Proposed Registration Decision PRD2016-17

Potassium Bicarbonate

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Overview

Proposed Registration Decision for Potassium Bicarbonate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Potassium Bicarbonate Technical and Potassium Bicarbonate, containing the technical grade active ingredient potassium bicarbonate, to partially suppress apple scab in apple orchards.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Potassium Bicarbonate Technical and Potassium Bicarbonate.

What Does Health Canada Consider When Making a Registration Decision?

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra.

Before making a final registration decision on Potassium Bicarbonate, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on potassium bicarbonate, which will include the

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."

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*.

decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Potassium Bicarbonate?

Potassium bicarbonate is a naturally occurring compound and is the active ingredient found in the end-use product Potassium Bicarbonate. It is currently registered in other fungicide products for the control or suppression of powdery mildew on vegetable crops, ornamentals, herbs and spices, hops, grapes, medical cannabis (marihuana) grown commercially indoors and stone fruit. It acts by inhibiting fungus mycelium development following spore germination.

Health Considerations

Can Approved Uses of Potassium Bicarbonate Affect Human Health?

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

Exposure to potassium bicarbonate may occur 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. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Potassium bicarbonate is of low toxicity by the oral, dermal and inhalation routes, and slightly irritating to the skin, eyes and mucous membranes. Based on a review of the available scientific literature, potassium bicarbonate is not expected to have any short- or long-term health effects.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is considered negligible based on the history of use of potassium bicarbonate as a food additive and its low toxicity.

It is anticipated that the uses of potassium bicarbonate in Canada on apple crops will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops.

No risk due to exposure from drinking water is anticipated. Minimal exposure to potassium bicarbonate and its naturally occurring by-products are expected in drinking water. In addition, toxicity to potassium bicarbonate is low.

Risks in Residential and Other Non-Occupational Environments

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

Potassium bicarbonate is proposed for use on agricultural crops only. The application directions on the product labels include statements to minimize spray drift. Consequently, it is unlikely that adults, youths and toddlers will be exposed to potassium bicarbonate. Even in the event of exposure, risk to the general population is not a concern due to the low toxicity of potassium bicarbonate and the history of its use as a food additive.

Occupational Risks From Handling Potassium Bicarbonate

Occupational risks are not of concern when Potassium Bicarbonate is used according to the proposed label directions, which include protective measures.

Applications of this product are to be made during rainfall. The precautionary label statements indicate that contact with skin, eyes, and clothing must be avoided as well as breathing of dusts and mists. The label also states that applicators in closed cabs must wear a long-sleeved shirt, long pants, gloves, shoes plus socks. When closed cab systems are not available, applicators must wear safety goggles, waterproof gloves, rain suit, waterproof boots and a mask. Other handlers that will not be exposed to the rain must wear safety goggles, long-sleeved shirt, long pants, gloves, shoes plus socks, and a mask. Precautionary and hygiene statements on the label are considered adequate to protect individuals from occupational exposure.

Environmental Considerations

What Happens When Potassium Bicarbonate Is Introduced Into the Environment?

Potassium Bicarbonate is not expected to pose risks of concern to the environment when used according to label instructions.

Potassium bicarbonate is highly soluble and, in the presence of water, will breakdown to potassium and bicarbonate ions within a short period of time. Both potassium and bicarbonate ions are used by living organisms and are part of naturally occurring nutrient cycles in the environment. Use of Potassium Bicarbonate on apples is not expected to cause adverse effects to non-target terrestrial and aquatic organisms.

Value Considerations

What Is the Value of Potassium Bicarbonate?

Potassium bicarbonate is a contact fungicide to be used against apple scab. Potassium Bicarbonate will reduce the need for conventional fungicides for the management of apple scab in apple orchards.

The use of Potassium Bicarbonate, containing potassium bicarbonate, would delay or reduce the need for conventional fungicides. There are several conventional products currently registered for use in apple orchards to manage apple scab; however, there are few non-conventional products available to growers, especially for organic production.

When used in an IPM program, Potassium Bicarbonate will reduce the need for conventional fungicides and may delay the development of resistance to conventional fungicides.

