by microorganisms in the environment. Pelargonic acid is not expected to move through soil to groundwater. Fatty acids, including pelargonic acid, are a significant part of the normal diet of birds, mammals and invertebrates, and are readily metabolized by animals. As such, pelargonic acid is not expected to accumulate in organisms.

Non-target species may be exposed to pelargonic acid through direct contact with spray or spray drift, contact with sprayed surfaces or from ingestion of contaminated food. The use of pelargonic acid as an herbicide may affect beneficial arthropods, and non-target terrestrial plants. Label statements to inform users of the toxicity to non-target organisms and buffer zones to reduce exposure to terrestrial habitats will be required to mitigate these risks. When pelargonic acid is used in accordance with the label and the required precautions, the resulting environmental risk is considered to be acceptable.

Value Considerations

What Is the Value of Beloukha Herbicide and Beloukha Agricultural Herbicide?

Beloukha Herbicide and Beloukha Agricultural Herbicide are non-conventional and non-selective contact herbicides for control of weeds, mosses, suckers and crop desiccation.

Both Beloukha Herbicide and Beloukha Agricultural Herbicide are formulated with pelargonic acid. They provide burndown, spot, and inter-row weed control in fruit, vegetable and field crops, desiccant and pre-harvest weed management in potato and cereal crops, sucker control in grapes and tree fruits, and control of weeds and mosses in non-crop areas.

Management of undesired plant growth is critical in crop production as well as in non-cropland. Beloukha Herbicide and Beloukha Agricultural Herbicide provide additional options for weed, moss and sucker control, as harvest aids, and for herbicide resistance management in many crops and in non-cropland areas.

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 Beloukha Herbicide and Beloukha Agricultural Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words “DANGER-SKIN AND EYE IRRITANT”, “CAUTION-POISON” and “POTENTIAL SKIN SENSITIZER” are required on the principal display panel of the label for Pelargonic Acid Technical. Additionally, the signal words “WARNING – SKIN AND EYE IRRITANT” and “CAUTION POISON”, are required on the principal display panels for Beloukha Herbicide and Beloukha Agricultural Herbicide. Standard hazard and precautionary statements are also required on the Technical grade active ingredient and end-use product labels to inform workers of the hazard irritation potential of the active ingredient to the skin and eyes and the respiratory tract. Workers handling Beloukha Herbicide and Beloukha Agricultural Herbicide will be required to wear standard personal protective equipment including chemical-resistant gloves, goggles or face shield, long-sleeved shirt, long pants, shoes and socks.

Individuals are restricted from re-entering treated areas until the sprays have dried. If re-entry is necessary before the sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks, shoes, and protective eyewear (goggles or face shield).

Environment

- Label statements to indicate toxicity to beneficial arthropods and non-target terrestrial plants.
- Buffer zones of 1 metre to protect sensitive terrestrial habitat.

Next Steps

Before making a final registration decision on pelargonic acid and Beloukha Herbicide and Beloukha Agricultural 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. 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.

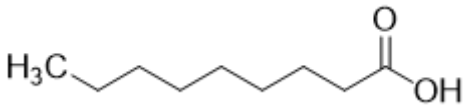
Other Information

When the Health Canada makes its registration decision, it will publish a Registration Decision on pelargonic acid, Beloukha Herbicide and Beloukha Agricultural 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

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Pelargonic acid (nonanoic acid)
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Nonanoic acid
2. Chemical Abstracts Service (CAS)	Nonanoic acid
CAS number	112-05-0
Molecular formula	$C_9H_{18}O_2$
Molecular weight	158.24
Structural formula	
Purity of the active ingredient	99.1 %

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

Technical Product—Pelargonic Acid Technical

Property	Result
Colour and physical state	Yellow liquid
Odour	Coconut odour
Melting range	Not applicable, the product is a liquid at ambient temperature
Boiling point or range	251 °C
Density at 20 °C	0.910 g/cm^3
Vapour pressure at 20°C	4.52 × 10^{-1} Pa
Ultraviolet (UV)-visible spectrum	pH / λ_{max} (nm) / ε (L/cm.mol) < 2 / 207.99 / 60 Neutral / 207.97 / 63

Property	Result
Solubility in water	Pure water: 0.171 g/L at 17 ºC – 20 °C Water at pH 7: 2.83 g/L at 19 ºC – 20 °C Water at pH 9: 13.9 g/L at 18 ºC – 20 °C
Solubility in organic solvents at 20°C	> 250 g/L in n-heptane, p-xylene, dichloromethane, methanol, acetone and ethyl acetate
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 5 — 3.0 7 — 2.4 9 — 0.0
Dissociation constant (pK_a)	pK_a = 4.96 at 25 ºC
Stability (temperature, metal)	The product was found to be stable when stored at 54 ºC for 2 weeks.

End-use Product—Beloukha Herbicide

Property	Result
Colour	Yellow
Odour	Characteristic
Physical state	Liquid
Formulation type	Emulsifiable Concentrate (EC)
Label concentration	500 g/L
Container material and description	0.1 L – bulk HDPE tubes, bottles and totes
Density	0.963 g/cm^3 at 20 °C
pH of 1% dispersion in water	3.8
Oxidizing or reducing action	The product has no oxidizing properties.
Storage stability	The product was found to be stable after 2 week storage at 54 ± 0.7 °C in its commercial container (HDPE).
Corrosion characteristics	No effects were observed on the commercial container (HDPE) after 2 week storage at 54 ± 0.7 °C.
Explodability	The product has no explosive properties.

End-use Product— Beloukha Agricultural Herbicide

Property	Result
Colour	Yellow
Odour	Characteristic
Physical state	Liquid
Formulation type	Emulsifiable Concentrate (EC)

Property	Result
Label concentration	680 g/L
Container material and description	0.1 L – bulk HDPE
Density	0.951 g/cm^3 at 20 °C
pH of 1% dispersion in water	3.5
Oxidizing or reducing action	The product has no oxidizing properties.
Storage stability	The product was shown to be stable after 14 days of storage at 54 °C in the commercial package.
Corrosion characteristics	No effects were observed on the commercial container (HDPE) after two year storage of the product at 20 °C.
Explodability	The product is not expected to be explosive.

1.3 Directions for Use

The application of Beloukha Herbicide and Beloukha Agricultural Herbicide provide control or suppression of a number of weed species and mosses (Appendix I, Table 11), sucker removal in fruit trees and grapes, and foliage desiccation of cereals and potatoes. The application rates, for both products, deliver similar amounts of active ingredient per hectare. For harder-to-control weeds and larger sized suckers, higher rates or repeat applications may be required.

Beloukha Herbicide (containing 500 g/L of pelargonic acid) is recommended for application 2–4 times per season at rates of:

1. 16 – 27 L/ha (8000 – 13 500 g a.i./ha) for
    a. annual crops: burndown weed control before or after seeding but prior to crop emergence and inter-row or spot weed control using directed or shielded spray after crop emergence and pastures
    b. perennial crops and orchards/vineyards older than 2 years: weed control and suppression using directed or shielded spray
    c. non-crop:
        i. post-harvest weed control
        ii. vegetation control in and around rights-of-way, buildings, structures, and walkways
        iii. moss control on benches, walls, floors, roofs, and cooling pads
2. 16–22 L/ha (8000–11 000 g a.i./ha) for potato crop desiccation and weed management prior to harvest
3. 11–22 L/ha (5500–11 000 g a.i./ha) for cereal (wheat, barley, oats) crop desiccation and weed management prior to harvest
4. 4–7 L/ha (2000–3500 g a.i./ha) for sucker removal in grape, pome fruit and stone fruit

Beloukha Agricultural Herbicide (containing 680 g/L of pelargonic acid) is recommended for application 2–4 times per season at rates of:

1. 12–20 L/ha (8160–13 600 g a.i./ha) for
    a. annual crops: burndown weed control before or after seeding but prior to crop emergence and inter-row or spot weed control using directed or shielded spray after crop emergence
    b. perennial crops and orchards/vineyards older than 2 years: weed control and grass suppression using directed or shielded spray
    c. non-crop:
        i. post-harvest weed control
        ii. vegetation control in and around rights-of-way, buildings, structures, and walkways
        iii. moss control on benches, walls, floors, roofs, and cooling pads
2. 12–16 L/ha (8160–10 880 g a.i./ha) for potato crop desiccation and weed management prior to harvest
3. 8–16 L/ha (5440–10 880 g a.i./ha) for cereal (wheat, barley, oats) crop desiccation and weed management prior to harvest
4. 3–5 L/ha (2040–3400 g a.i./ha) for sucker removal in grape, pome fruit and stone fruit

Beloukha Herbicide and Beloukha Agricultural Herbicide can be used in all tillage systems, including conventional, reduced and no-tillage systems.

