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Proposed Registration Decision

PRD2022-06

Potassium chloride and Potash Molluscicide

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Table of Contents

| | |
|---|----|
| Overview | 1 |
| Proposed Registration Decision for Potassium Chloride | 1 |
| What does Health Canada consider when making a registration decision? | 1 |
| What is potassium chloride? | 2 |
| Health considerations | 2 |
| Environmental considerations | 4 |
| Value considerations | 5 |
| Measures to minimize risk | 5 |
| Next steps | 6 |
| Other information | 6 |
| Science evaluation | 7 |
| 1.0 The active ingredient, its properties and uses | 7 |
| 1.1 Identity of the active ingredient | 7 |
| 1.2 Physical and chemical properties of the active ingredient and end-use product | 7 |
| 1.3 Directions for use | 8 |
| 1.4 Mode of action | 9 |
| 2.0 Methods of analysis | 9 |
| 2.1 Methods for analysis of the active ingredient | 9 |
| 2.2 Method for formulation analysis | 9 |
| 2.3 Methods for residue analysis | 9 |
| 3.0 Impact on human and animal health | 9 |
| 3.1 Toxicology summary | 9 |
| 3.2 Health-related incident reports | 12 |
| 3.3 Occupational, residential and bystander exposure and risk assessment | 12 |
| 3.3.1 Dermal absorption | 12 |
| 3.3.2 Use description | 12 |
| 3.3.3 Mixer, loader, and applicator exposure and risk | 13 |
| 3.3.4 Postapplication exposure and risk | 14 |
| 3.3.5 Residential and bystander exposure and risk | 14 |
| 3.4 Food residue exposure assessment | 15 |
| 3.4.1 Food | 15 |
| 3.4.2 Drinking water | 15 |
| 3.4.3 Acute and chronic dietary risks for sensitive subpopulations | 15 |
| 3.4.4 Aggregate exposure and risk | 15 |
| 3.4.5 Cumulative assessment | 16 |
| 3.4.6 Maximum residue limits | 16 |
| 4.0 Impact on the environment | 16 |
| 4.1 Fate and behaviour in the environment | 16 |
| 4.2 Environmental risk characterization | 17 |
| 4.2.1 Risks to terrestrial organisms | 18 |
| 4.2.2 Risks to aquatic organisms | 18 |
| 4.2.3 Environmental incident reports | 20 |

| | | |
|------------|---|----|
| 5.0 | Value | 20 |
| 6.0 | Pest control product policy considerations | 22 |
| 6.1 | Toxic Substances Management Policy considerations | 22 |
| 6.2 | Formulants and contaminants of health or environmental concern..... | 23 |
| 7.0 | Proposed regulatory decision..... | 23 |
| | List of abbreviations | 24 |
| Appendix I | Tables and figures | 26 |
| Table 1 | Toxicity of potassium chloride to non-target freshwater organisms | 26 |
| Table 2 | Toxicity endpoints used in the screening level risk assessment | 29 |
| Table 3 | Toxic Substances Management Policy considerations | 31 |
| | References..... | 32 |

Overview

Proposed Registration Decision for Potassium Chloride

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 Potassium Chloride Technical and Potash Molluscicide, containing the technical grade active ingredient potassium chloride, for control of zebra and quagga mussels in water reservoirs and other water bodies as well as in water pipelines and closed systems, including fire suppression systems in hydroelectric plants.

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 potassium chloride and Potash Molluscicide.

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 acceptable¹ 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 value² 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.

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 potassium chloride and Potash Molluscicide, 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 Decision⁴ on potassium chloride and Potash Molluscicide, 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 potassium chloride?

Potassium chloride is a new active ingredient for the control of invasive zebra and quagga mussels in certain bodies of water and certain closed systems, including agricultural irrigation pipelines and hydroelectric plants. It releases potassium ions into the water, which interferes with valve closure and respiration and reduces filtration rate, resulting in the mortality of the target mussel species.

Health considerations

Can approved uses of potassium chloride affect human health?

Potassium Chloride is unlikely to affect human health when it is used according to label directions.

Potential exposure to potassium chloride may occur when handling and applying the product Potash Molluscicide, as well as during typical occupational activities following application. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The 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 at which no effects are observed.

Potassium Chloride Technical is considered to be of low acute toxicity by the oral route. No data are available on the acute dermal or inhalation toxicity, but based on the low octanol/water partition coefficient and low vapour pressure of potassium chloride, it can be assumed that the

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*.

salt will be poorly absorbed across the skin and be non-volatile. Based on the information from the material safety data sheet (MSDS), potassium chloride may cause eye, skin, and respiratory tract irritation by mechanical means, and it is not likely a dermal sensitizer.

Based on the weight-of-evidence of the available data for potassium chloride, which is a common salt form of potassium, and taking into consideration the history of use of potassium chloride in the human diet and in pharmaceuticals, the low toxicity profile of potassium chloride, and the anticipated limited human exposure based on the proposed use patterns, no short-term toxicity, developmental toxicity, genotoxicity, or other adverse effects are anticipated for potassium chloride.

Potash Molluscicide is a repack of Potassium Chloride Technical; therefore, the toxicological profile of Potash Molluscicide is identical to that of Potassium Chloride Technical.

Residues in water and food

Dietary risks from food and water are not of concern.

Potash Molluscicide is not proposed for food or feed use, and its application to water bodies, water reservoirs, pipelines or closed systems populated by zebra and quagga mussels is not expected to exceed the natural background levels of potassium and chloride following treatment. Dietary risk from food and drinking water is therefore expected to be negligible and not of concern. 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 not of concern.

There are no residential uses for Potash Molluscicide. Non-occupational exposure to individuals coming into contact with Potash Molluscicide during handling and application is not expected to result in unacceptable risk when Potash Molluscicide is used according to label directions.

The end-use product label will include measures to minimize bystander exposure, such as a spray drift statement and a statement to notify the public that certain bodies of water are closed for recreation, fishing, and commercial activities for ten days after the last treatment of Potash Molluscicide by using signs and other markers.

Occupational risks from handling Potash Molluscicide

Occupational risks are acceptable when Potash Molluscicide is used according to the label directions, which include protective measures.

Potash Molluscicide is to be used only by a certified applicator for control of mussels. Occupational exposure to Potash Molluscicide is expected to be short-term and predominantly by the inhalation, dermal, and ocular routes when workers are exposed to the dust from handling the end-use product for pre-mixing. Exposure to mixed solution is also possible by the dermal and ocular routes during storage, transportation, and preparatory work for the treatment.

Potential exposure to Potash Molluscicide can be reduced by following precautionary statements on the label, the use of appropriate personal protective equipment (PPE), and by following general occupational hygiene practices.

The occupational risks are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when potassium chloride is introduced into the environment?

When used according to label directions, environmental risks associated with potassium chloride and its end-use product, Potash Molluscicide, are acceptable.

Potassium chloride can enter the environment when Potash Molluscicide is used to control invasive zebra and quagga mussels in water related infrastructure (including irrigation systems), closed loop fire suppression systems, reservoirs and water bodies. Potassium chloride is a naturally occurring salt that is highly soluble in water. It is commonly found in the environment and is widely used as a fertilizer.

