Proposed Registration Document PRD2014-15

Acetic Acid

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Overview

Proposed Registration Decision for White Vinegar 12% Technical

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 White Vinegar 12% Technical and White Vinegar 12%, containing the technical grade active ingredient acetic acid, for the control of perennial weeds in cranberry crop.

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 White Vinegar 12% Technical and White Vinegar 12%.

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 (for example, those most sensitive to environmental contaminants). 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 healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on acetic acid, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on acetic acid, which will include the decision, the reasons for it, a summary of comments received on the proposed final 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 Acetic Acid?

Acetic acid (CH_3COOH) is a molecule composed of carbon (C), hydrogen (H) and oxygen (O_2). It is an organic acid that is readily biodegradable into non-toxic substances such as carbon dioxide (CO_2) and water (H_2O). Acetic acid acts as a non-selective contact herbicide. When it comes into contact with any parts of the plant, the acid quickly destroys the cell membrane, causing desiccation of the foliar tissues and ultimately killing the plant.

White Vinegar 12% is a new liquid herbicide containing 12% acetic acid. The product consists of non-synthetic acetic acid, which is naturally present in food-grade white vinegar. White Vinegar 12% contains no surfactants or adjuvants, making it suitable for both conventional and organic cranberry production.

Health Considerations

Can Approved Uses of Acetic Acid Affect Human Health?

Acetic Acid is unlikely to affect human health when used according to label directions.

Exposure to acetic acid at 12 % (v/v) may occur when handling the end-use product, White Vinegar 12%, such as during mixing, loading or applying the product, or during clean up and maintenance activities. People entering areas treated with acetic acid are not likely to be exposed since the product is applied directly into the soil. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient, containing acetic acid, is expected to be of low toxicity by the oral and inhalation routes. Based on the low pH of the solution, it is expected to be slightly acutely toxic by the dermal route, mildly irritating to the respiratory tract, and mildly to moderately irritating to the skin. It is corrosive to the eyes, and is not likely to be a skin sensitizer.

Exposure to humans from the commercial use of the end-use product, White Vinegar 12%, is not expected to be of concern due to the precautionary statements present on the end-use product label that are aimed at mitigating exposure.

Residues in Water and Food

Dietary risks on food and water are not of health concern.

The end-use product, White Vinegar 12%, is injected into the soil surrounding cranberry plants and is not applied directly to food. In soil, acetic acid is expected to degrade rapidly. Also, the end-use product label has precautionary statements not to contaminate food, feed, and water with the end-use product; therefore, dietary exposure to acetic acid from the proposed use is anticipated to be negligible. The PMRA has determined that a maximum residue limit (MRL) is not required for White Vinegar 12%.

No risk due to exposure from drinking water is anticipated as acetic acid is unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Occupational Risks From Handling White Vinegar 12%

Occupational risks are not of concern when White Vinegar 12% is used according to label directions, which include precautionary statements.

White Vinegar 12%, is to be applied by commercial applicators who will inject the product directly into the soil surrounding cranberry plants with a specially-designed injection tool.

Occupational exposure to individuals handling White Vinegar 12% is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary statements (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Acetic Acid Is Introduced Into the Environment?

White Vinegar 12% is proposed for control of perennial weeds in cranberry fields by injection into the soil at the root system level. Due to the nature of the proposed use and the known properties of acetic acid, the potential for exposure of non-target terrestrial and aquatic organisms to White Vinegar 12% is expected to be low. Therefore, the risk associated with the use of this product at the proposed application rates and use pattern is expected to be negligible.

Value Considerations

What is the Value of White Vinegar 12% Herbicide?

An application of White Vinegar 12% by injection into the soil can control perennial weeds that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families, in cranberry production, including organic production.

White Vinegar 12% has shown efficacy against target weeds such as grasses, sedges, bulrushes and rushes. Pre-emergence herbicides registered for use in cranberry production cannot control biennial plants or established perennials. Acetic acid could serve as a complementary treatment or an alternative to the large-scale application of sprout inhibitors. Since White Vinegar 12% is used in localized applications, it could help to reduce the use of conventional herbicides.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the label of White Vinegar 12% to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words “CAUTION– SKIN IRRITANT” and “DANGER – CORROSIVE TO EYES” are required on the principal display panels of both the technical product and the end-use product label.

Standard hazard and precautionary statements are also required on both the technical and end-use product labels to inform workers of the irritation potential of the active ingredient and to caution that it is corrosive to eyes and that it causes irritation when inhaled or absorbed through the skin.