1.4 Mode of Action

Pelargonic acid is a non-selective contact herbicide that controls actively growing plants. Pelargonic acid penetrates the plant tissues to disrupt the cell membrane resulting in leakage of cell contents leading to plant tissue death. Pelargonic acid does not translocate in the plant nor have any residual activity in the soil.

Pelargonic acid is classified as a Group Z herbicide by the Herbicide Resistance Action Committee (HRAC).

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 pelargonic acid due to its low toxicity (see Section 3.0 for additional details).

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The data and information submitted in support of Pelargonic Acid Technical, Beloukha Herbicide and Beloukha Agricultural Herbicide was determined to be acceptable to assess the toxicological effects that may result from exposure to pelargonic acid (Appendix I, Tables 1 to 3).

The data package consisted of acute toxicity (acute oral and dermal toxicity, skin and eye irritation, dermal sensitization), short-term oral toxicity, and genotoxicity studies for Pelargonic Acid Technical, as well as acute toxicity studies (acute oral and dermal toxicity, skin and eye irritation, dermal sensitization) in support of Beloukha Herbicide and Beloukha Agricultural Herbicide. Publicly available information on the active ingredient and structurally similar medium chain fatty acids and scientific rationales were also submitted to waive acute inhalation toxicity, and developmental toxicity testing for Pelargonic Acid Technical and to waive acute inhalation toxicity testing for the end-use products.

The technical grade active ingredient is Pelargonic Acid Technical; pelargonic acid is the common name for pelargonic acid, a C9 medium chain, saturated fatty acid. In this document, the term pelargonic acid will be used for the active ingredient in the technical grade active ingredient, in accordance with the terminology established by the International Union of Pure and Applied Chemistry (IUPAC). Medium chain fatty acids (C6–C12 fatty acids) are found naturally in foods (such as meat/fish, dairy, vegetables and plant oils), as triglycerides that consist of three fatty acids esterified to a glycerin backbone. The majority of these fatty acids have carbon chain lengths that are even-numbered (for example, C8, C10), rather than odd-numbered but odd-numbered fatty acids are present in low amounts (particularly in ruminant fats). In the United States, pelargonic acid is used as a food additive for its antimicrobial properties. Fatty acids are regarded primarily as nutrients, which yield energy and contribute to various essential cell functions and structures. Metabolism of medium-chain fatty acids in mammals is well understood and expected to be complete. Medium chain triglycerides are hydrolyzed by the lingual lipase enzyme in the stomach and absorbed directly into the bloodstream from the intestinal lumen and transported to the liver via the portal vein. Afterwards, they are catabolized, two carbons at a time, by beta-oxidation, a cellular process carried out by mitochondria. 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. In contrast to long chain fatty acids, medium chain fatty acids are not typically stored in adipose tissues. Odd-chain fatty acid metabolism follows the same process, producing one propionyl-CoA as a final degradation product. This metabolite is converted through a series of steps to succinyl-Co-A which then enters the citric acid cycle. No other metabolites of odd-chain fatty acids are expected after it is completely oxidized by the mitochondria.

In acute testing, Pelargonic Acid Technical was of low acute toxicity by the oral and dermal routes, severely irritating to the eyes and skin and was a dermal sensitizer.

To address short-term oral toxicity for Pelargonic Acid Technical, a 28-day oral (dietary) toxicity study in SPF-bred Wistar rats with VVH 86081, a product containing 62.1% pelargonic acid, was submitted as surrogate data. No toxicologically significant changes were noted in any of the parameters investigated in this study (in other words, clinical appearance, functional observations, body weight, food consumption, clinical laboratory investigations, macroscopic examination, organ weights, and microscopic examination). The short-term oral NOAEL (rat) is greater than 976 mg pelargonic acid/kg bw/day for males; greater than 982 pelargonic acid/kg bw/day for females (values are corrected for test substance intake, purity and stability), the highest dose tested.

In genotoxicity testing, pelargonic acid showed no evidence of induced mutant colonies over background in a bacterial reverse gene mutation assay and was not clastogenic in an in vitro cytogenetic test system in human peripheral blood lymphocytes, in the absence nor in the presence of metabolic activation. In a mammalian cell gene mutation assay based on the mouse lymphoma thymidine kinase locus with L5178Y/TK$^{+/-}$ cells, pelargonic acid was weakly positive with, and without, mammalian metabolic activation at concentrations approaching cytotoxic levels. There were no signs of clastogenicity. Based on weight of evidence, pelargonic acid was considered not to be mutagenic.

A scientific rationale to waive acute inhalation toxicity testing with pelargonic acid was accepted based on a publicly available acute inhalation study for a C9 product containing 31.2% pure pelargonic acid, which had an LC_{50} value of greater than 1.66 mg/mL (4-hour; nose only exposure). Based on its vapour pressure, pelargonic acid is considered to be moderately to highly volatile. The predominant effect from acute inhalation exposure to medium chain fatty acids is expected to be irritation of the mucosal membrane. Pelargonic Acid Technical is considered to be slightly acutely toxic by the inhalation route.

A scientific rationale to waive prenatal developmental toxicity testing for Pelargonic Acid Technical was also accepted based on: toxicological summaries from the United States Environmental Protection Agency (USEPA) and from published scientific literature; the identity of the active ingredient, in other words, pelargonic acid, is a medium chain fatty acids for which its metabolism is well understood; and the review of fatty acids by European Food Safety Authority (EFSA) which identified no concerns.

Toxicological summaries were submitted to describe the prenatal developmental toxicity of pelargonic acid. In one summary, CD rats were exposed at a single dose of 1500 mg/kg/d of pelargonic acid by gavage during gestational days (GD) 6–15 (N=20 litters; n= 243 fetuses). There were no signs of maternal toxicity, however, a non-statistically significant increase in incidence of cleft palate was reported in four fetuses in one litter from the treatment group (fetal incidence: 1.6% in test group vs 0.7% in controls). Based on the limited information available for review, there were no other malformations in fetuses noted. The effects were seen at a dose that is in excess of the limit dose recommended for testing.

In other published prenatal developmental toxicity studies conducted on mixtures of medium- and long-chain triacylglycerols (MLCT), no maternal toxicity and no prenatal developmental toxicity was observed in CD rats following dietary exposure to a mixture containing 30% w/w medium chain fatty acids up to 8.0 g/kg bw/day during organogenesis. In intravenous (iv) infusion studies, no signs of prenatal developmental toxicity were reported in Crl:CD rats administered a 20% w/w lipid emulsion containing a 3:1 mixture medium- and long-chain fatty acids in soybean oil at a dose of 1.0 g lipid/kg bw/day (low dose) or 4.28 g lipid/kg bw/day (high dose) during organogenesis. Maternal toxicity, including decreased feed consumption and lower body weight, was reported but there were no signs of prenatal developmental toxicity. This study was repeated in Hra:(NZW)SPF rabbits and reported similar maternal toxicity as well as statistically significant signs of prenatal developmental toxicity (for example, increased post-implantation loss, lower fetal body weights, and higher incidence of various morphological anomalies) in the high dose group. The NOEL for prenatal developmental toxicity (via iv infusion) in rabbit was reported to be greater than 1.0 g lipid/kg bw/day but less than to 4.28 g lipid/kg bw/day in rabbits. These studies are considered supplemental based on a lack of study details and the route of administration (iv) is not biologically relevant for developmental toxicity.