The use of potassium chloride and its end-use product, Potash Molluscicide, is restricted and is only permitted where zebra and/or quagga mussels have been confirmed to occur. The establishment of invasive mussels presents a high threat to aquatic ecosystems. While there is a risk to non-target aquatic organisms from the use of potassium chloride to control invasive mussels, the PMRA recognizes that control of invasive species is necessary in order to help protect habitats for native species. When used according to label directions, Potash Molluscicide will have the desired effect of controlling zebra and quagga mussels that pose a risk to aquatic habitats.

Value considerations

What is the value of Potash Molluscicide?

Potash Molluscicide can be used to control zebra and quagga mussels, which are damaging invasive species and biofouling agents that are spreading across Canada.

The registration of Potash Molluscicide is intended to provide a means to manage or control invasive zebra and quagga mussels throughout Canada.

Potash Molluscicide can provide effective control of invasive zebra and quagga mussels.

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 labels of Potassium Chloride Technical and Potash Molluscicide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The applicant-proposed hazard signal words “CAUTION – EYE IRRITANT” are present on the technical grade active ingredient label and the end-use product label. In addition, standard hazard and precautionary statements are required on both the labels to inform workers of the potential for irritation to eye, skin, and respiratory tract.

The PPE requirements on the end-use product label instruct personnel to wear goggles or a face shield, chemical-resistant gloves, long-sleeved shirt, long pants, shoes, and socks during handling, mixing/loading, clean-up or repair of equipment, and additionally, a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) while handling Potash Molluscicide in its solid form.

The end-use product label instructs that the public be notified that certain bodies of water are closed for recreation, fishing, and commercial activities for ten days after the last treatment of Potash Molluscicide by using signs and other markers.

Standard precautionary drift statements are required to mitigate bystander exposure.

Environment

- This product will be classified as restricted. The product can be used only by licensed pesticide applicators under appropriate federal or provincial authorizations.
- Precautionary label statement to inform users of the toxicity of potassium chloride to aquatic organisms.
- A label requirement to confirm the presence of zebra and/or quagga mussels prior to use.

Next steps

Before making a final registration decision on potassium chloride and Potash Molluscicide, 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 potassium chloride and Potash Molluscicide (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. For more information, please contact the PMRA's [Pest Management Information Service](#).

Science evaluation

Potassium chloride and Potash Molluscicide

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

| | |
|--|--------------------------|
| Active substance | Potassium chloride |
| Function | Insecticide/Molluscicide |
| Chemical name | |
| 1. International Union of Pure and Applied Chemistry (IUPAC) | Potassium chloride |
| 2. Chemical Abstracts Service (CAS) | Potassium chloride |
| CAS number | 7447-40-7 |
| Molecular formula | KCl |
| Molecular weight | 74.555 |
| Structural formula | KCl |
| Purity of the active ingredient | 96.88 |

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product—Potassium Chloride Technical

| Property | Result |
|-----------------------------------|---|
| Colour and physical state | Brownish-red mixed with white and clear solid (granules) |
| Odour | Odourless |
| Melting range | ~770–773°C |
| Boiling point or range | Sublimes at 1500°C |
| Density | 1.984–1.988 g/cm ³ |
| Vapour pressure | 573 Pa at 906°C |
| Ultraviolet (UV)-visible spectrum | Not required since the substance does not contain a chromophore |
| Solubility in water at 25°C | 0.355 g/mL |

| Property | Result |
|--|---|
| Solubility in organic solvents at 20°C | Insoluble in ethanol (4 mg/mL), acetone, ether, glycerol (71.4 mg/mL) |
| <i>n</i> -Octanol-water partition coefficient (K_{ow}) | Log K_{ow} = -0.46 at 20°C |
| Dissociation constant | Not required since the product does not contain acid or base functionality |
| Stability (temperature, metal) | Stable up to 770°C. Known to be stable to sunlight and corrosive to metals. |

End-use product—Potash Molluscicide

| Property | Result |
|------------------------------------|--|
| Colour | Brownish-red mixed with white |
| Odour | Odourless |
| Physical state | Solid (granules) |
| Formulation type | Soluble granules |
| Label concentration | 96.88% |
| Container material and description | Rail car, truck, fiberglass and plastic bags |
| Density | 1.984–1.988 g/cm ³ |
| pH of 10% dispersion in water | 7–10 |
| Oxidizing or reducing action | Not expected to have oxidizing or reducing action |
| Storage stability | The PMRA has waived this requirement since the product is used immediately and not stored. Excess product is used as fertilizer. |
| Corrosion characteristics | The PMRA has waived this requirement since the product is used immediately and not stored. Excess product is used as fertilizer. |
| Explosibility | Not expected to have explosive properties |

1.3 Directions for use

Potash is the common name for potassium chloride (KCl), a mineral that contains high amounts of potassium (K⁺). Potassium is an important nutrient in plant nutrition and potash is mainly used in the production of fertilizers.

Potash Molluscicide is to be pre-mixed with water in high density polyethylene (HDPE) tanks to prepare a stock solution of 300 g/L KCl and allowing insoluble materials to settle. The tank should be agitated to keep the KCl in solution until it is applied, at which time the concentration of potassium should be adjusted to 100 mg/L (100 ppm K⁺). Target areas for application include

water reservoirs and bodies of water such as lakes. The target concentration needs to be maintained for a period of time, determined by bioassays, to obtain 100% mortality of target mussels. At ambient temperatures of 15°C, mortality of zebra and quagga mussels should occur within five days of application. Large bodies of water (in other words, harbours) can be segregated using geotextile curtains or other means to create smaller treatment zones.

Potash Molluscicide is also proposed for use in closed systems such as pipelines and water treatment plants where a potash solution is applied via an injection system to achieve a concentration of 100 ppm K^+ until 100% zebra and quagga mussel mortality is observed using bioassays. Note that Potash Molluscicide is a Restricted Class product and may require further permitting for use depending on the province or territory of use.

1.4 Mode of action

Potassium chloride releases K^+ ions, when mixed with water, and this inhibits valve closure and reduced filtration rate in zebra and quagga mussels, leading to death. Potassium ions may also disrupt membrane integrity in the gill epithelium of adult zebra and quagga mussels which hinders respiration, eventually leading to mussel death.

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.

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 Potash Molluscicide as there is no food use (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 was conducted in support of Potassium Chloride Technical. The data package consisted of publicly available toxicology information on KCl, which included an OECD SIDS (screening information data set) on KCl and an MSDS. Most of the information available is from toxicity studies that have not been carried out under national or international guidelines and good laboratory practice compliance, and the summaries

lack necessary details. However, since KCl has well-established mechanisms of action, the information available is sufficient to characterize the toxicity. Additionally, a previous research authorization review for KCl as a molluscicide was also considered.

KCl, a common salt form of potassium, is typically used as a partial substitute for table salt (sodium chloride) in food processing and manufacturing. Potassium and chloride are essential elements required for normal human health. Potassium is involved in numerous enzymatic reactions, nerve conduction, muscle contraction, and carbohydrate metabolism. Chloride is the main extracellular anion in the body, which is involved in maintaining proper osmotic pressure, water balance and acid–base balance and plays an important role in renal function, neurophysiology, and nutrition. Diet is the primary source of potassium and chloride. In Canada, the total average intake of potassium from all sources is approximately 3.1 g/day for an adult, well below the Adequate Intake set at 4.7 g/day for an adult. The total daily intake of chloride is about 6 g (may range as high as 12 g) and comes almost entirely from food. Potassium or chloride do not accumulate in the body as they are well-regulated, and they are rapidly excreted in the absence of renal impairment; also, large single doses usually induce vomiting. Adverse health effects due to potassium or chloride consumption from drinking water are unlikely to occur in healthy individuals.