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 Potassium Bicarbonate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To prevent irritation to skin, eyes and mucous membranes, applicators in closed cabs must wear a long-sleeved shirt, long pants, gloves, shoes plus socks. When closed cab systems are not available, anyone applying Potassium Bicarbonate must wear safety goggles, waterproof gloves, rain suit, waterproof boots and a mask. Similarly, other handlers that will not be exposed to the rain must wear safety goggles, long-sleeved shirt, long pants, gloves, shoes plus socks, and a mask.

Environment

Risks to non-target organisms were negligible. The label for Potassium Bicarbonate reflects current labelling standards. General precautionary environmental label statements are included on the label.

Next Steps

Before making a final registration decision on Potassium Bicarbonate, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

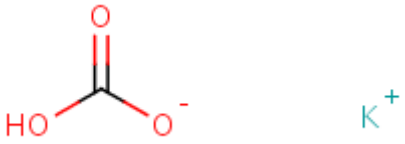
When the PMRA makes its registration decision, it will publish a Registration Decision on Potassium Bicarbonate (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Potassium Bicarbonate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Potassium bicarbonate
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Potassium hydrogen carbonate
2. Chemical Abstracts Service (CAS)	Carbonic acid, potassium salt (1:1)
CAS number	298-14-6
Molecular formula	$CHKO_3$
Molecular weight	100.1 g/mol
Structural formula	
Purity of the active ingredient	100%

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

Technical Product – Potassium Bicarbonate Technical

Property	Result
Colour and physical state	White solid
Odour	None
Melting range	292˚C but decomposes at 100˚C
Boiling point or range	N/A
Bulk density	2.17 g/cm^3
Vapour pressure at 20°C	Negligible as product is a solid.

Property	Result
Ultraviolet (UV)-visible spectrum	Not expected to absorb at λ >300 nm
Solubility in water	Temp (˚C) Solubility (g/L) 20 322 25 362
Solubility in organic solvents at 20°C	Product is an ionic salt so solvent solubility is expected to be negligible.
n-Octanol-water partition coefficient (K_{ow})	N/A as product is an ionic salt
Dissociation constant (pK_a)	pK_{a1} = 6.37 for dissociation of carbonic acid to bicarbonate pK_{a2} = 10.25 for further dissociation to carbonate
Stability (temperature, metal)	Stable under normal conditions.

End-Use Product – Potassium Bicarbonate

Property	Result
Colour	White
Odour	None
Physical state	Solid
Formulation type	Soluble granules
Guarantee	100%
Container material and description	Plastic and polyethylene double-walled plastic bags, 25 kg
Density	2.17 g/cm^3
pH of 1% dispersion in water	7.1–8.8
Oxidizing or reducing action	Not an oxidizing agent; forms carbon dioxide on contact with acids
Storage stability	Known to be stable at ambient temperature under normal dry storage conditions
Corrosion characteristics	Not corrosive; not expected to cause adverse effects to its plastic packaging
Explodability	Not explosive

1.3 Directions for Use

Potassium Bicarbonate is applied via foliar application to apples for the partial suppression of apple scab (*Venturia inaequalis*). It is applied at a rate of 4 kg/ha in a spray volume of 500-800 L/ha (0.5-0.8%). It may be applied using an airblast sprayer.

1.4 Mode of Action

Potassium bicarbonate, a contact fungicide, acts by inhibiting fungus mycelium development following spore germination. The mode of action is not well understood.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The characterization of the product as per the criteria in the Food Chemicals Codex for food-grade potassium bicarbonate is acceptable, and further analytical methods are not required.

2.2 Method for Formulation Analysis

A method for the analysis of the active ingredient in the formulation is not required.

2.3 Methods for Residue Analysis

Methods for the analysis of the active ingredient in environmental matrices are not required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A scientific rationale was submitted in lieu of toxicological studies. Potassium bicarbonate is a naturally occurring substance found in many living and non-living environments. Potassium bicarbonate is an inorganic salt which dissociates completely and quickly into potassium ions and bicarbonate ions when in the presence of water. In animals, potassium ions play essential roles in many vital cellular functions such as metabolism, growth, repair and regulation of volume, as well as in maintaining the electrical properties of the cells.

Potassium bicarbonate is used in baking powders and as a potassium supplement. As a formulation ingredient, potassium bicarbonate is considered as a List 4A formulation ingredient. The source of potassium bicarbonate is not certified as food grade; however, each batch of potassium bicarbonate will be analyzed to ensure that it conforms with the food grade requirements established by the United States Pharmacopeial Convention Food Chemicals Codex.