The EFSA review of fatty acids as pesticides noted the poor quality of available developmental toxicity data for fatty acids. Its review indicated that humans and animals are continually exposed to moderate levels of medium-chain fatty acids through dietary intake, and considering the low oral toxicity of fatty acids in rodents, EFSA determined that conducting further animal studies to investigate developmental and reproductive effects was not warranted. Based on a weight of evidence of available information, and considering that exposure resulting from use as agrochemicals would add an insignificant proportion to the normal daily intake of fatty acids, EFSA concluded a low developmental and reproductive risk for fatty acids.

In consideration of all available information characterizing the potential prenatal developmental toxicity of pelargonic acid, the weight of evidence indicates a low concern for developmental toxicity.

The data requirements for acute toxicity testing for the end-use products, Beloukha Herbicide and Beloukha Agricultural Herbicide were addressed with studies as well as rationales to bridge the toxicity test results between formulations.

Acute oral and acute dermal toxicity testing, and dermal sensitization testing was performed only with Beloukha Agricultural Herbicide (680 g a.i./L; Table 2 in Appendix I). Scientific rationales to waive testing for these endpoints for the second end-use product, Beloukha Herbicide (500 g a.i./L) were based on the results of toxicity testing conducted with Beloukha Agricultural Herbicide, as both products contain similar formulants. However because analyses of the test substance contained less than the specified lower certified limits (LCL) of the end-use products, the results of acute toxicity testing with Pelargonic Acid Technical (99.1% pelargonic acid; discussed above) were also considered. The formulants present in the end-use product are not expected to adversely affect the toxicology findings. The studies submitted for Beloukha Agricultural Herbicide are acceptable as bridging data for acute toxicity testing for Beloukha Herbicide. Beloukha Herbicide and Beloukha Agricultural Herbicide are of low acute toxicity via oral and dermal routes and are not dermal sensitizers.

Results of testing with both formulations, Beloukha Herbicide and Beloukha Agricultural Herbicide, confirm these products will be moderately irritating to the eyes and skin (Table 2 and Table 3 in Appendix I).

A scientific rationale was accepted to waive acute inhalation toxicity studies for the end-use products based on: the acute inhalation endpoint for pelargonic acid (published by EFSA) and an assessment of the formulation ingredients. Based on the acute inhalation LC_{50} of greater than 1.66 mg/mL (4-hour; nose only exposure), Beloukha Herbicide and Beloukha Agricultural Herbicide is classified as slightly toxic by the acute inhalation route.

Incident Reports

As of 17 July 2019, 32 human incident reports and 72 domestic animal incident reports involving pelargonic acid, or related fatty acids, ammonium salt of fatty acid, or potassium salts of fatty acid had been reported to the PMRA.

There were 21 human incidents that were determined to have some association to exposure to a pesticide product containing ammonium salt of fatty acid or potassium salts of fatty acid, and they were mainly minor in severity. Individuals were exposed through the skin during the application or handling of the pesticide product and effects such as rash, itchy skin, erythema, and eye irritation were most frequently reported. Incidents involving the exposure of children after the application of products containing potassium salts of fatty acid and other active ingredients to residential lawns were also reported; symptoms including red skin, itchy skin and rash were reported in 4 cases and continued for up to two months.

The majority of the domestic animal incidents involved pets exposed to a residential lawn treated with pelargonic acid, ammonium salt of fatty acid or potassium salts of fatty acid. There were 24 domestic animal incidents that were determined to have some association to exposure to the pesticide product, and the majority involved a product containing pelargonic acid and another active ingredient. The incidents frequently involved dogs who were exposed through the skin or ingestion after walking or rolling on a treated lawn, or licking or ingesting treated grass or plants, respectively. While the majority of the incidents resulted in death, and other reported effects included lethargy, anorexia, ataxia, seizure and vomiting, the presence of multiple active ingredients in the reported products introduces confounding elements due to the simultaneous exposure to other pesticides, in addition to pelargonic acid and related fatty acids. Therefore, it is not possible to determine whether pelargonic acid or its related fatty acids may have contributed to the reported health effects in humans and animals. In addition, the concern for the serious effects in dogs is tempered by the low acute toxicity potential of Beloukha Herbicide and Beloukha Agricultural Herbicide by the oral and dermal routes of exposure. Having said that, in addition, the proposed label instructions for Beloukha Herbicide and Beloukha Agricultural Herbicide prohibit the entry of humans and companion animals in treated areas until the sprays have dried and exposure in residential areas is considered negligible, provided that the label directions are followed.

Overall, no additional mitigation measures are proposed based on incidents, as the personal protective equipment required during the application or handling of the proposed products are considered adequate to minimize potential exposure to users (Sections 3.2.3. Mixer, Loader, and Applicator Exposure and Risk; 3.2.4. Postapplication Exposure and Risk) and there is a low likelihood of exposure of children and companion animals to pelargonic acid products with the proposed postapplication restrictions in place for residential areas (Section 3.2.5 Residential and Bystander Exposure and Risk).

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

Medium chain fatty acids, in general, are known to be rapidly absorbed through the skin and have been used to enhance skin permeation for dermal drug delivery. However, dermal absorption is expected to be limited when the precautionary statements on the label are observed.

3.2.2 Use Description

Beloukha Herbicide and Beloukha Agricultural Herbicide are non-selective contact herbicides proposed for use outdoors on food and non-food agricultural field crops, as well as in non-agricultural sites. On field crops, the products will be used after crop emergence as a foliage desiccant, or directed ground spraying. Beloukha Herbicide and Beloukha Agricultural Herbicide can also be used as dessicants for vegetation management at harvest and for sucker removal on listed fruit crops. Post-harvest weed control is also specified. Non-crop uses include in and around rights-of-ways, walkways, roads, benches and other structures to control unwanted vegetation outdoors.

Both products are prepared as a spray mixture in water and applied with hand-held equipment, boom sprayers, and pressure sprayers. When applying these products in a broadcast application, workers should use a directed or shielded applicator that uses a physical barrier to protect desirable vegetation from the herbicide spray. Also, nozzles that are designed to produce large spray droplets to prevent drift from the target site should be used. Beloukha Herbicide and Beloukha Agricultural Herbicide are most effective when applied to newly emerged, actively growing weeds.

Beloukha Herbicide and Beloukha Agricultural Herbicide are applied such that the weeds are thoroughly covered while being careful to avoid spraying desired plants. The maximum application rate is for fruit, vegetable and field crops at 13.6 kg a.i./ha with up to four applications per growing season, at a 7 to 14 day repeat interval.

Beloukha Herbicide and Beloukha Agricultural Herbicide are available in various container sizes ranging from 100 mL plastic bottles up to bulk containers.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

When Beloukha Herbicide and Beloukha Agricultural Herbicide are 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 Beloukha Herbicide and Beloukha Agricultural Herbicide, the label states to wear goggles or face shield, long-sleeved shirt, long pants, socks, shoes, and chemical-resistant gloves.