No drinking water guidelines have been established for potassium. Both Health Canada and the World Health Organization have established drinking water guidelines for chloride of ≤ 250 mg/L, but these are not health-based. Both relate to the prevention of corrosion of piping in drinking water distribution systems and avoiding aesthetic (taste) problems with drinking water.

Potassium chloride is of low acute toxicity via the oral route ($LD_{50} = 2600$ mg/kg bw in rat). No data are available on the acute dermal or inhalation toxicity, but based on the low octanol/water partition coefficient (-0.46 at 20°C) and low vapour pressure (573 Pa at 906°C) of KCl it can be assumed that the salt will be poorly absorbed across the skin and will be non-volatile. Instillation of 500 mg KCl into the rabbit eye caused a mild irritation response at 24 hours. The MSDS for the end-use product indicates that KCl may cause eye, skin, and respiratory tract irritation by mechanical means.

A limited amount of published information was identified to characterize the short- and long-term repeated dose toxicity of KCl in laboratory animals.

In a 15-week rat study, KCl when administered in drinking water at 4250 mg/kg bw per day resulted in decreased heart weight, increased kidney weight, and enlargement of part of the adrenals (only organs examined) in ten animals at study termination.

In developmental toxicity studies in rats (Wistar) and mice (CD-1 outbred mice), a KCl solution in water (10 mL/kg bw) was administered to groups of pregnant animals (21 – 24 /treatment group) by single daily oral gavage from gestation day 6 to 15 . The controls were sham treated with water only. Mice were dosed at 2.35 – 235.0 mg/kg bw, and rats were dosed at 3.1 – 310.0 mg/kg bw.

Treatment with KCl up to 235 mg/kg bw in pregnant mice or up to 310 mg/kg bw in pregnant rats did not show any significant maternal or developmental effects. The parental and offspring No-Observed-Adverse-Effect-Levels (NOAELs) were > 235 mg/kg bw in mice, and > 310 mg/kg bw in rats.

No published studies on the reproductive toxicity of KCl were identified. Information available on KCl indicates that there is no concern for reproductive toxicity if the plasma KCl concentrations are within the normal range. It is unlikely that occupational exposure or dietary exposure to KCl will result in increased plasma concentration as potassium and chloride do not accumulate in the body and they are well-regulated.

Potassium chloride showed no carcinogenic effects in a long-term dietary study in male rats, where groups of 50 male rats were administered the compound at doses of 110, 450 or 1820 mg/kg bw/day for two years. The only treatment-related effects observed were gastritis (inflammation of the stomach lining), an irritant effect. The NOAEL from the study was 1820 mg/kg bw/day.

Potassium chloride did not induce mutations in a *Salmonella typhimurium* assay using strains TA100, TA1535, TA1537, and TA98 with and without metabolic activation at doses up to 10 000 µg/plate. The compound was also negative in mouse lymphoma cell (L5178Y) mutagenicity assays in the absence of metabolic activation, but caused an increase in mutation frequency in multiple assays at concentrations of 3645–5000 µg/mL with activation. The study authors indicated that the high concentrations affected the ionic balance and osmotic pressure of the growth medium and induced mutations in cells surviving treatment.

Potassium chloride induced significant increases in chromosomal aberrations, but not sister chromatid exchanges, in V79 Chinese Hamster cells in vitro at concentrations causing high osmotic pressures (in other words, 12 000 µg/mL). Sister chromatid exchanges were significantly increased in Chinese Hamster Ovary (CHO) cells in vitro at concentrations inducing cytotoxicity and cell cycle delays (in other words, 180 mM). Non-significant increases in chromosomal aberrations and DNA single strand breaks were observed in the same cells at cytotoxic concentrations (≥ 140 mM).

In two chromosomal aberration tests in CHO cells, KCl concentrations of 75 and 80 mM (approximately 5500 and 6000 µg/mL) resulted in 19% and 28% aberrant cells, respectively. KCl concentrations that resulted in reduced cell survival ($\geq 40\%$) showed increased numbers of chromosome aberrations. The study authors concluded that the increased mutagenicity and chromosomal aberrations observed were related to cytotoxicity resulting from the high KCl concentrations used.

The mutagenic effects of KCl reported in the in vitro studies are considered to be the result of a disruption of the osmotic balance of cells. This can interfere with chromatic stability causing clastogenic effects (DNA breakage and chromosome structural instability) due to K^+ effects on sequestering of Mg^{2+} ions, which are required for normal maintenance of chromatin integrity. Therefore, KCl is not considered to be mutagenic or clastogenic.

Potash Molluscicide is a 100% repack of the technical grade active ingredient; therefore, the toxicology profile of Potash Molluscicide is identical to that of the technical grade active ingredient.

3.2 Health-related incident reports

Potassium chloride is a new active ingredient pending registration for use in Canada, and as of 21 September 2021, no health-related incident reports had been submitted to the PMRA.

3.3 Occupational, residential and bystander exposure and risk assessment

3.3.1 Dermal absorption

Based on the low octanol/water partition coefficient (-0.46 at 20°C) of KCl, it can be assumed that the salt will be poorly absorbed across the skin.

3.3.2 Use description

Potash Molluscicide (agricultural grade KCl) is a restricted use product, to be used only by certified applicators, intended for control of dreissenid mussels (zebra and quagga) in open water bodies, water reservoirs, pipelines, and closed systems (including closed loop fire suppression systems in hydro plants).

The solid end-use product (soluble granules) is pre-mixed to prepare a stock solution (0.3 kg/L), which is then stored in high density polyethylene tanks. The storage tanks will have spill containment and electric tank mixers to keep the KCl in solution. In the storage tank, the potassium concentration should be at 120 mg/L, and at application, near 100 mg/L. The prepared solution should be used within a week. The storage tank is delivered to a mobile shore based staging area close to each treatment site, which will facilitate easy access to the treatment area. The staging area should be enclosed with portable fencing and contain all chemical dosing equipment, chemical storage, fuel and equipment.

Prior to application to water bodies and water reservoirs, each treatment site will be sealed off from the rest of the open water body (for example, in a lake) using non-permeable geotextile membrane curtains to contain the potash solution. Application can be made by boat with a hose or drip lines off the boat, and mixing with the boat propeller. Two centrifugal pumps and a floating supply line (3.18 cm diameter) will be used to continuously feed the stock solution from the shore based storage tank to a diffuser on a 6.7 m Sealander work boat. The diffuser assembly (3 m × 1 m) consists of a 3 m horizontal hose to which six perforated, vertical, flexible, capped, and weighted hoses are attached. Application to pipelines and closed systems is done via injection system.

Potash Molluscicide is to be applied just before and/or as soon as ice breaks up at each harbour, for approximately 60 days, depending on water temperatures. Targetted application rate is 100 ppm K^+ , and concentration should be maintained for a sufficient length of time during treatment (at least 5 days at 15°C) as determined by bioassays. Re-application is required if the concentration of potassium ions in the water drops below 100 ppm during the treatment period.

Monitoring potassium ion concentrations by sample analysis and bioassays for the effectiveness of the treatment are the main post-application activities until the treatment is completed. Upon determining complete mortality in bioassays, the operation will be decommissioned by removing the segregation curtains, cinder blocks, lines, buoys and bioassay bags from the treatment site. By removing the curtains used to contain the treatment zone, the KCl treated water will mix with the open water and potassium and chloride ions will be diluted to the background levels. The treated water from closed systems will be discharged on to crop fields/vegetation as fertigation, which is fertilizer application by drip irrigation.