Based on the hazard profile (for example, corrosive to eyes, likely to irritate skin and the respiratory tract), standard personal protective equipment are required for workers handling the product, for example, long clothing, shoes and socks, chemical resistant gloves, and protective eyewear.

A precautionary statement on the end-use product label indicating that handling of the end-use product (including the clean-up and maintenance activities) should be performed in a well-ventilated area is required.

Label statements advising individuals not to allow contact of the product with skin, eyes or clothing and to avoid breathing vapours or spray mist are also required.

Based on the method of application of the product (soil injection), a restricted-entry interval is not required.

The end-use product label instructs that workers not contaminate food or feed.

Value
White Vinegar 12% can serve as a complementary treatment or an alternative to the large-scale application of sprout inhibitors. Furthermore, it can be applied to localized areas and thereby reduce the use of conventional herbicides.

Next Steps

Before making a final registration decision on acetic acid, the PMRA will consider all 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

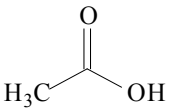
When the PMRA makes its registration decision, it will publish a Registration Decision on acetic acid (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the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

Science Evaluation

Acetic acid

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Acetic acid
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Acetic acid
2. Chemical Abstracts Service (CAS)	Ethanoic acid
CAS number	64-19-7
Molecular formula	$C_2H_4O_2$
Molecular weight	60.05 g/mol
Structural formula	
Purity of the active ingredient	12 %

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

Technical Product—White Vinegar 12% Technical

Property	Result
Colour and physical state	Clear liquid
Odour	Vinegar odour
Melting range	N/A
Boiling point or range	101.1°C (214°F) at 760 mmHg
Density at 20 °C	1.012 – 1.022 g/cm^3
Vapour pressure at 20°C	16.9 mmHg

Property	Result
Ultraviolet (UV)-visible spectrum	N/A
Solubility in water at 20°C	Miscible with water
Solubility in organic solvents	Complete solubility in ethanol, acetone, diethyl ether, glycerol and benzene
n-Octanol-water partition coefficient (K_{ow})	log K_{ow} = –0.17
Dissociation constant (pK_a)	pKa = 4.74–4.76
Stability (temperature, metal)	Stable, reacts with bases and oxidizing agents.

End-Use Product—White Vinegar 12%

Property	Result
Colour	Clear
Odour	Vinegar odour
Physical state	Liquid
Formulation type	Liquid (LI)
Guarantee	12%
Container material and description	Paper and HDPE container
Density	1.012–1.022 g/cm^3
pH of 1% dispersion in water	2 - 3
Oxidizing or reducing action	Reducing agent, corrosive to metals and reacts with bases
Storage stability	The product is expected to be stable when store in commercial packages at ambient temperature.
Corrosion characteristics	The product is not expected to be corrosive to the commercial package.
Explodability	N/A

1.3 Directions for Use

White Vinegar 12% can be used to control perennial weeds that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families, in cranberry production.

White Vinegar 12% is applied using a specially designed injection system. A localized application is made by injecting the acetic acid into the soil near the crowns of weeds in order to acidify the root zone of undesirable plants. The product is applied near the crowns of weeds or in

the middle of the tuft, at a depth of about 6.5 centimetres. For a small tuft measuring about 7 cm in diameter or less, a single injection per plant should suffice. For a larger tiller, two to three injections are required, and depending on soil conditions at the time of treatment as well as the size of the tiller and the maturity of the treated plant, a second application may be necessary seven days after the first.

The injector must be calibrated to inject about 35 to 40 mL of white vinegar per injection at a pressure of 240 to 275 kPa.

1.4 Mode of Action

White Vinegar 12% is a non-selective contact herbicide. When it comes into contact with any parts of the plant, the acid quickly destroys the cell membrane, causing desiccation of the foliar tissues and ultimately killing the plant. White Vinegar 12% must therefore be applied in a localized manner, by injecting it into the soil near the crowns of weeds using a specially designed injector. The acidity of the herbicide burns the roots of the weeds. Dieback symptoms are generally visible three to seven days after the treatment.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The method provided for the analysis of the active ingredient in White Vinegar 12 % Technical has been assessed to be acceptable for the determination.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in White Vinegar 12 % Technical was found to be acceptable for use as an enforcement analytical method for the end-use product.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The applicant submitted toxicology information from databases and published sources, a material safety data sheet, and a list of citations on acetic acid to address the data requirements for the technical grade active ingredient, White Vinegar 12 % Technical. Since the end-use product, White Vinegar 12 %, is a repack of the technical grade active ingredient, the toxicological profiles of the technical grade active ingredient and the end-use product are the same.