Precautionary statements such as the wearing of PPE on the end-use product labels 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 Beloukha Herbicide or Beloukha Agricultural Herbicide. Given the nature of the postapplication activities typically performed (for example, scouting treated areas), dermal contact with treated plants, soil, and surfaces is possible. Individuals must remain out of the treated area until the sprays have dried. If re-entry is necessary before the sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield).

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

3.2.5 Residential and Bystander Exposure and Risk

The use of Beloukha Herbicide and Beloukha Agricultural Herbicide outdoors may result in bystander exposure due to drift. Bystander exposure will be mitigated by the inclusion of a spray drift statement on the labels, 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.

Beloukha Herbicide and Beloukha Agricultural Herbicide are proposed for use in residential areas, such as on walkways and around benches in 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 pelargonic acid may occur through consumption of treated crops, the risk from consuming food crops treated with Beloukha Herbicide and Beloukha Agricultural Herbicide is acceptable due to their low toxicity profiles and the prevalence of medium chain fatty acids in food.

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 pelargonic acid. Health risks from residues of pelargonic acid in drinking water are acceptable due to the low toxicity profile and limited exposure following application of Beloukha Herbicide and Beloukha Agricultural Herbicide.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for pelargonic 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 pelargonic acid including developmental effects from pre- or post-natal 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 inter-species 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 pelargonic acid to the general population in Canada, including infants and children, when Beloukha Herbicide and Beloukha Agricultural Herbicide are 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 pelargonic acid may share a common moiety with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to pelargonic acid and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of pelargonic 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 are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* 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 pelargonic acid on agricultural and non-agricultural crops is acceptable due to the low toxicity profile of pelargonic acid and because Beloukha Herbicide and Beloukha Agricultural Herbicide are 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 pelargonic acid.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Pelargonic acid is very soluble in water and organic solvents. Its vapour pressure indicates that it is intermediately to highly volatile under field conditions. The Henry's law constant indicates that it is slightly volatile from moist soil and water surfaces. However, the potential for exposure in the atmosphere is low due to rapid degradation and adsorption to soil particles. Additionally, the pK_a of 4.96 indicates that a considerable fraction would be in ionic form under environmental conditions, further reducing the potential for volatilization. Pelargonic acid is quickly broken down by microorganisms in the environment, with half-lives of $\leq$1.65 and <1 days in soil and water, respectively. Pelargonic acid is considered to be mobile in soil and may have a tendency to leach; however, pelargonic acid is unlikely to persist long enough in the environment to move through the soil profile. Hydrolysis is unlikely for fatty acids due to the lack of functional groups that are readily hydrolyzed under environmental conditions. Pelargonic acid does not absorb ultraviolet radiation and, therefore, is not expected to be susceptible to phototransformation.

Fatty acids are natural components in the environment as they are produced by both plants and animals. The log K_{ow} indicates that pelargonic acid is fat soluble at pH 5 and that there may be a potential for bioaccumulation; however, it is rapidly degraded in the environment and readily metabolized by animals. As such, pelargonic acid is not expected to bioaccumulate in organisms. Pelargonic acid is degraded into carbon dioxide and naturally occuring organic substances, such as smaller esters. Transformation products of environmental concern are not expected.

Data on the fate and behaviour of pelargonic acid are summarized in Appendix I, Table 4.

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 that 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). If the screening level risk quotient is below the LOC, 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 LOC, 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.

4.2.1 Risks to Terrestrial Organisms

Environmental toxicity data are summarized in Appendix I, Table 5. A screening level risk assessment for terrestrial organisms is shown in Appendix I, Table 6.

Terrestrial organisms, such as earthworms, honeybees, beneficial arthropods, birds, small mammals and terrestrial vascular plants can be exposed to pelargonic acid through direct contact with spray or spray drift, contact with sprayed surfaces or from ingestion of contaminated food. A risk assessment of pelargonic acid and its end-use products, Beloukha Herbicide and Beloukha Agricultural Herbicide, was undertaken based on available toxicity data for earthworms, honeybees and other beneficial arthropods, small wild mammals and terrestrial plants. A rationale to waive the requirement of avian oral, dietary and reproductive studies indicated that fatty acids are naturally occurring and a significant part of the normal daily diet of birds, mammals and invertebrates. The rationale was reviewed and accepted by the PMRA.

At the screening level, the EEC for soil was calculated based on a direct overspray, considering the maximum cumulative rate of four applications of 13 600 g a.i./ha with a 7-day reapplication interval and a soil half-life of ≤1.65 days. Soil EECs were converted from g a.i./ha to mg a.i./kg soil using the assumption that pelargonic acid was homogeneously mixed in the top 15 cm soil layer with a bulk density of 1.5 g/cm^3. For direct overspray to plant surfaces in the field, the maximum cumulative application rate was considered with a 7-day reapplication interval and a default foliar half-life of 10 days.

Non-target terrestrial organisms can also be exposed to pelargonic acid via spray drift. The amount of spray drift depends on the type of equipment used, the size of the spray droplets, as well as the type of crop. To calculate off-field EECs, spray drift factors were applied to the in-field EECs. The spray drift factor is defined as the maximum percentage of spray drift deposition at one metre downwind from the point of application. For pelargonic acid, application using a medium spray, with a corresponding spray drift factor of 6%, was considered.

Earthworms

The acute toxic effects of pelargonic acid and its end-use product, Beloukha Agricultural Herbicide, to earthworms (*Eisenia fetida*) were determined in a laboratory study. The results were compared to the screening level soil EEC of 6.38 mg a.i./kg. The resulting RQ did not exceed the LOC (Appendix I, Table 6). As such, risks to earthworms from the use of pelargonic acid are acceptable.

Beneficial arthropods

The screening level risk assessment for beneficial arthropods is shown in Appendix I, Table 6. A refined risk assessment is shown in Appendix I, Table 7.

Beneficial arthropods can be exposed to pelargonic acid on plant surfaces immediately after application both in-field, and off-field via spray drift. Risks from exposure to the maximum cumulative exposure rate (in other words, 13 600 g a.i./ha × 4 applications) both in-field and off-field, assuming a foliar half-life of 10 days, were evaluated. Pelargonic acid exceeded the LOC for beneficial arthropods when exposed in-field (RQs <2.94 for lacewing and 5.40 for pirate bug). The RQs for off-field exposure, assuming 6% spray drift from a ground sprayer using medium spray quality, were below the LOC (RQs ≤0.32).

The screening level EEC for in-field exposure was calculated assuming the maximum cumulative exposure rate and a foliar half-life of 10 days. This assumption likely overestimates the EEC given that the half-lives of pelargonic acid in soil and water are ≤1.65 and <1 days, respectively. Furthermore, pelargonic acid is a contact herbicide, with visible plant desiccation occurring within 24 hours of application.

The maximum cumulative exposure rate (in other words, 13 600 g a.i./ha) is applied with a directed or shielded sprayer after crop emergence to protect desirable plants, with the exception of burndown prior to crop emergence, post harvest weed control or for non-crop uses (in other words, in and around rights-of-way, buildings, structures, walkways and to control mosses and algae outdoors on benches, walls, floors, roofs and cooling pads). As such, this would reduce the exposure of beneficial arthropods as the herbicide is only sprayed onto weeds and not the crop itself.

Given that risk was identified for beneficial arthropods in-field, the risk assessment was refined by considering the single maximum application rate in order to assess risk without the uncertainty related to the foliar half-life. The LOC was marginally exceeded for both the lacewing (RQ <1.32) and the pirate bug (RQ = 2.42).

A hazard statement will be required on the label to inform users of the potential adverse effects to certain beneficial arthropods.