The application of Potash Molluscicide is done on a large scale, estimated at an average of 44.8 metric tonnes of liquid KCl (20%) used per day (average application volume is around 34 000–48 825 L/day). Fertigation rate of K^+ ranges from 3–29 kg/ha (average of 12 kg/ha), which is low compared with fertilizer use of KCl (50 to 52% K and 45 to 47% Cl^- , which corresponds to 129/280 kg/ha for soybean). A crop can remove from 16 to 270 kg/ha of KCl, depending on the crop type.

3.3.3 Mixer, loader, and applicator exposure and risk

Based on the low toxicity profile of KCl and anticipated limited human exposure based on the proposed use pattern, occupational and postapplication risks were assessed qualitatively.

Occupational exposure to Potash Molluscicide is expected to be short-term in duration and predominantly by the inhalation, dermal, and ocular routes when workers are exposed to the dust from handling the end-use product for pre-mixing. Exposure to mixed solution is also possible by the dermal and ocular routes during storage, transportation, and preparatory work for the treatment. Potash Molluscicide is mildly irritating to eyes, and may cause skin, and respiratory tract irritation. Since the application is done via hose or driplines off boat, or by injection system, there is minimal exposure during application.

Potential irritation from exposure to Potash Molluscicide can be mitigated by following the precautionary statements on the label, the use of appropriate PPE, and by following general occupational hygiene practices. The proposed end-use product label instructs workers to avoid contact with the eyes and skin, and avoid inhaling/breathing any dust generated while handling the solid form.

The PPE requirements on the end-use product label instruct personnel to wear goggles or a face shield, chemical-resistant gloves, long-sleeved shirt, long pants, shoes, and socks during handling, mixing/loading, clean-up or repair of equipment, and additionally, a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) while handling Potash Molluscicide in its solid form. Occupational exposure is acceptable when workers follow label requirements.

3.3.4 Postapplication exposure and risk

Postapplication activities include sampling treated water for potassium analysis during and after treatment, activities related to bioassaying of the treatment efficiency, cleaning-up activities, and discharge of treated water as fertigation to crop lands, which would likely involve limited duration exposures to water containing low potassium levels (approximately 50 to 100 mg/L). Exposure to personnel from discharging potash-treated water would be minimal as irrigation equipment is used, which is mostly automated. Based on the concentration of K^+ and the amount of water applied, the estimated application rate of K^+ on the fields is likely to range from 3 to 29 kg/ha, with a mean of 12 kg/ha.

In general, naturally occurring levels of potassium and chloride in Canadian lakes and rivers are less than 10 mg/L, and based on provincial monitoring data, potassium levels in Canadian drinking water range from < 0.01 to 51 mg/L (average: < 0.1 to 8.0 mg/L), while the limit for chloride levels in drinking water is set at ≤ 250 mg/L. Additionally, the use of KCl-based water softeners to control hard water could increase drinking water concentrations, in some cases to as high as 400 mg/L potassium or greater. Finally, the concentrations of potassium and chloride in seawater are approximately 380 mg/L and 19 400 mg/L, respectively. Based on the naturally occurring levels of potassium and chloride in lake water, sea water, and levels in drinking water, it is expected that any occupational risks from dermal and ocular exposures to diluted KCl from the intended use of Potash Molluscicide would be minimal. Therefore, risks to workers performing post-application activities are acceptable.

3.3.5 Residential and bystander exposure and risk

There are no residential uses for Potash Molluscicide. Bystander exposure from the proposed use of the end-use product is expected to be low as the handling and application of Potash Molluscicide is done by certified applicators; the end-use product is applied using either a hose or drip lines off a boat, or via injection system for pipelines or closed systems; and the required mitigation measures present on the label prevent bystander exposure. For example, bystander exposure is possible if recreational activities (such as swimming, fishing, etc.) occur in treated water bodies after application; however, the end-use product label instructs that the public be notified that certain bodies of water are closed for recreation, fishing, and commercial activities for ten days after the last treatment of Potash Molluscicide, by using signs and other markers. In addition, there is a standard spray drift statement to mitigate bystander exposure when irrigating crop land with treated water. Therefore, risk to bystanders is acceptable.

3.4 Food residue exposure assessment

3.4.1 Food

There are no food or feed uses proposed for Potash Molluscicide; therefore, there is no dietary exposure to residues of KCl.

In addition, the expected concentration of KCl in discharged treated water from closed water systems as fertigation is several folds lower than the application rate of KCl as a fertilizer.

3.4.2 Drinking water

Water levels of potassium and chloride are not likely to exceed natural background levels after the treatment, since treated water will be diluted in an open body of water once the segregation curtains are removed. For use in closed systems, the treated water will be used for fertigation. Consequently, the anticipated intake of potassium and chloride from drinking water from the proposed use is expected to be negligible and well below the level at which adverse health effects may occur. Moreover, as noted above, potassium and chloride are essential constituents that are well-regulated by the human body.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

Calculations of acute reference doses and acceptable daily intakes are not required for KCl as potassium and chloride are part of the normal human diet. Based on all the available information and hazard data, KCl is 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 determination. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of KCl including developmental effects from pre- or post-natal exposures, and cumulative effects on infants and children of KCl and other registered products containing KCl, do not apply to this active ingredient. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of KCl to human health.

3.4.4 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Based on available information on KCl, there is reasonable certainty that no harm will result from aggregate exposure of residues of KCl to the general Canadian population, including infants and children, when the end-use product is used as labelled.

3.4.5 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. While KCl dissociates in the environment to K^+ and Cl^- , moieties which may be common to other pesticide active ingredients, the potential health risks from cumulative exposure to these moieties from pest control products are acceptable given that potassium and chloride are essential elements in mammalian nutrition, readily available in the diet, and humans have efficient mechanisms in place to regulate levels of potassium and chloride in the body. Moreover, the proposed restricted use pattern of Potash Molluscicide is not likely to result in exceedance of natural background levels of potassium and chloride.

3.4.6 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Potassium chloride is a food ingredient. Moreover, the dietary risks from food and drinking water are expected to be negligible given that Potash Molluscicide is not proposed for direct food or feed use, and its application to water bodies, water reservoirs, pipelines, or closed systems populated by mussels is not expected to result in exceedance of natural background levels of potassium and chloride after the treatment. Consequently, the specification of an MRL for KCl under the *Pest Control Products Act* will not be required, since although KCl will be registered as a pesticide, it is also a food ingredient, and MRLs are not specified for food ingredients.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Potassium chloride (KCl) is a naturally occurring, highly soluble, ionisable salt. It is ubiquitous in the environment and is widely used as a fertilizer. Potassium chloride is not subject to photodegradation or biotransformation reactions. In soil and water, KCl ionizes to the cation, K^+ , and the anion, Cl^- . It is non-volatile and is not expected to partition to air. Potassium chloride is not expected to bioaccumulate in the environment.

The transport and leaching of potassium and chloride in soil is affected by pH, organic matter and the presence of clay minerals. K^+ is fairly immobile in soil as it tends to adsorb to the surface of negatively charged soil particles. As such, it is not subject to leaching or downward movement and is likely to remain in surface soil. Chloride binds weakly to soils and is transported by the movement of water.