According to the various sources of toxicological information by the applicant, potassium bicarbonate is of low toxicity via the oral, dermal and inhalation routes of exposure. It is not reported as a skin irritant, but it was reported as slightly irritating to the eyes and respiratory tract. A Material Safety Data Sheet (MSDS) for potassium bicarbonate indicated that it may be irritating to skin. These findings are consistent with information found in TOXNET (http://toxnet.nlm.nih.gov/). Following exposure to very large concentrations, potassium bicarbonate can cause metabolic alkalosis (irritability, agitation, neuromuscular excitability, tetany, edema, hypocalcemia, hypoglycemia) and kidney failure. Potassium bicarbonate is not a developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant.

Incident Reports

As of 11 December 2015, no human, domestic animal or environment incident reports involving potassium bicarbonate had been submitted to the PMRA.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Dermal Absorption

No information was provided on the dermal absorption of potassium bicarbonate. The dermal absorption of potassium bicarbonate is expected to be minimal since it completely dissociates into potassium and bicarbonate ions in water, and ionized substances do not typically penetrate the dermis.

3.2.2 Use Description

Potassium Bicarbonate is proposed for use in orchards for the suppression of apple scab disease (*Venturia inaequalis*). Applications of Potassium Bicarbonate are to be made at bud-break stage and when meteorological conditions allow the disease to spread. The end-use product is to be applied during the germination or infection period of spores (measured in degree-hours). Applications are to be made during rainfall up to 3 mm of rain/hour. If rain intensifies over 3mm/hour, the label requires that applicators wait until rain falls below 3mm/hour to continue the spraying. Repeat applications over the same wetting period may be needed based on the re-calculated degree-hours from the beginning of the previous treatment.

Applications to apple tree canopies are to be done using a calibrated air-blast sprayer at a rate of 4kg/ha with sufficient water to cover the entire canopy of the trees. Spray volume per hectare of treated surface can vary depending on size of trees (tree age, dwarf, semi-dwarf or standard) and stage of development. A spray volume of 500–800 L/ha is recommended.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk Assessment

The proposed use of potassium bicarbonate may result in exposure to workers during handling, mixing, loading and applying the product. Workers will be primarily exposed by dermal and inhalation routes and to a lesser extent the ocular route.

The end-use product label has a number of exposure reduction statements (for example, wearing of personal protective equipment, clothing, hygiene statement) to protect mixers, loaders and applicators against risk from exposure. The label instructs that:

i. applicators in closed cabs must wear a long-sleeved shirt, long pants, and shoes plus socks;
ii. where closed cabs are not available, applicators must wear safety goggles, waterproof gloves, rain suit, waterproof boots and a mask;
iii. other handlers that will not be exposed to rain must wear safety goggles, waterproof gloves, long-sleeved shirt and pants, shoes and a mask;
iv. avoid breathing spray mists and dusts;

v. avoid contact with eyes and skin; and
vi. remove contaminated clothing and wash clothing before reuse.

These statements should be effective in minimizing the potential for exposure.

No significant risk is expected from exposure to potassium bicarbonate for mixers, loaders and applicators as well as those responsible for clean-up, maintenance and repair activities due to the low toxicity of the active ingredient and reduced occupational exposure when label directions are followed.

3.2.4 Postapplication Exposure and Risk

Postapplication exposure is minimal when workers enter the treated orchards soon after the application since the product is applied in the rain. As a result, no restricted re-entry intervals are recommended.

3.2.5 Residential and Bystander Exposure and Risk

Negligible residential and bystander exposure is expected when the end-use product is used according to the label directions. The product is to be applied in orchards by authorized personnel during periods of rain.

3.3 Dietary Exposure and Risk Assessment

3.3.1 Food

Due to the low toxicity of potassium bicarbonate, and its history of use as a food additive, no adverse effects are anticipated from the presence of residues on food.

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of potassium bicarbonate from the proposed use in apple orchards in the general population and potentially sensitive subpopulations, including infants and children.