Honeybees

Foraging bees could be exposed to pelargonic acid during application or to residues on the surface of leaves. They can also be exposed through ingestion of contaminated pollen or nectar. A screening level risk assessment was conducted considering both acute contact and acute oral exposures. The LOC of 0.4 was only exceeded for acute oral exposure (Appendix I, Table 6). It should be noted that the toxicity study was conducted as a limit test and 50% mortality was not observed at the concentration tested. As such, it is likely that the available toxicity endpoints overestimate the risk to honeybees.

The submitted studies indicate that pelargonic acid is practically non-toxic to honeybees (LD_{50}s>210.7 µg a.i./bee). The LOC was exceeded due to the high application rate (13 600 g a.i./ha). The very high application rate used would be expected to have a toxic effect based on physical effects alone. Pelargonic acid is to be applied to weeds using a shielded applicator as a physical barrier to protect desirable plants (with the exception of burndown prior to crop emergence, cereal and potato desiccation at harvest, post harvest weed control or for non-crop uses), and it dissipates quickly in soil. Furthermore, it is a contact herbicide and is not systemic. Therefore, there would not be exposure in pollen and nectar (LOC was exceeded for the oral pathway). As such, exposure to bees is expected to be very limited.

Terrestrial Vertebrates

A rationale to waive the requirement of avian oral, dietary and reproductive studies indicated that fatty acids are naturally occurring and a significant part of the normal daily diet of birds, mammals and invertebrates. The rationale was reviewed and accepted by the PMRA.

Pelargonic acid is practically non-toxic to mammals. The RQs for all mammal size classes slightly exceeded the LOCs in the screening level risk assessment when considering the on-field maximum residue concentration on food items (RQs = 1.35 to 2.61; Appendix I, Table 8). The RQs for mammals did not exceed the LOC when considering the mean on-field residue concentration on food items, or off-field exposure (Appendix I, Table 9). Given that the risk

quotients marginally exceed the LOC when considering maximum residues and that risk quotients are below the LOC when considering mean residues, the probability that adverse effects would occur following exposure to residues on food items is considered to be low, particularly given that a definitive endpoint was not determined in the toxicity study for mammals. The risks to birds and mammals from the use of pelargonic acid are expected to be acceptable.

Terrestrial Plants

Pelargonic acid is a contact herbicide and is expected to be toxic when applied to terrestrial vascular plants. The RQs exceeded the LOC for non-target terrestrial plants exposed to direct application of pelargonic acid (RQ = 15.7). Buffer zones of 1 metre to protect sensitive terrestrial habitats and a label statement to inform users of the potential adverse effects to non-target terrestrial plants will be required.

4.2.2 Risks to Aquatic Organisms

Environmental toxicity data are summarized in Appendix I, Table 5. A screening level risk assessment for aquatic organisms exposed to pelargonic acid in surface water is presented in Appendix I, Table 10.

Aquatic organisms, such as invertebrates, fish, amphibians and aquatic plants can be exposed to pelargonic acid if spray drift from use as a crop desiccant/harvest aid enters an aquatic habitat. Pelargonic acid is slightly toxic to freshwater invertebrates and fish (Appendix I, Table 5). EECs in surface water were calculated considering a direct overspray of pelargonic acid at the maximum cumulative seasonal rate (in other words, four applications of 13 600 g a.i./ha, 7-day re-application interval, DT_{50} in water of <1 day). Water bodies of two different depths were evaluated: EEC in surface water of 15-cm depth was used to determine risk to amphibians while the 80-cm depth was used to evaluate risks to all other aquatic organisms. Risks to aquatic organisms from exposure to a direct overspray of pelargonic acid at the cumulative maximum application rate were considered to be acceptable (RQs <1).

4.2.3 Incident Reports

As of 20 March 2019, there were no environmental incident reports involving pelargonic acid in the PMRA Incident Reporting Database; however, there were 25 environmental incidents involving potassium salts of fatty acids and ammonium salt of fatty acid in Canada. These incidents involved abnormal leaf discolouration, visible plant injury or death of herbaceous plants, trees or shrubs after application of products containing potassium salts of fatty acids and ammonium salt of fatty acid. All of these incidents were classified as minor severity.

No environmental incidents involving pelargonic acid were found in the USEPA EIIS database, which was last updated 5 October 2015. Nine environmental incidents involving potassium salts of fatty acids were found in the EIIS database. These incidents involved plant mortality, and were deemed possible or probable for certainty by the USEPA. The USEPA also reported that there were two fish kill incidents involving a biopesticide containing pelargonic acid. It was reported that the product was misused due to a user applying the product directly to water.

Overall, no additional risk mitigation measures are proposed based on the incident reports, as the proposed labels are adequate to mitigate potential risk.

5.0 Value

Weed control trials were conducted on non-crop land, in ornamental fields and in vineyards across multiple sites in Europe, having comparable climate conditions and soil characteristics to Canada. Additional studies carried out in North America confirmed the efficacy observed in Europe. Trials were conducted on a large number of annual and perennial broadleaf weeds, grasses and mosses using both products. Weight of evidence supported control or suppression of the pests listed in Appendix I, Table 11.

Potato desiccation trials were conducted across multiple sites in Europe to assess top growth desiccation of potatoes by considering flailing alone, desiccant alone, and combined flailing and desiccant strategies. Data demonstrated that one application of Beloukha Herbicide or Beloukha Agricultural Herbicide at the lower rate within the recommended rate range provided adequate top growth desiccation when flailing was included as part of the pre-harvest management of potatoes. If mechanical top beaters are not used, a higher rate within the recommended rate range is required to provide adequate top growth desiccation of potatoes. Several post-harvest quality assessments including tuber storage quality were conducted on harvested potatoes. Information demonstrated that potato tuber quality from the Beloukha Herbicide and Beloukha Agricultural Herbicide treatments were not significantly different from that of the untreated check.

Cereal desiccation trials were conducted in Alberta, Canada. Data demonstrated adequate desiccation of wheat and barley at the recommended application rate range. Barley quality assessments revealed no significant differences in protein content or germination of harvested seeds between the Beloukha Herbicide or Beloukha Agricultural Herbicide treatments and the untreated check. Since pre-harvest application of some herbicides affects germination of harvested seeds, Beloukha Herbicide and Beloukha Agricultural Herbicide are feasible alternative desiccation options for crops grown for seed production or processing where germination is a requirement.

Grapevine sucker control was assessed in Europe on established grapevines older than 2 years. Comparisons included manual sucker removal and an untreated check. Since suckers are not uniform, individual suckers were classified according to size, from < 5 cm to > 25 cm. The data demonstrated that the recommended application rate range was efficacious at controlling grape vine suckers of various sizes from < 5 cm to > 25 cm. Sucker control will be efficacious in other tree crops given the non-selective the nature of pelargonic acid.

As a non-selective, contact herbicide/desiccant, Beloukha Herbicide and Beloukha Agricultural Herbicide should not be sprayed on any desired vegetation that is green and actively growing. Precautions must be taken such as shielded or directed spraying and spot treatments to prevent contact with actively growing vegetation and foliage.

Rotational crop safety to Beloukha Herbicide and Beloukha Agricultural Herbicide was assessed in successive bean, lettuce, and tomato crops. No phytotoxicity was observed in any of the tested crops at any time in the growing season. Since pelargonic acid breaks down rapidly in the soil and has no residual activity, there is no labelled restriction for crops grown in rotation.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

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

During the review process, pelargonic acid and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03

[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that pelargonic acid and its transformation products do not meet all of the TSMP Track 1 criteria.

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.*[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 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:

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

6 SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

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

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

- Technical grade Pelargonic Acid Technical and its end-use products, Beloukha Herbicide and Beloukha Agricultural Herbicide 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.

7.0 Summary

7.1 Human Health and Safety

The available information for Pelargonic Acid Technical, Beloukha Herbicide and Beloukha Agricultural Herbicide is adequate to qualitatively identify the toxicological hazards that may result from human exposure to pelargonic acid. Pelargonic acid is of low acute toxicity by the oral and dermal routes, and slightly acutely toxic by the inhalation route. It is severely irritating to the skin and eyes, and it is a skin sensitizer.