In surface water, K^+ is redox-inactive and does not readily bind with molecules other than water. Potassium is removed from solution by adsorption reactions with clays and organic matter, as well as biological processes (uptake by microorganisms and plants). Chloride does not undergo oxidation or reduction reactions, does not form strong solute complexes, and does not significantly adsorb to mineral surfaces. Dilution is the predominant process to reduce concentrations of chloride in the environment.

4.2 Environmental risk characterization

An environmental risk assessment integrates environmental exposure and ecotoxicology information to estimate the potential for adverse effects in non-target species. This integration is achieved by comparing the estimated environmental concentration (EEC) to the concentrations at which adverse effects have been shown to occur in non-target organisms.

Acute and chronic ecotoxicology information for non-target freshwater invertebrates, fish and aquatic plants was obtained from the scientific literature and are summarized in Appendix I, Table 1. For non-target freshwater invertebrates, there was a sufficient number of acute toxicity endpoints available to calculate a species sensitivity distribution (SSD). The SSD is used to calculate the hazardous concentration to 5% of species (HC_5), which is theoretically protective of 95% of all species at the effect level used in the analysis. Two SSDs were calculated for the environmental risk assessment: (1) an SSD for all non-target freshwater invertebrates, and (2) an SSD for non-target freshwater invertebrates excluding bivalves.

In the risk assessment, toxicity endpoints were adjusted to calculate an effects metric. The effect metric accounts for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level). For characterizing acute risk to fish and aquatic plants, the effects metric was calculated by dividing LC_{50} and EC_{50} values by an uncertainty factor (UF; for example, 10 for fish, 2 for aquatic plants). The HC_5 values calculated from SSDs were used to evaluate acute risks to non-target freshwater invertebrates; a UF of 1 was used as the HC_5 is theoretically protective of 95% of invertebrate species in the ecosystem. Chronic risks to aquatic organisms were assessed using no-observed effect concentration (NOEC) values with a UF of 1. The toxicity endpoints and uncertainty factors used in the risk assessment are presented in Appendix I, Table 2.

Initially, a screening level risk assessment was performed to identify specific uses that do not pose a risk to non-target organisms, and groups of organisms for which there may be a potential risk. The screening level risk assessment used simple methods, conservative exposure scenarios and sensitive toxicity endpoints. A risk quotient (RQ) was calculated by dividing the EEC by an appropriate toxicity value ($RQ = EEC/\text{toxicity endpoint}$), and was then compared to the level of

concern (LOC) of 1. If the screening level RQ was below the LOC, risk was considered negligible and no further risk characterization was required. If the screening level RQ was equal to, or greater than the LOC, a refined risk assessment was performed to further characterize the risk.

4.2.1 Risks to terrestrial organisms

Potassium and chloride are essential elements for plants and animals. Exposure of terrestrial organisms to KCl may occur when treated water used to control invasive zebra and quagga mussels in water-related infrastructure (for example, irrigation systems) and closed loop fire suppression systems is discharged to the terrestrial environment. These uses are not expected to result in a significant increase in the exposure of non-target terrestrial organisms to KCl given that it is naturally occurring, ubiquitous in the environment, and is widely used as a fertilizer. Given the above, risks to terrestrial organisms were not evaluated further.

4.2.2 Risks to aquatic organisms

Aquatic organisms may be exposed to KCl when Potash Molluscicide is applied directly to water bodies to control zebra and quagga mussels, or via runoff of potassium chloride-treated water after it is discharged to the terrestrial environment. Exposure of aquatic organisms to KCl via runoff is expected to be significantly lower than via direct application to water.

Potash Molluscicide is proposed for application directly to water bodies at a concentration of 100 mg K⁺/L to control zebra and quagga mussels. The concentration of potassium must be maintained until 100% mortality of the target mussels is achieved, as determined by a bioassay. The length of the treatment varies, but mortality should occur within five days at 15°C.

In order to calculate the EEC for the risk assessment, the application rate (100 mg K⁺/L) was converted from mg K⁺/L to mg KCl/L to account for the chloride in the active ingredient and to allow for comparison to endpoints derived from toxicity studies. The EEC for the aquatic risk assessment is 190.7 mg KCl/L water. Once the treatment is complete, the concentrations of potassium and chloride in the water column will be reduced by dilution, uptake by biological processes and via adsorption to clays and organic matter.

Potassium chloride is practically non-toxic to non-target aquatic organisms (endpoints >100 mg KCl/L), with the exception of freshwater mussels. It is classified as practically non-toxic to slightly toxic to freshwater mussels (EC₅₀/LC₅₀ values 59.1 to >2000 mg KCl/L). Based on the available toxicity data, freshwater invertebrates are more sensitive to KCl than fish or aquatic plants. The results of the screening level risk assessment are presented in Appendix I, Table 2.

Screening level risk assessment

Aquatic Plants

Risks to algae and aquatic vascular plants from the proposed use are negligible (RQs ≤ 0.43).

Non-target freshwater invertebrates

Acute risk to non-target freshwater invertebrates was assessed using the HC₅ value of 45.91 mg KCl/L. Considering this value, the RQ of 4.15 exceeds the LOC of 1. This RQ is largely driven by the inclusion of bivalves in the SSD. As a molluscicide, it is expected that KCl will be toxic to native mussels. Potential risks to bivalves are discussed further below.

Non-bivalve freshwater invertebrates

In order to evaluate acute risks of the proposed use of KCl to non-bivalve freshwater invertebrates, an HC₅ value of 165.2 mg KCl/L was calculated from an acute SSD for non-target, non-bivalve, freshwater invertebrates. The resulting RQ of 1.15 marginally exceeds the LOC.

The most sensitive chronic endpoint for freshwater invertebrates was for a 21-day NOEC for *Daphnia magna* (<101 mg KCl/L). The associated lowest-observed effect concentration (LOEC) for *D. magna* from this study was determined to be 101 mg KCl/L based on a 16% impairment of reproduction. The RQs of >1.89 and 1.89, based on the NOEC and LOEC values respectively, marginally exceed the LOC.

Based on the marginal exceedance of LOC by the above RQs, risks to non-bivalve freshwater invertebrates from the proposed use are considered to be low. The risk assessment for non-target freshwater invertebrates is discussed further in the qualitative risk assessment section below.

Fish

The fish species most sensitive to KCl is the channel catfish, with a 48h-LC₅₀ value of 720 mg KCl/L. Using the effects metric of 72 mg KCl/L (the LC₅₀ divided by an UF of 10), the resulting RQ for this species is 2.65, which exceeds the LOC. This indicates that the proposed use may pose a low acute risk to some fish. Acute toxicity endpoints for seven fish species were available, with LC₅₀ values ranging from 720 to 5500 mg KCl/L (resulting in effects metrics of 72 to 550 mg KCl/L). This demonstrates that the toxicity of KCl to fish spans a wide range of concentrations, most of which are above the EEC of 190.7 mg KCl/L. The risk assessment for freshwater fish is discussed further in the qualitative risk assessment section below.

The available sub-chronic endpoints (7d-NOECs) for freshwater fish range from 250 to 2000 mg KCl/L. Given that these values exceed the EEC of 190.7 mg KCl/L, sub-chronic risks to freshwater fish are considered to be negligible.

Qualitative risk assessment of the proposed use

The screening level risk assessment indicates that the proposed use of KCl to control zebra and quagga mussels poses a low risk to non-bivalve freshwater invertebrates and fish, and a negligible risk to aquatic plants. As noted above, the proposed use presents a risk to native freshwater mussel species.