3.3.2 Drinking Water

Although the end-use product will not be applied near or directly to water, some drinking water exposure may be possible through run-off from treated areas since the product will be applied during rainfall. In water, potassium bicarbonate completely dissociates into potassium and bicarbonate ions. Potassium ions are essential in cells and they are likely to be absorbed rapidly in the environment. Bicarbonate ions further dissociate into carbon dioxide and carbonate ions, and enter the carbon cycle. Exposure to potassium bicarbonate and its naturally occurring by-products in drinking water are expected to be minimal. In addition, toxicity to potassium bicarbonate and its ions is low. Consequently, no risk due to exposure from drinking water is anticipated

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

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

3.3.4 Aggregate Exposure and Risk

Based on all the relevant information in the PMRA files, there is reasonable certainty that no harm will result from aggregate exposure of residues of potassium bicarbonate to the general Canadian population, including infants and children, when the end-use product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation).

3.3.5 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a 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.

Potassium bicarbonate is a food ingredient. While this source of potassium bicarbonate is not certified as food grade, each batch of potassium bicarbonate will be analyzed to ensure that it conforms to the food grade requirements established by the United States Pharmacopeial Convention Food Chemicals Codex. Consequently, a MRL is not specified for the proposed use in apple orchards.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Potassium bicarbonate is a naturally occurring compound in soil and water, and dissociates completely under environmental conditions to potassium and bicarbonate ions. These ions are present in virtually all living organisms as they are important for the biological processes within

all living cells in animal and plant tissues. Potassium is an essential microbial and plant nutrient which is used by these organisms and cycled back to the environment through decomposition. Bicarbonate is also subject to natural nutrient cycling in plant matter, soil and water. It would not be possible to differentiate between potassium and bicarbonate ions naturally present and those of other sources (for example, fungicides). The environmental fate and behaviour of potassium bicarbonate is, therefore, well documented and not expected to produce transformation products of concern.

Potassium bicarbonate is highly soluble (322 g/L, 20^{o}C) and will rapidly dissociate in water to potassium and bicarbonate ions. As Potassium Bicarbonate is applied in water, dissociation is likely occurring in the spray tank. Neither the potassium bicarbonate molecule nor its dissociated ions are volatile. Dissociation in the presence of water to potassium and bicarbonate ions is the primary fate of potassium bicarbonate, and no hydrolysis or phototransformation will occur. In water, bicarbonate presence is due to the equilibrium between dissolved carbon dioxide and carbonic acid, carbonic acid and bicarbonate, and bicarbonate and carbonate. Potassium and bicarbonate are mobile in soil and will leach (particularly in soils that are low in organic matter content), but this would be limited to the unbound form of the ions only.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models, which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications (where possible).

The use of Potassium Bicarbonate in apple orchards, applied to foliar surfaces (single or multiple applications), may result in the release of potassium bicarbonate to the environment through spray drift and/or overland runoff. However, due to its rapid dissociation in presence of water to potassium and bicarbonate ions, and that potassium and bicarbonate ions are used and processed by biological systems and subject to nutrient cycling in soil and water, effects to the environment from this use are not expected to be of concern. Various ecotoxicity endpoints from publicly available sources of information also support that potassium bicarbonate is not expected to pose a risk to the environment from this use. These are discussed in Section 4.2.1.

4.2.1 Risks to Non-Target Species

Some ecotoxicity data were available and were reviewed as part of the assessment of the risk of potassium bicarbonate to non-target organisms in the environment (Appendix I, Table 3). Potassium bicarbonate was shown to cause no effects to the bumble bee (*Bombus impatiens*) at the highest rate tested of 560 g a.i./ha and was practically non-toxic to honey bee with an LD_{50} > 24 µg a.i./ bee. No adverse acute effects were observed on chicken at a dietary rate of 8075 mg sodium bicarbonate/kg bw/day. Effects on parasitic and predatory terrestrial invertebrates were

also not a concern. Potassium bicarbonate was practically non-toxic to freshwater fish and invertebrates with a 96-h LC_{50} > 1.2 g a.i./L for rainbow trout and a 48-h EC_{50} of 0.63 g a.i./L for *Daphnia*. Potassium bicarbonate had no adverse effects on green algae.

A screening level risk assessment was conducted with these data and the level of concern (LOC) was not exceeded for bees, predatory and parasitic terrestrial insects or aquatic organisms (fish, amphibians, aquatic invertebrates or algae; Appendix I, Table 4). Potassium Bicarbonate is to be applied to apple orchards during rainfall. Insect activity, such as foraging and flying, is expected to be minimal during a precipitation event, which will further reduce the risk to pollinators.