A short-term dietary toxicity study, and a scientific rationale based on a weight of evidence of published information, were acceptable to address short-term toxicity and prenatal developmental toxicity for pelargonic acid. The mutagenic potential of pelargonic acid was considered to be of no concern based on a weight of evidence evaluation of mutagenicity data.

The end-use products, Beloukha Herbicide and Beloukha Agricultural Herbicide, are of low acute toxicity by oral and dermal routes. There was evidence of moderate irritation to the skin and eyes of rabbits after acute dosing. Beloukha Herbicide and Beloukha Agricultural Herbicide are not dermal sensitizers. Waivers were accepted in lieu of acute inhalation toxicity testing based on the toxicity of Pelargonic Acid Technical; that the formulants are not expected to increase inhalation toxicity; and that measures are in place to reduce the potential for inhalation exposure for workers.

Workers can be exposed to pelargonic acid while mixing, loading, and applying Beloukha Herbicide and Beloukha Agricultural Herbicide, as well as during clean-up, and equipment maintenance or repair. Consequently, the labels will include statements to wear goggles or face shield, long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves. Postapplication exposure would occur mainly by the dermal route. Individuals must remain out of the treated area until the sprays have dried. If re-entry is necessary before the sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield). The above precautionary statements (for example, wearing of personal protective equipment) on the end-use product labels aimed at mitigating exposure are considered adequate to protect individuals from risk due to occupational exposure.

Exposure to bystanders during the application of Beloukha Herbicide and Beloukha Agricultural Herbicide may be minimized if the end-use products are 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 consider wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Beloukha Herbicide and Beloukha Agricultural Herbicide are proposed for use in residential areas, such as to control unwanted vegetation in parks. Observing the recommended label instructions that prohibit entry in treated areas until the sprays have dried will ensure minimal exposure. Consequently, the risks to individuals in residential areas are considered acceptable.

While dietary exposure to pelargonic acid could occur through consumption of treated crops, the dietary risks to humans are acceptable due to the low toxicity profile and that direct application of Beloukha Herbicide and Beloukha Agricultural Herbicide on food crops is to be avoided. The specification of MRLs under the *Pest Control Products Act* is not being recommended.

7.2 Environmental Risk

Pelargonic acid is readily degraded in the environment and the formation of transformation products of environmental concern are not expected. Pelargonic acid is toxic to terrestrial plants, and may pose a potential risk to beneficial insects. Precautionary statements to inform users of the toxicity of pelargonic acid to these organisms will be required. Buffer zones of 1 metre to minimize drift to non-target terrestrial habitats will also be required on the label. When used according to the label directions, the risks to non-target organisms from the use of this product are acceptable.

7.3 Value

Value information demonstrated that Beloukha Herbicide and Beloukha Agricultural Herbicide, which contain the active ingredient pelargonic acid, can be expected to provide acceptable control or suppression of undesired plant growth in the form of weeds, mosses, suckers and pre-harvest foliage. The registrations of Beloukha Herbicide and Beloukha Agricultural Herbicide would provide Canadian users access to another integrated weed management option for weed control and resistance management in many crops and in non-cropland areas.

8.0 Proposed Regulatory Decision

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 Pelargonic Acid Technical, Beloukha Herbicide and Beloukha Agricultural Herbicide, containing the technical grade active ingredient pelargonic acid, to provide burndown, spot, and inter-row weed control in fruit, vegetable and field crops, desiccant and pre-harvest weed management in potato and cereal crops, sucker control in grapes and tree fruits, and control of unwanted weeds and mosses in non-crop areas.

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

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
pK_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 Profile of Pelargonic Acid Technical
(Effects are known or assumed to occur in both sexes unless otherwise noted)

STUDY Type/Animal/PMRA#	Study Result
Acute oral toxicity (Acute toxic class method– Limit test) Rat, Sprague-Dawley (3 ♀) PMRA# 2838353	LD_{50} (♀) > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Rat, Sprague Dawley 5/sex PMRA# 2838354	LD_{50} > 2000 mg/kg bw Low toxicity
Eye irritation Rabbit, New Zealand albino (3 ♀) PMRA# 2838356	MAS[a] = 52.7/110 MIS[b] = 55.3/110 (1 hr) MAS was not 0/110 by 24 hours. MIS was 0/110 by 21 days. Severely irritating
Skin irritation Rabbit, New Zealand albino (3/sex) PMRA# 2838357	MAS[a] = 5.9/8 MIS[b] = 5.7/8 (72-hrs.) MAS was not 0/110 by 24 hours. MIS was 0/110 by 14 days. Severely irritating
Skin sensitization (Guinea Pig maximization test) Albino Guinea pig/Dunkin Hartley (10 ♀) PMRA# 2838358	Positive for skin sensitization
Short-term oral toxicity (28 day; dietary) Rat (SPF-bred Wistar) 5/sex/dose PMRA# 2985552	NOAEL ♂ > 976 mg pelargonic acid/kg bw/day[c] NOAEL ♀ > 982 mg pelargonic acid/kg bw/day[c]
Gene mutation in bacteria	Negative

STUDY Type/Animal/PMRA#	Study Result
PMRA# 2838359	
Gene mutations in mammalian cells in vitro Mouse Lymphoma Assay (TK locus)[d] PMRA# 2838360	Weakly positive (with and without S9 activation) at concentrations approaching cytoxocity No evidence of clastogenicity.
Chromosome Aberration assay (*in vitro*) Human peripheral blood lymphocytes PMRA# 2838361	Negative

[a] MAS = Maximum Average Score for 24, 48, and 72 hrs
[b] MIS = Maximum Irritation Score (average)
[c] The test substance was VHH 86081, a formulation containing 62.1% pelargonic acid. The doses were adjusted to account for relative amount of active ingredient (pelargonic acid) and for a 10% decrease in stability in the high dose diets over 8 days.
[d] TK: thymidine kinase locus

Table 2 Toxicity Profile of Beloukha Agricultural Herbicide containing Pelargonic Acid

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

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity (Acute toxic class method– Limit test) Rat, Sprague-Dawley (♂) PMRA# 2839130	LD_{50} (♂) > 5000 mg/kg bw Low toxicity
Acute dermal toxicity (Acute toxic class method– Limit test) Rat, Sprague-Dawley PMRA# 2839131	LD_{50} > 5000 mg/kg bw Low toxicity
Eye irritation Rabbit, New Zealand White PMRA# 2839133	MAS a = 38.7/110 (at 24, 48 and 72 hours) MIS b = 55.6/110 (at 24, 48 and 72 hours) MIS was 0/110 by Day 21. MAS was not 0/110 by 24 hours. Moderately irritating

Eye irritation Rabbit, New Zealand White PMRA# 2839134	MAS [a] = 40.2/110 (at 24, 48 and 72 hours) MIS [b] = 43.6/110 (at 24, 48 and 72 hours) MIS was 0/110 by Day 21. MAS was not 0/110 by 24 hours. Moderately irritating
Skin Irritation Rabbit, New Zealand White PMRA# 2839135	MAS [a] = 3.33/8 (at 24, 48 and 72 hours) MIS [b] = 4/8 (at 72 hours) Moderately irritating
Dermal sensitization (Buehler) Guinea Pig, Dunkin Hartley-Albino PMRA# 2839136	Negative Not a dermal sensitizer

Table 3 Toxicity Profile of Beloukha Herbicide containing Pelargonic 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
Eye irritation Rabbit, New Zealand White PMRA# 2839440	MAS [a] = 24.2/110 (at 24, 48 and 72 hours) MIS [b] = 37/110 (at 24, 48 and 72 hours) MIS was 0/110 by Day 14. MAS was not 0/110 by 24 hours. Mildly irritating