Fisheries and Oceans Canada (DFO) has identified zebra and quagga mussels as a high threat to waters in western Canada (DFO, 2012; PMRA# 3213542). DFO has determined that the establishment of zebra and/or quagga mussels would have negative impacts on pelagic (offshore) biota (for example, declines in phytoplankton, zooplankton, planktivorous fish, and unionid mussels (freshwater mussels of the order Unionida)).

Zebra and quagga mussels compete with native mussels for food and/or space. They also attach to, and incapacitate, native mussels, leading to their death. Zebra and/or quagga mussels have been identified as a limiting factor in the recovery of native mussels that are species at risk. The establishment of invasive mussel populations has led to large declines in unionid mussel populations and loss of unionid species. DFO (2012; PMRA# 3213542) reported that the establishment of invasive dreissenid mussels (in other words, zebra mussel, quagga mussel, and the dark false mussel (*Mytilopsis leucophaeta*)) was associated with a 90% decline in unionid mussel abundance within 10 years. There are 54 species of freshwater mussels in Canada. Zebra mussels have seriously affected the population stability of several “At Risk” native freshwater mussel species in Canada, including the Northern riffleshell (*Epioblasma torulosa*), the kidneyshell (*Ptychobranchnus fasciolaris*), and the round pigtoe (*Pleurobema sintoxia*) (PMRA# 3213543).

Potassium chloride was used to successfully eradicate zebra mussels without harming other aquatic organisms in Millbrook Quarry, Virginia in 2006, and in four harbours of Lake Winnipeg in 2014. The proposed use of KCl to control zebra and quagga mussels is restricted, will be conducted by trained applicators, and will only be used where zebra and/or quagga mussels have been confirmed to occur. The establishment of zebra and/or quagga mussels is a high threat to ecosystem structure and function, and will likely result in decreases in the populations of pelagic/profundal invertebrates, pelagic/planktivorous fish and unionid mussels. While there is a risk to non-target aquatic organisms from the use of KCl to control invasive mussels, the PMRA recognizes that control of invasive species is necessary in order to help protect habitats for native species. When used according to label directions, Potash Molluscicide will have the desired effect of controlling zebra and quagga mussels that pose a risk to aquatic habitats.

4.2.3 Environmental incident reports

As of 21 September 2021, no environmental incident reports involving KCl have been submitted to the PMRA.

5.0 Value

Zebra mussels (*Dreissena polymorpha*) and quagga mussels (*Dreissena bugensis*) are native to the Black Sea and Caspian Sea regions of Eastern Europe. It is believed they were both introduced into the Great Lakes via the dumping of ballast water from ocean-going vessels in the mid-to-late 1980s where the first population was discovered in Lake St. Clair straddling the Canada-United States border. Although both species are established throughout the Great Lakes and St. Lawrence River basin, zebra mussels have spread more widely in Canada and were found in Lake Winnipeg in 2013.

The treatment of invasive zebra and quagga mussels with Potash Molluscicide can be effective on different growth stages of the mussels. The life cycle of these mussels consists of three primary life stages: veligers (larvae), juveniles and adults. Oogenesis occurs in the fall with eggs developing until release and fertilization in the spring. However, reproduction can occur throughout the year. Up to a million eggs can be laid in a single spawning season. Veligers emerge 3–5 days after fertilization and settle at the bottom of the water column or are moved around by currents. Once they contact a suitable anchor point, preferably a rock or other hard surface, they attach themselves using a “byssus” consisting of many threads, found outside the body near the foot. They remain attached as they develop through the juvenile stage to adults.

In the literature provided, the ecological and economic impacts of zebra and quagga mussels in Canada is described as follows:

- Zebra and quagga mussels filter water to the point where food sources such as plankton are removed, altering food webs. This also causes clearer water, allowing sunlight to penetrate deeper into the water column, increasing growth of aquatic vegetation.
- Impact fish and wildlife by increasing toxic algal blooms.
- Females can release up to a million eggs each season which enhances the natural dispersal of this species from locations where it is introduced.
- Large colonies affect spawning areas, potentially impacting the survival of fish eggs.
- Cause millions of dollars in damage to boat engines, power plant and public water intakes by fouling infrastructure, blocking water flow and costing time and money removing them from affected structures.

Information provided in support of the registration of Potash Molluscicide indicates that KCl can be effective against veligers, juveniles and adult zebra and quagga mussels. Substantial information in the form of public literature was submitted in support of the mode of action of potassium and the toxicity of KCl and other potassium containing compounds on dreissenid mussels.

The information provided supports a claim of control of zebra and quagga mussels in reservoirs and bodies of water at the targetted application rate when concentrations of K^+ are maintained at 100 ppm for a duration of time determined by bioassays. The supporting information includes numerous publicly available reviews and published literature from peer-reviewed journals, outlining the efficacy of potassium containing compounds on the mortality of dreissenid mussels as well as detailing real-world examples of the use of potash for the control of zebra and quagga mussels in both the United States and Canada. Efficacy may vary and can be impacted by water quality and temperature; however, studies support the use of potash as an effective management tool for invasive zebra and quagga mussels in Canada.

The efficacy of KCl in pipelines and other closed systems can be supported based on studies conducted in Alberta in five irrigation districts, as well as the information provided in support of open-water use.

Research conducted by the Alberta Agriculture and Forestry Irrigation Technology Centre in Lethbridge indicates that potential damage / corrosion to pipes and fittings (irrigation infrastructure), as well as impacts to crops and soils resulting from the addition of KCl to irrigation water are not expected.

The following are alternatives to KCl for the control of zebra and quagga mussels:

- Hand harvesting
- Re-suspending sediments (artificially elevating and maintaining suspended sediments in the harbours)
- De-watering the harbours
- Use of Zequanox biological pesticide (Reg. No. 30486)
- Reduction of pH in harbours
- Use of chlorine in closed systems only for potable and industrial users

Presently registered control measures are few with no alternatives for use in open water scenarios. Zequanox Biological Zebra and Quagga Mussel Control is the only pest control product registered (for use in industrial systems only), and chlorine is authorized for use for municipal water intakes of potable water and certain industrial users (hydroelectric plants).

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* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, KCl was assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that Potassium Chloride Technical does not meet all of the TSMP Track 1 criteria.

Please refer to Appendix I, Table 3 for further information on the TSMP assessment.

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

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use product are compared against Parts 1 and 3 of 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 NOI2005-01⁷ and is based on existing policies and regulations, including the Toxic Substance Management Policy and Formulants Policy,⁸ and taking into consideration the Ozone-Depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that Potassium Chloride Technical and its end-use product, Potash Molluscicide, 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 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 Potassium Chloride Technical and Potash Molluscicide, containing the technical grade active ingredient KCl, for the control of zebra and quagga mussels in water reservoirs and other water bodies as well as in water pipelines and closed systems, including fire suppression systems in hydroelectric plants.

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.