5.0 Value

5.1 Consideration of Benefits

The risk for resistance development for potassium bicarbonate is considered low. Use of Potassium Bicarbonate, early in the growing season, may reduce the need for applications of conventional fungicides later in the growing season. There are several conventional products currently registered for use on apples to manage apple scab; however, there are only two non-conventional products available to producers. Registration of Potassium Bicarbonate will allow Canadian apple growers, especially organic producers, access to a new non-conventional product.

5.2 Effectiveness Against Pests

In support of the proposed claim, four published articles and efficacy data from one trial were considered. Based on the weight of evidence submitted, it was confirmed that potassium bicarbonate is effective at partially suppressing apple scab at a concentration of 0.5–0.8%.

5.3 Non-Safety Adverse Effects

No signs of phytotoxicity or any other adverse effects were observed from the use of Potassium Bicarbonate when applied according to label directions.

5.4 Supported Uses

Based on the value information provided a claim of partial suppression of apple scab (*Venturia inaequalis*), at an application rate of 4 kg/ha in a spray volume of 500-800 L/ha (0.5–0.8%), can be supported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: in other words, persistent (in air, soil, water and/or

sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*.

During the review process, potassium bicarbonate was assessed in accordance with the PMRA Regulatory Directive DIR99-03[9] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Potassium bicarbonate does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Appendix I, Table 5 for comparison with Track 1 criteria.

- Potassium bicarbonate does not contain any impurities and is not expected to form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette.*[10] The list is used as described in the PMRA Notice of Intent NOI2005-01[11] and is based on existing policies and regulations including DIR99-03[12] and DIR2006-02[13] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Potassium Bicarbonate Technical does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The end-use product, Potassium Bicarbonate, does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

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

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

10 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1*
Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

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

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

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for potassium bicarbonate is adequate to define the toxic effects that may result from exposure to this chemical. The technical product (Potassium Bicarbonate Technical) and end-use product (Potassium Bicarbonate) containing the active ingredient, potassium bicarbonate, are expected to be of low acute toxicity via the oral, dermal, and inhalation routes. They are not considered to be dermal sensitizers, but are expected to be slightly irritating to the skin, eyes and mucous membranes. Potassium bicarbonate is also not a developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant.

Loaders, mixers, applicators, and workers are not expected to be exposed to levels of potassium bicarbonate that will result in an unacceptable risk due to exposure when Potassium Bicarbonate is used according to label directions. Bystander and postapplication exposure is also likely to be minimal and not of concern.

Dietary exposure to potassium bicarbonate from the use of Potassium Bicarbonate is not expected to result in unacceptable dietary risks when the product is used according to label instructions. PMRA did not specify an MRL for potassium bicarbonate.

7.2 Environmental Risk

Potassium bicarbonate will undergo rapid dissociation into potassium (K^+) and bicarbonate (HCO_3^-) ions in presence of water and, once dissociated, bicarbonate and potassium ions will enter their natural cycle in the environment. No potential for concern for aquatic and terrestrial organisms was identified during the risk assessment, and Potassium Bicarbonate is not expected to pose risks of concern to the environment when used according to the label directions. Environmental risk from the use of Potassium Bicarbonate on apple trees is acceptable.

7.3 Value

Potassium Bicarbonate will provide partial suppression of apple scab on apples. When used in an IPM program, this product will reduce the need for conventional fungicides and delay the development of fungicide resistance.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Potassium Bicarbonate Technical and Potassium Bicarbonate, containing the technical grade active ingredient potassium bicarbonate, to control to partially suppress apple scab in apple orchards.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	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
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
C	conventional
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
EEC	estimated environmental concentration
ER_{25}	effective rate for 25% of the population
ER_{50}	effective rate on 50% of the population
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IPM	integrated pest management
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
NC	non-conventional
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Toxicity Profile of Potassium Bicarbonate (End-Use Product)
(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Acute dermal toxicity Acute inhalation toxicity Dermal irritation Eye irritation Dermal sensitization PMRA # 2497973 and 2498125	A detailed waiver request was submitted along with supporting documentation. Based on all the available information, the acute oral, dermal and inhalation toxicity of the end-use product is expected to be low. The end-use product, however, is expected to be slightly irritating to the skin, eyes and mucous membranes. Potassium bicarbonate is not a dermal sensitizer. The request for a waiver was accepted.