Table 4 Fate and Behaviour of Pelargonic Acid in the Environment

Property	Value	Comments	PMRA#
Abiotic transformation			
Hydrolysis	N/A	Hydrolysis not expected	2838319
Photolysis	N/A	Photolysis not expected	2838319
Biotransformation			
Biotransformation in soil	Half-life $\leq$ 1.65 days	Calculated by PMRA from the results of the biotransformation in aerobic soil study.	2838365
Biotransformation in water	Half-life < 1 day		2704942

Property	Value	Comments	PMRA#
Mobility			
Adsorption coefficient		**Highly mobile in soil**	
	K_{oc} = 52.75 L/kg (estimated from molecular connectivity index)	Modelled with KOCWin v2.00(1)	2838367
	K_{oc} = 30.43 L/kg (estimated from log K_{ow})	Modelled with KOCWin v2.00(1)	
	K_{oc} = 47.26 L/kg	EPI Suite QSAR calculation	2838319
	K_{oc} = 1700 to 340 000 L/kg	**Immobile in soil** Undissociated fatty acids should have low to practically no mobility in soils.	PRD2017-04
Soil leaching	GUS = 0.2 to 0.5	Non-leacher	Calculated with inputs from: 2838364 2838365 PRD2017-04
Volatility	Vapour pressure = 0.452 Pa Henry's law constant at 20 °C = 4.12×10^{-06} atm m^3mol^{-1}	The vapour pressure indicates that it is intermediately to highly volatile under field conditions. The Henry's law constant indicates that it is slightly volatile from moist soil and water surfaces. Strong adsorption to soil particles and rapid degradation would limit volatilization.	2875481

(1) Program in EPI Suite to estimate the organic carbon-normalized sorption coefficient for soil and sediment

Table 5 Toxicity to Non-Target Species

Species	Study	Toxicity end-points	Classification	Reference
Terrestrial Species				
Earthworm (*Eisenia fetida*)	Acute (14-d)	LC_{50} = 546.6 mg a.i./kg soil NOEC = 301 mg a.i./kg soil	-	2838371
Honeybee (*Apis mellifera carnica*)	Acute oral (48-hr)	LD_{50} > 226.1 µg a.i./bee	Practically non-toxic	2838372
	Contact (96-hr)	LD_{50} > 210.7 µg a.i./bee	Practically non-toxic	
Lacewings (*Chrysoperla carnea*)	Extended contact (15-day)	LR_{50} > 10,314 g a.i./ha	-	2838373
Pirate bugs (*Orius laevigatus*)	Extended contact (13-15 day exposure of larvae)	LR_{50} = 5610 g a.i./ha	-	2838375
Mammals (rat)	14d-acute	LD_{50} > 5000 mg/kg bw	Practically non-toxic	2838353
Terrestrial plants - Ryegrass	Seedling emergence (dry weight)	ER_{50} = 15 935 g a.i./ha	-	2838382
Terrestrial plants - cucumber	Vegetative vigour	ER_{50} = 3862 g a.i./ha	-	2838383
Aquatic Species				
Daphnia (*Daphnia magna*)	Acute (48-hr)	EC_{50} = 56.8 mg a.i./L NOEC = 38.3 mg a.i./L	Slightly toxic	2838376
Rainbow trout (*Oncorhynchus mykiss*)	Acute (96-hr)	LC_{50} = 87.7 mg a.i./L NOEC = 26.9 mg a.i./L	Slightly toxic	2838377
Common carp (*Cyprinus carpios*)	Acute (96-hr)	LC_{50} = 39.9 mg a.i./L NOEC = 26.9 mg a.i./L	Slightly toxic	2838378
Blue-green algae (*Anabaena flos-aquae*)	Acute (72-hr)	EyC_{50} = 9.56 mg a.i./L NOEC (yield) = 0.655 mg a.i./L	-	2838380
Green algae (*Pseudokirchneriella subcapitata*)	Acute (72-hr)	EyC_{50} = 9.69 mg a.i./L NOEC (yield) = 0.46 mg a.i./L	-	2838381
Aquatic plant (*Lemna gibba*)	Acute (7-d)	EC_{50} (frond #) > 60.2 mg a.i./L NOEC (frond #) = 19.3 mg a.i./L	-	2838384

Table 6 Screening Level Risk Assessment of Non-Target Terrestrial Species Exposed to VVH-86086

Species	Exposure Route	EEC	Toxicity Value	RQ	LOC	LOC Exceeded?
Terrestrial Invertebrates						
Earthworm (*E. fetida*)	Soil	6.38 mg a.i./kg(1)	NOEC = 301 mg a.i./kg	0.02	1	No
Lacewings (*C. carnea*)	Foliar (on-field)	30 300 g a.i./ha(2)	LR_{50} > 10 314 g a.i./ha	**< 2.94**	1	**Yes**
	Foliar (off-field, 6% drift)	1818 g a.i./ha		< 0.18	1	No
Pirate bugs (*O. laevigatus)*	Foliar (on-field)	30 300 g a.i./ha(2)	LR_{50}= 5610 g a.i./ha	**5.40**	1	**Yes**
	Foliar (off-field, 6% drift)	1818 g a.i./ha		0.32	1	No
Honey Bees (*Apis mellifera carnica*)	Contact – max. single application	32.64 µg a.i./bee(3)	LD_{50} > 210.7 µg a.i./bee	<0.15	0.4	No
	Oral – max. single application	389.2 µg a.i./bee(4)	Acute oral LD_{50} > 226.1 µg a.i./bee	**<1.72**	0.4	**Yes**
Terrestrial Plants						
Lettuce (seedling emergence)	Soil	14 359 g a.i./ha(1)	½ ER_{50} = 8003 g a.i./ha	**1.80**	1	**Yes**
Cucumber (vegetative vigour)	Direct spray	30 300 g a.i./ha(2)	½ ER_{50} = 1931 g a.i./ha	**15.7**	1	**Yes**

(1) Cumulative application rate in soil after the fourth application of 13 600 g a.i./ha, assuming a half-life in soil of 1.65 days, soil bulk density if 1.5 g/cm^3, soil depth of 15 cm and a re-application interval of 7 days.

(2) Cumulative application rate on plants after the fourth application of 13 600 g a.i./ha, assuming a foliar half-life of 10 days and a re-application interval of 7 days

(3) EEC (Contact) = ((Application rate (kg a.i./ha))*2.4 µg a.i./bee

(4) EEC (Diet) = (Application rate (kg a.i./ha))* adjustment factor (28.6 µg a.i./bee per kg a.i./ha for adults)
Adult adjustment factor 28.6 ug ai/bee per kg ai/ha = food consumption 0.292 g/ bee per day × default tall grass residues 98.21 µg a.i./g per kg ai/ha

Table 7 Refined Risk Assessment for Beneficial Arthropods Exposed to VVH-86086

Species	Exposure Route	EEC (g a.i./ha)	Toxicity Value (g a.i./ha)	RQ	LOC	LOC Exceeded?
Lacewings (*C. carnea*)	Foliar (in-field)	13 600[(1)]	LR_{50} > 10,314	**< 1.32**	**1**	**Yes**
Pirate bugs (*O. laevigatus)*			LR_{50} = 5610	**2.42**		**Yes**
(1) Maximum single application rate						

Table 8 Screening Level Risk Assessment of Pelargonic Acid for Mammals.