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 PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

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

List of abbreviations

| | |
|------------------|--|
| µg | micrograms |
| bw | body weight |
| °C | degree centigrade |
| CAS | Chemical Abstracts Service |
| CEPA | <i>Canadian Environmental Protection Act</i> |
| CHO | Chinese Hamster Ovary |
| Cl ⁻ | chloride anion |
| cm | centimetres |
| d | day(s) |
| DFO | Fisheries and Oceans Canada |
| DIR | Regulatory Directive |
| DNA | deoxyribonucleic acid |
| EC ₅₀ | effective concentration on 50% of the population |
| EEC | estimated environmental concentration |
| g | gram |
| h | hour(s) |
| ha | hectare(s) |
| HC ₅ | hazardous concentration to 5% of species |
| IC ₅₀ | inhibition concentration on 50% of the population |
| IUPAC | International Union of Pure and Applied Chemistry |
| K ⁺ | potassium ions |
| KCl | potassium chloride |
| kg | kilogram |
| K _{ow} | <i>n</i> -octanol-water partition coefficient |
| L | litre |
| LC ₅₀ | lethal concentration 50% |
| LD ₅₀ | lethal dose 50% |
| LOC | level of concern |
| LOEC | lowest observed effect concentration |
| mg | milligram |
| Mg ²⁺ | magnesium ions |
| mL | millilitre |
| mM | millimolar |
| MRL | maximum residue limit |
| MSDS | material safety data sheet |
| n | number |
| N/A | not applicable |
| NIOSH | National Institute for Occupational Safety and Health |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOI | Notice of Intent |
| OECD | Organisation for Economic Co-operation and Development |
| Pa | Pascal |
| PMRA | Pest Management Regulatory Agency |

| | |
|-------|---|
| PPE | personal protective equipment |
| ppm | parts per million |
| RQ | risk quotient |
| SIDS | screening information data set |
| SSD | species sensitivity distribution |
| TSMP | Toxic Substances Management Policy |
| UF | uncertainty factor |
| USEPA | United States Environmental Protection Agency |
| UV | ultraviolet |

Appendix I Tables and figures

Table 1 Toxicity of potassium chloride to non-target freshwater organisms

| Category | Species | Endpoint | Degree of Toxicity ⁽¹⁾ | PMRA# |
|-------------------------------------|---|---|-----------------------------------|---------|
| Invertebrates (Non-bivalve) - Acute | Water flea (<i>Daphnia magna</i>) | 32h-NOEC = 373 mg KCl/L | Practically non-toxic | 3086930 |
| | | 24h-LC ₅₀ = 343 mg KCl/L | | 3086931 |
| | | 48h-LC ₅₀ = 177.4 mg KCl/L | | 3086932 |
| | | 24h-LC ₅₀ = 547.9 mg KCl/L | | 3086934 |
| | | 48h-LC ₅₀ = 196 mg KCl/L | | 3125207 |
| | | 48h-LC ₅₀ = 660 mg KCl/L | | 3144709 |
| | | 64h-EC ₅₀ = 432 mg KCl/L | | 3211096 |
| | Water flea (<i>Daphnia similis</i>) | 48h-LC ₅₀ = 690 mg KCl/L | | 3086933 |
| | Water flea (<i>Ceriodaphnia dubia</i>) | 48h-LC ₅₀ = 630 mg KCl/L | | 3144709 |
| | Sudanese fairy shrimp (<i>Streptocephalus proboscideus</i>) | 24h-LC ₅₀ = 1871 mg KCl/L | | 3086943 |
| | Midge (<i>Chironomus tentans</i>) | 96h-LC ₅₀ = 1250 to 6830 mg KCl/L; n = 14 ⁽²⁾ | | 3211107 |
| | Chironomid (<i>Cricotopus trifascia</i> Edwards) | 48h-LC ₅₀ = 2987 mg KCl/L | | 3086936 |
| | Caddisfly (<i>Hydroptila angusta</i> Ross.) | 48h-LC ₅₀ = 4415 mg KCl/L | | |
| | Oligochaete (<i>Nais variabilis</i>) | 48h-LC ₅₀ = 143 mg KCl/L | | |
| | Rotifer (<i>Brachionus calyciflorus</i>) | 24h-LC ₅₀ = 1692 mg KCl/L | | 3086943 |
| | Amphipod (<i>Hyallela azteca</i>) | 96h-LC ₅₀ = 216 mg KCl/L | | 3211099 |
| | | 96h-LC ₅₀ = 320 mg KCl/L | | |
| | | 96h-LC ₅₀ = 134 mg KCl/L | | 3211107 |
| | | 96h-LC ₅₀ = 232 to 372.4 mg KCl/L; n = 9 ⁽²⁾ | | |
| | Planarian (<i>Polycelis nigra</i>) | 96h-LC ₅₀ > 667 mg KCl/L | | 3211147 |
| | Snail (<i>Physa heterostrophia</i>) | 96h-LC ₅₀ = 940 mg KCl/L | Practically non-toxic | 3086938 |
| | Snail eggs (<i>Lymnaea</i> sp.) | 72h-LC ₅₀ = 1018 mg KCl/L | | 3086943 |
| | Fingernail clam (<i>Musculium transversum</i>) | 120h-LC ₅₀ = 320.3 mg KCl/L | | 3086937 |

| Category | Species | Endpoint | Degree of Toxicity ⁽¹⁾ | PMRA# |
|----------------------------------|--|--|---|---------|
| Invertebrates (Bivalves) - Acute | Mussel – threehorn wartyback (<i>Obliquaria reflexa</i>) | 48h-LC ₅₀ > 2000 mg KCl/L | | 3086174 |
| | Mussel - western pearlshell (<i>Margarutifera falcate</i>) | 96h-EC ₅₀ = 72.5 mg KCl/L | Slightly toxic | 3211098 |
| | Mussel - threeridge (<i>Amblema plicata</i>) | 96h-EC ₅₀ = 59.1 mg KCl/L | | |
| | Mussel - paper pondshell (<i>Utterbackia imbecillis</i>) | 96h-EC ₅₀ = 72.5 mg KCl/L | | |
| | Mussel - washboard (<i>Megalonaias nervosa</i>) | 96h-EC ₅₀ = 91.5 mg KCl/L | | |
| | Mussel - fatmucket (<i>Lampsilis siligoidea</i>) | 96h-EC ₅₀ = 87.8 mg KCl/L | | |
| Invertebrate Chronic | Water flea (<i>Daphnia magna</i>) | 21d-NOEC < 101 mg KCl/L 21d-LOEC = 101 mg KCl/L | N/A | 3086932 |
| | Water flea (<i>Ceriodaphnia dubia</i>) | 12d-NOEC (growth) = 690 mg KCl/L | | 3086933 |
| | | | 12d-NOEC (survival and fecundity) <600 mg KCl/L | |
| Fish acute | Rainbow trout (<i>Oncorhynchus mykiss</i>) | 48h-LC ₅₀ = 1610 mg KCl/L | Practically non-toxic | 3086174 |
| | Channel catfish (<i>Ictalurus punctatus</i>) | 48h-LC ₅₀ = 720 mg KCl/L | | |
| | Fathead minnow (<i>Pimephales promelas</i>) | 96h-LC ₅₀ = 880 mg KCl/L | | 3144709 |
| | Bluegill sunfish (<i>Lepomis macrochirus</i>) | 96h-LC ₅₀ = 2010 mg KCl/L | | 3086938 |
| | | 24h-LC ₅₀ = 5500 mg KCl/L | | 3086942 |
| | Mosquitofish (<i>Gambusia affinis</i>) | 96h-LC ₅₀ = 920 mg KCl/L | | 3086946 |
| | Chinook salmon (<i>Oncorhynchus tshawytscha</i>) | 96h-LC ₅₀ > 800 mg KCl/L NOEC ≥ 800 mg/L | | 3125207 |
| | Brook trout (<i>Salvelinus fontinalis</i>) | 96h-LC ₅₀ > 800 mg KCl/L NOEC ≥ 800 mg/L | | 3125207 |
| Fish sub-chronic | Rainbow trout (<i>Oncorhynchus mykiss</i>) | 7d-NOEC (growth) = 500 mg KCl/L | N/A | 3086940 |
| | Brook trout (<i>Salvelinus fontinalis</i>) | 7d-NOEC (survival/growth) = 2000 mg KCl/L | N/A | |
| | Fathead minnow (<i>Pimephales promelas</i>) | 7d-NOEC (survival/growth) = 500 mg KCl/L | | |