Table 2 Toxicity Profile of Potassium Bicarbonate Technical
(Effects are known or assumed to occur in both sexes unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Acute dermal toxicity Acute inhalation toxicity Dermal irritation Eye irritation Dermal sensitization PMRA # 2497973 and 2498125	A detailed waiver request was submitted along with supporting documentation. Based on all the available information, the acute oral, dermal and inhalation toxicity of the technical grade active ingredient is expected to be low. The technical grade active ingredient, however, is expected to be slightly irritating to the skin, eyes and mucous membranes. Potassium bicarbonate is not a dermal sensitizer. The request for a waiver was accepted.
Short-term Oral Toxicity PMRA # 2497973 and 2498125	A detailed waiver request was submitted along with supporting documentation. Based on all the available information, the short term oral toxicity of technical grade active ingredient is expected to be low. The request for a waiver was accepted.
Prenatal Developmental Toxicity PMRA # 2497973 and 2498125	A detailed waiver request was submitted along with supporting documentation. Based on all the available information, the technical grade active ingredient is not a developmental toxicant. The request for a waiver was accepted.

Study Type/Animal/PMRA #	Study Results
Genotoxicity: bacterial reverse mutation assay Genotoxicity: *in vitro* mammalian cell assay PMRA # 2497973 and 2498125	A detailed waiver request was submitted along with supporting documentation. Based on all the available information, the technical grade active ingredient is not a genotoxicant. The request for a waiver was accepted.

Table 3 Toxicity of Potassium Bicarbonate to Non-Target Species

Category	Species	Toxicity	USEPA Classification	Ref. PMRA#
Bumble bee Acute Oral	*Bombus impatiens*	NOEC= 0.081 mg /g pollen (or 560 g /ha)	NA[a]	2497989
Honeybee Acute Contact	Bee (not specified)	LD_{50} > 24 µg a.i./ bee	Practically non-toxic	2497987
Chicken	*Galus galus*	LD_{50} >8,075 mg/kg bw/day)[c]	Practically non-toxic	2497990
Freshwater Fish Acute, Other species	Rainbow trout	96 h – LC_{50} > 1.2 g a.i. /L	Practically non-toxic	2497987
Freshwater Invertebrate Acute	*Daphnia magna*	48 h – EC_{50} = 0.63 g a.i./L	Practically non-toxic	2497987
Green algae	*S. subcapitata*	72 h EC_{50}>0.1 g/L[b]	NA	2497987
Predatory arthropod	*Typhlodromus pyri*	ER_{50}: 6.49 kg /ha[b]	NA	2497987
Parasitoid	*Aphidius rhopalosiphi*	ER_{50} > 8.5 kg /ha[b]	NA	2497987

[a]NA: not applicable;
[b]Study conducted with Armicarb (containing 85% potassium bicarbonate + a mixture of formulants :sulfuric acid, C12-14 alkyl esters and sodium salts). Armicarb is a formulation used in Europe; [c] The value is expressed as HCO_3, therefore refers only to bicarbonate.

Table 4 Screening Level (Acute) Risk Assessment (RA) for Non-Target Species Exposed to Potassium Bicarbonate

Organism	Toxicity value	RA endpoint = Toxicity value ÷ Uncertainty factor[a]	EEC[b]	RQ[c]	LOC[d] Exceeded
Honey bee	LD_{50} > 24 µg a.i./ bee	> 24 µg a.i./ bee	9.6 µg a.i./ bee[c]	**<0.4**	**No**
Chicken	LD_{50} >8,075 mg/kg bw/day	8075/10 = 807.5 mg/kg bw/day	165.42 mg a.i/kg bw[g]	**<0.2**	**No**
Rainbow trout	96 h – LC_{50} >	1200/10 = 120 mg	0.504 mg	**<0.004**	**No**