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw) [(1)]	RQ	LOC	LOC Exceeded?
Small Mammal (0.015 kg)						
Acute	> 500	Insectivore	672.2	**< 1.34**	1	**Yes**
Medium-sized Mammal (0.035 kg)						
Acute	> 500	Herbivore (short grass)	1304	**< 2.61**	1	**Yes**
Large-sized Mammal (1 kg)						
Acute	> 500	Herbivore (short grass)	696.7	**< 1.39**	1	**Yes**

(1) EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/bw) × EEC, where:
FIR: Food Ingestion Rate (Nagy, 1987). For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(bw in g) $^{0.822}$
bw: Generic Body Weight
EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

Table 9 Further Characterization of the Acute Risk of Pelargonic Acid to Mammals.

Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues	
		On-field exposure		Off-field exposure (6% spray drift)		On-field exposure	
		EDE (mg a.i./kg bw)[1]	RQ[2]	EDE (mg a.i./kg bw)[1]	RQ[2]	EDE (mg a.i./kg bw)[1]	RQ[2]
Small mammal (0.015 kg)							
>500	Insectivore (insects)	672.23	**<1.34**	40.33	<0.08	464.16	<0.93
	Granivore (grain and seeds)	104.04	<0.21	0.21	<0.01	49.62	<0.10
	Frugivore (fruit)	208.07	<0.42	0.42	<0.03	99.23	<0.20
Medium-sized Mammal (0.035 kg)							
>500	Insectivore (small insects)	589.29	**<1.18**	35.36	<0.07	406.89	<0.81
	Granivore (grain and seeds)	91.20	<0.18	5.47	<0.01	43.50	<0.09
	Frugivore (fruit)	182.40	<0.37	10.94	<0.02	86.99	<0.17
	Herbivore (short grass)	1303.78	**<2.61**	78.23	<0.16	463.03	<0.93
	Herbivore (long grass)	796.06	**<1.60**	47.76	<0.10	259.94	<0.52
	Herbivore (forage crops)	1206.28	**<2.41**	72.38	<0.14	398.77	<0.80
Large-sized Mammal (1 kg)							
>500	Insectivore (small insects)	314.88	<0.63	18.89	<0.04	217.42	<0.43
	Granivore (grain and seeds)	48.73	<0.10	2.92	<0.01	23.24	<0.05
	Frugivore (fruit)	97.46	<0.19	5.85	<0.01	46.48	<0.09
	Herbivore (short grass)	696.65	**<1.39**	41.80	<0.08	247.41	<0.50
	Herbivore (long grass)	425.36	<0.85	25.52	<0.05	138.89	<0.28
	Herbivore (broadleaf plants)	644.56	**<1.29**	38.67	<0.08	213.08	<0.43

Bold and shaded indicates that the LOC was exceeded (LOC = 1)

(1) See Table 5 for details on calculation of EDE.

(2) Assuming a toxicity value for mammals of >500 mg a.i./kg bw

Table 10 Screening Level Risk Assessment for Aquatic Species Exposed to VVH-86086 in Surface Water via Direct Spray

Species	EEC (mg a.i./L)[(1)]		Toxicity Value	RQ		LOC	LOC Exceeded?
	15 cm	80 cm		15 cm	80 cm		
Daphnia magna	-	1.71	NOEC = 38.3 mg a.i./L	-	0.04	1	No
Rainbow trout			NOEC = 26.93 mg a.i./L	-	0.06	1	No
Common carp			NOEC = 26.93 mg a.i./L	-	0.06	1	No
Green algae *(P. subcapitata)*			½ EyC50 = 4.85 mg a.i./L	-	0.35	1	No
Blue-green algae (*A. flos-aquae*)			½ EyC50 = 4.78 mg a.i./L	-	0.36	1	No
Vascular aquatic plants *Lemna gibba*			½ EyC50 > 30.1 mg a.i./L	-	<0.06	1	No
Amphibians (rainbow trout surrogate)	9.14	-	NOEC = 26.93 mg a.i./L	0.34	-	1	No

(1) Cumulative application rate after the fourth application of 13 600 g a.i./ha, assuming a half-life in water of <1 day and a re-application interval of 7 days

Table 11 Weeds controlled or suppressed with Beloukha Herbicide and Beloukha Agricultural Herbicide at application rates of 8120-13 600 g a.i./ha.

WEEDS CONTROLLED		WEEDS SUPPRESSED	
Scientific Name	**Common Name**	**Scientific Name**	**Common Name**
Amaranthus retroflexus	Common amaranth	*Abientinella abietina*	Fir tamarisk-moss
Aphanes arvensis	Parsley piert	*Anagallis arvensis*	Care-all
Bunias orientalis	Hill mustard	*Bromus erectus*	Upright Bromegrass
Capsella bursa-pastoris	Shepherd's purse	*Bromus sp.*	Bromegrass
Cardamine flexuosa	Flexuous bittercress	*Bryophyta*	Mosses
Cerastium fontanum	Mouse-ear chickweed	*Calendula officinalis*	Marigold
Cerastium glomeratum	Sticky chickweed	*Ceratodon purpureus*	Ceratodon moss
Chaenorhinum minus	Dwarf snapdragon	*Chamerion angustifolium*	Fireweed or rosebay willowherb
Chenopodium album	Common lambsquarters	*Convolvulus arvensis*	Field bindweed
Chenopodium hybridum	Mapleleaf goosefoot	*Conyza canadensis*	Canada horseweed
Digitaria ischaemum	Smooth crabgrass	*Cynodon dactylon*	Bermudagrass
Diplotaxis tenuifolia	Wall rocket	*Echinochloa crus-galli*	Cockspur
Euphorbia helioscopia	Sun spurge	*Epilobium parviflorum*	Hoary willowherb
Festuca sp.	Fescue	*Epilobium sp.*	Willowherb
Galinsoga parviflora	Small flower galinsoga	*Festuca pratensis*	Meadow fescue
Geranium dissectum	Cut-leaved cranesbill	*Geranium pusillum*	Small geranium
Geranium sp.	Cranesbill	*Geranium rotundifolium*	Round-leaved cranesbill
Hypericum perforatum	Common St. Johnswort	*Holcus lanatus*	Yorkshire fog
Hypericum sp.	St. Johnswort	*Matricaria sp.*	Mayweed
Lamium amplexicaule	Henbit	*Myosotis arvensis*	Forget-me-not

WEEDS CONTROLLED		WEEDS SUPPRESSED	
Scientific Name	**Common Name**	**Scientific Name**	**Common Name**
Lamium purpureum	Purple deadnettle	*Panicum dichotomiflorum*	Smooth witchgrass
Lolium perenne	Perennial ryegrass	*Picris echioides*	Bristly oxtongue
Matricaria recutita	Wild chamomile	*Plantago coronopus*	Buck's horn plantain
Medicago lupulina	Black medic	*Plantago lanceolata*	Ribwort/Narrowleaf plantain
Mercurialis annua	Common mercury	*Poa annua*	Annual meadowgrass
Picris hieracioides	Hawkweed oxtongue	*Poa sp.*	Bluegrass
Plantago sp.	Plantain	*Polygonum aviculare*	Knotgrass or prostrate knotweed
Portulaca oleracea	Common purslane	*Rubus fruticosus*	Bramble
Sagina procumbens	Procumbent pearlwort	*Scorzoneroides autumnalis*	Fall hawkbit
Senecio vulgaris	Common groundsel	*Sonchus oleraceus*	Annual sowthistle
Solanum nigrum	Black nightshade	*Sonchus sp.*	Sowthistle
Sonchus arvensis	Perennial sowthistle	*Taraxacum officinale*	Dandelion
Stellaria media	Common chickweed	*Trifolium dubium*	Small hop clover
		Trifolium repens	Dutch clover
		Urtica dioica	Common nettle
		Veronica arvensis	Corn speedwell
		Veronica persica	Bird's-eye speedwell

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B. Additional Information Considered

i) Published Information

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