| Category | Species | Endpoint | Degree of Toxicity ⁽¹⁾ | PMRA# |
|-------------------------|---|--|-----------------------------------|---------|
| | | 7d-NOEC (growth (7days old) = 250 mg KCl/L | | 3086944 |
| Freshwater alga | Green algae, (<i>Pseudokirchneriella subcapita</i>) | Fluorescence/ log10 cell density: 96h-EC ₅₀ = 894.6 mg KCl/L | Practically non-toxic | 3086949 |
| | Diatom (<i>Nitzschia linearis</i> W. Sm) | 120h-LC ₅₀ = 1337 mg KCl/L | | 3086938 |
| Aquatic Vascular Plants | Duckweed (<i>Lemna minor</i>) | 7d-EC ₅₀ = 3206 mg KCl/L | | 3086949 |
| | | 7d-IC ₅₀ = 4770 mg KCl/L | | 3086951 |
| Acute SSD | Non-target freshwater invertebrates | median HC ₅ = 45.91 mg KCl/L | N/A | N/A |
| | Non-target freshwater invertebrates, excluding bivalves | median HC ₅ = 165.2 mg KCl/L | | |

(1) USEPA classification, where applicable

(2) This study reported multiple endpoints for the same test organism from an interlaboratory round robin test to test interlaboratory variability of the test methods. As such, the endpoints were considered to be independent.

Table 2 Toxicity endpoints used in the screening level risk assessment

| Category | Species | Endpoint | UF | Effects Metric (mg KCl/L) | RQ | LOC of 1 Exceeded? |
|---|--|--|----|---------------------------|-----------------|--------------------|
| The EEC for all non-target organisms is 190.7 mg KCl/L | | | | | | |
| Invertebrates – Acute | SSD – non-target freshwater invertebrates | median HC ₅ = 45.91 mg KCl/L | 1 | 45.91 | 4.15 | Yes |
| | SSD – non-target freshwater invertebrates excluding bivalves | median HC ₅ = 165.2 mg KCl/L | 1 | 165.2 | 1.15 | Yes |
| Invertebrate Chronic | Water flea (<i>Daphnia magna</i>) | 21d-NOEC < 101 mg KCl/L | 1 | 101 | >1.89 | Yes |
| | Water flea (<i>Ceriodaphnia dubia</i>) | 12d-NOEC (growth) = 690 mg KCl/L | 1 | 690 | 0.28 | No |
| | | 12d-NOEC (survival and fecundity) <600 mg KCl/L | 1 | <600 | >0.32 | No |
| Fish acute | Rainbow trout (<i>Oncorhynchus mykiss</i>) | 48h-LC ₅₀ = 1610 mg KCl/L | 10 | 161 | 1.18 | Yes |
| | Channel catfish (<i>Ictalurus punctatus</i>) | 48h-LC ₅₀ = 720 mg KCl/L | 10 | 72.0 | 2.65 | Yes |
| | Fathead minnow (<i>Pimephales promelas</i>) | 96h-LC ₅₀ = 880 mg KCl/L | 10 | 88.0 | 2.17 | Yes |
| | Bluegill sunfish (<i>Lepomis macrochirus</i>) | 96h-LC ₅₀ = 2010 mg KCl/L | 10 | 201 | 0.95 | No |
| | | 24h-LC ₅₀ = 5500 mg KCl/L | 10 | 550 | 0.35 | No |
| | Mosquitofish (<i>Gambusia affinis</i>) | 96h-LC ₅₀ = 920 mg KCl/L | 10 | 92.0 | 2.07 | Yes |
| | Chinook salmon (<i>Oncorhynchus tshawytscha</i>) | 96h-LC ₅₀ > 800 mg KCl/L NOEC ≥ 800 mg/L | 10 | >80.0 | <2.38 | Yes |
| Fish sub-chronic | Brook trout (<i>Salvelinus fontinalis</i>) | 96h-LC ₅₀ > 800 mg KCl/L NOEC ≥ 800 mg/L | 10 | >80.0 | <2.38 | Yes |
| | Rainbow trout (<i>Oncorhynchus mykiss</i>) | 7d-NOEC (growth) = 500 mg KCl/L | 1 | 500 | 0.38 | No |
| | Brook trout (<i>Salvelinus fontinalis</i>) | 7d-NOEC (survival/growth) = 2000 mg KCl/L | 1 | 2000 | 0.10 | No |

| Category | Species | Endpoint | UF | Effects Metric (mg KCl/L) | RQ | LOC of 1 Exceeded? |
|-------------------------|--|--|----|---------------------------|------|--------------------|
| | Fathead minnow (<i>Pimephales promelas</i>) | 7d-NOEC (survival/growth) = 500 mg KCl/L | 1 | 500 | 0.38 | No |
| | | 7d-NOEC (growth (7days old) = 250 mg KCl/L | 1 | 250 | 0.76 | No |
| Freshwater alga | Green algae, (<i>Pseudokirchneriella subcapita</i>) | Fluorescence/ log10 cell density: 96h-EC ₅₀ = 894.6 mg KCl/L | 2 | 447 | 0.43 | No |
| | Diatom (<i>Nitzschia linearis</i> W. Sm) | 120h-LC ₅₀ = 1337 mg KCl/L | 2 | 669 | 0.29 | No |
| Aquatic vascular plants | Duckweed (<i>Lemna minor</i>) | 7d-EC ₅₀ = 3206 mg KCl/L | 2 | 1603 | 0.12 | No |
| | | 7d-IC ₅₀ = 4770 mg KCl/L | 2 | 2385 | 0.08 | No |

Table 3 Toxic Substances Management Policy considerations

| TSMP Track 1 Criteria | TSMP Track 1 Criterion value | | Active Ingredient Endpoints | Transformation Products Endpoints |
|---|-------------------------------------|--|---|-----------------------------------|
| CEPA toxic or CEPA toxic equivalent ¹ | Yes | | Yes | No transformation products. |
| Predominantly anthropogenic ² | Yes | | No | |
| Persistence ³ : | Soil | Half-life ≥ 182 days | Potassium chloride is a naturally occurring ionisable salt. Potassium and chloride are not degraded in the environment. | |
| | Water | Half-life ≥ 182 days | | |
| | Sediment | Half-life ≥ 365 days | | |
| | Air | Half-life ≥ 2 days or evidence of long range transport | Potassium chloride is non-volatile and is not expected to partition to air. | |
| Bioaccumulation ⁴ | Log $K_{ow} \geq 5$ | | Potassium chloride does not bioaccumulate. | |
| | Bioconcentration Factor ≥ 5000 | | | |
| | Bioaccumulation Factor ≥ 5000 | | | |
| Is the chemical a TSMP Track 1 substance (all four criteria must be met)? | | | No, does not meet TSMP Track 1 criteria. | |

¹ All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).

² The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

³ If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

⁴ Field data (for example, Bioaccumulation FactorS) are preferred over laboratory data (for example, Bioconcentration Factors) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

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