Organism	Toxicity value	RA endpoint = Toxicity value ÷ Uncertainty factor[a]	EEC[b]	RQ[c]	LOC[d] Exceeded
	1200 mg a.i. /L	a.i./L	a.i./L		
Amphibians[e]			2.7 mg a.i./L	**<0.02**	**No**
Daphnia magna	48 h – EC_{50} = 630 mg a.i./L	630/2 = 310 mg a.i./L	0.504 mg a.i./L	**0.001**	**No**
S. subcapitata	72 h EC_{50}>0.1 g Armicarb[f] /L (85 mg a.i/L)	85/2 = 42.5 mg a.i./L	0.504 mg a.i./L	**<0.01**	**No**
Typhlodromus pyri	ER_{50}: 6.49 kg Armicarb /ha (5.5 kg a.i./ha)	5.5 kg a.i./ha	10.32 kg a.i./ha	**1.9**	**No**
Aphidius rhopalosiphi	ER_{50} > 8.5 kg Armicarb /ha (7.2 kg a.i/ha)	>7.2 kg a.i./ha	10.32 kg a.i./ha	**<1.4**	**No**

[a]For characterizing acute risk, toxicity values are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (for example, community, population, individual). Uncertainty factors are 10 for fish and amphibians, 2 for aquatic and terrestrial invertebrates. The difference in value of the uncertainty factors reflect, in part, the ability of certain organisms at a certain trophic level to withstand, or recover from, a stressor at the level of the population.

[b]Estimated environmental concentrations (EECs) were determined using cumulative seasonal rates calculated based on defaut foliar half-life of 10 days; for bees, based on the conversion for contact exposure (4 kg a.i./ha x 2.4 µg a.i./bee per kg/ha = 9.6 µg a.i./bee); application parameters are: rate of 4.032 kg a.i./ha, immediate dissociation after each application, 10 applications spaced 7 days apart, concentrations in surface water 80 cm deep (fish, *Daphnia* and algae), and in a seasonal pond of 15 cm (amphibians) .

[c] Risk quotient = EEC ÷ (toxicity value / uncertainty factor)

[d] Level of Concern (LOC): values are 0.4 for bees, 2 for terrestrial invertebrates, 1 for fish, amphibians, *Daphnia* and algae.

[e] Data for the most sensitive fish species is used as a surrogate for amphibians.

[f] Armicarb is a formulation used in Europe, and contains 85% potassium bicarbonate.

[g] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/bw) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used: Passerine Equation (body weight <or = 200 g): FIR (g dry weight/day) = 0.398(bw in g)0.850. All birds Equation (body weight >200 g): FIR (g dry weight/day) = 0.648 (bw in g) 0.651.

Table 5 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Potassium Bicarbonate technical Endpoints
Toxic or toxic equivalent as defined by the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		No
Persistence[3]	Soil	Half-life ≥ 182 days	No
	Water	Half-life ≥ 182 days	No
	Sediment	Half-life	No

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Potassium Bicarbonate technical Endpoints
		≥ 365 days	
	Air	Half-life ≥ 2 days or evidence of long range transport	NA
Bioaccumulation[4]	Log K_{OW} ≥ 5		NA
	BCF ≥ 5000		NA
	BAF ≥ 5000		NA
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 toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion 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 [BAFs]) are preferred over laboratory data (for example, bioconcentration factors [BCFs]), which, in turn, are preferred over chemical properties (for example, log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2497942	2014, Analyses purete et carbonate, DACO: 2.13.1,2.13.2 CBI
2497943	2015, Analyse Identification Bicarbonate, identification Potassium et [CBI REMOVED], DACO: 2.13.1,2.13.2
2497944	2013, analyses impurete [CBI REMOVED], DACO: 2.13.1,2.13.2 CBI
2497945	2012, Specefications du fabricant, DACO: 2.13.1,2.13.2 CBI
2497946	1999, Bicarbonate de potassium, DACO: 2.13.1,2.13.2
2497953	2014, Fiche de donnees de securite. Bicarbonate de potassium 99.7%, DACO: 2.0,2.14.11,2.14.13,2.14.7,4.2,9.2.4
2497954	2014, Nom et adresse commerciale du demandeur, DACO: 2.1
2497955	2014, Technology process of potassuim bicarbonate, DACO: 2.11.1,2.11.2,2.11.3 CBI
2497956	2014, Propriete physico-chimiques, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
2497957	2010, Ficche signaltique du bicarbonate de potasium technique, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,4.2 CBI
2497959	2014, Nom et adresse du fabricant, DACO: 2.2 CBI
2497960	2014, Proproete chimiques de la MAQT, DACO: 2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2497961	2010, Fiche signaletique du bicarbonate de potassium technique, DACO: 2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2497962	2014, MSDS Potassium bicarbonate, DACO: 2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9,4.2 CBI
2497969	1987, Service du repertoire toxicologique. Bicarbonate de potassium, DACO: 2.0,4.2,4.6
2497970	2009, MSDS Potassium bicarbonate, DACO: 2.0,4.2,4.6

PMRA Document Number	Reference
2497971	2014, Pesticides Properties DataBase (PPDB) Potassium Bicarbonate, DACO: 2.0,2.14.10,2.14.12,2.14.7,2.14.8,4.2,4.6,9.2.4
2497972	2010, Fiche de donnees de securite. Bicarbonate de potassium, DACO: 2.0,2.14.11,2.14.6,2.14.9,4.2,4.6,9.2.4
2532836	2015, Flow chart, DACO: 2.11.3
2537171	2015, Propriete Physico-chimique de la MAQT mai 2015, DACO: 2.14.10
2498123	2014, Proprietes chimiques de la PC, DACO: 3.0 CBI
2498124	2014, Proprietes physico-chimiques de la PC, DACO: 3.0 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2497966	2006, Note reglementaire REG2006-03 Bicarbonate de potassium, DACO: 4.2, 4.6
2497967	1999, Potassium bicarbonate (073508) and sodium bicarbonate (073505) fact sheet, DACO: 4.2, 4.6
2497968	2014, Fiche toxicologique sante. Bicarbonate de potassium, DACO: 4.2, 4.6
2497973	2014, Demande d'expemption de donne toxicologique, DACO: 4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.6, 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, 4.6.6
2497976	2006, Manuel surla fertilite du sol, DACO: 4.2, 4.6, 9.2.4
2497977	2009, Fonction et importance du potassium pour l'organisme humain, DACO: 4.2, 4.6, 9.2.4
2497979	2008, Document de conseils sur le potassium provenant des adoucisseurs d'eau, DACO: 4.2, 4.6, 9.2.4
2497980	2013, Fiche signaletique du Milstop, DACO: 4.2, 4.6, 9.2.4
2497981	2012, Fiche de donnees de securite Armicarb, DACO: 4.2, 4.6, 9.2.4
2497982	2012, Fiche de donnees de securite Armicarb, DACO: 4.2, 4.6, 9.2.4
2497985	2014, Toxicologie de la Matiere active: Bicarbonate de potassium, DACO: 4.2, 4.6, 9.2.4
2497986	2014, Registration report Product code: Vitisan (99.9% potassium hydrogen carbonate), DACO: 4.2, 4.6, 9.2.4
2498125	2014, Demande d'exemption de donnees toxicologiques pour le CODO 4, DACO: 4.6
2498126	2014, Données requises pour le CODO 5.2, DACO: 5.2

3.0 Environment

2497986	2014, Registration report Product code: Vitisan (99.9% potassium hydrogen carbonate), DACO: 4.2,4.6,9.2.4
2497987	2014, Demande d'exemption de données sur l'exposition dans l'environnement et écotoxicologie, DACO: 8.1,9.1,9.2.4
2497988	2013, Guide de référence en production fruitière intégrée à l'intention des producteurs de pommes du Québec, DACO: 9.2.4
2497989	2009, Effects of reduce risk pesticides for use in greenhouse vegetable production on *Bombus impatiens* (Hymenoptera: Apidae), DACO: 9.2.4
2497990	2011, Conclusion on the peer-review of the pesticide risk assessment of the active substance potassium hydrogen carbonate, DACO: 9.2.4
2497991	2014, Substance Bicarbonate de potassium, Effets non-intentionnels, DACO: 9.2.4

4.0 Value

PMRA Document Number	**Reference**
2498134	2007, Control of apple scab (*Venturia inaequalis*) with bicarbonate salts under controlled environment., DACO: 10.1,10.2.1
2498135	2010, Primary scab control using a during-infection spray timing and the effect on fruit quality and yield in organic apple production, DACO: 10.1,10.2.2
2498138	2009, Potassium bicarbonate in preventing and control of apple scab, DACO: 10.1
2498148	2014, Effect of potassium bicarbonate (Armicarb) on the control of apple scab (*Venturia inequalis*) in the region of Puka in ALbania, DACO: 10.2.1
2498155	2014, Essai terrain sur l'effet du bicarbonate de potassium pour contrôler la tavelure primaire du pommier, DACO: 10.2.3.3