The PMRA conducted a detailed review of the submitted information and publicly available toxicological information for acetic acid. Acetic acid is of low acute toxicity in the rat by the oral and inhalation routes (Table 1, Appendix 1). It is slightly acutely toxic by the dermal route in rats and in rabbits. Based on its low pH, it is considered corrosive to the eyes, and mildly to moderately irritating to the respiratory tract and to the skin. In humans, it has been reported to irritate the skin, eyes and respiratory tract. It is not likely to be a skin sensitizer.

Information from the toxicity databases for acetic acid indicates that it is not a mutagen or a developmental toxicant.

The concentration of acetic acid in the technical grade active ingredient is slightly above the levels found in house-hold vinegar (≤6–8% v/v). Therefore no long-term or short-term toxicological effects are anticipated.

Because acetic acid is a naturally occurring intermediary metabolite found in all plants, animals including humans, and because it has a history of use as a food ingredient (vinegar), it is not likely to be a carcinogen.

Information on the developmental toxicity of acetic acid indicates that it is not considered to be a developmental toxicant.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Incidents were searched and reviewed for the active ingredient acetic acid. As of 2 January 2014, there were 21 humans and 20 domestic animals in incident reports submitted to the PMRA involving the active ingredient acetic acid, alone or in combination with other active ingredients.

In 12 human incidents, there was some degree of association between the reported symptoms and the suspected pesticide exposure. Most of these incidents were minor in severity and involved irritation of the skin, eye, or respiratory tract occurring during or shortly after product application. The labels for the products involved in these incidents all contain statements warning of the potential for irritation.

The symptoms in 11 of the 20 animals involved in incidents related to acetic acid were deemed to have some degree of association (causality level of possible or higher) to the reported pesticide exposure. These animals were all dogs that experienced minor symptoms, including vomiting, diarrhea, lethargy, anorexia, retching, coughing, polydipsia and/or adipsia. Exposure of most of these animals occurred through contact with the treated area.

The PMRA concluded that the information supported the current toxicity database; however, it did not impact the risk assessment.

Other Incident Reports

No other incident reports were located in the California Department of Pesticide Regulation's Pesticide Illness Query database or the United States Environmental Protection Agency database.

3.2 Food Residue Exposure Assessment

3.2.1 Food and Drinking Water

White Vinegar 12% contains food-grade acetic acid at a concentration that is slightly above the levels expected in household vinegar. The end-use product is applied to the soil surrounding cranberry plants at a depth of 6.5 cm, where it is readily biodegradable. Therefore the proposed use of acetic acid is not likely to result in residues in or on cranberry fruit. Furthermore, the label has precautionary statements not to contaminate food or feed.

Consequently, dietary exposure to acetic acid from the proposed use of the end-use product is anticipated to be negligible. As such, a quantitative assessment of residues from dietary intake is unnecessary.

Since the end-use product is applied as localized injection into the soil surrounding cranberry plants where it is readily biodegradable, no risk due to exposure from drinking water is anticipated.

Therefore, the use of White Vinegar 12% is not expected to result in unacceptable dietary risk when the product is used according to label directions.

3.2.2 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 established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of acetic acid based on the low toxicity and long history of safe consumption of acetic acid, and the use of food-grade quality acetic acid in the end-use product, White Vinegar 12%. Furthermore, as the proposed use of White Vinegar 12% involves direct injection to the soil surrounding cranberry plants, this method of application is unlikely to result in residues in or on cranberry fruit. Consequently, the PMRA has concluded that the setting of a specific MRL for acetic acid at 12% (v/v) for use on cranberries is not necessary. The General MRL of 0.1 ppm does not apply.

There are no CODEX MRLs established for acetic acid and the USEPA has established an exemption from the requirement of a tolerance for residues of acetic acid (also known as vinegar) in or on all food crops resulting from unintentional spray and drift to non-target vegetation (including non-food, food and feed crops) when used as a non-selective contact herbicide spray.

3.3 Occupational Exposure and Risk Assessment

3.3.1 Use Description

White Vinegar 12% is proposed for commercial application in a localized manner to the soil surrounding cranberry plants. Applications will be made near the crown of weeds, particularly weeds with growth in tillers or compact tufts (for example, such as grasses in the Gramineae, Cyperaceae, and Juncaceae families).

The end-use product contains food-grade acetic acid at a level that is above that expected in house-hold vinegar (6–8% v/v). Furthermore, the end-use product will be injected into the soil at a depth of 6.5 cm where it will degrade rapidly (half-life < 2 days). Injections are made at 35 to 40 mL/injection with one to three injections per plant. A second application may be made seven days after the first, depending on the size of the weeds. The label instructs applicators to not contaminate food, feed, or any body of water.

3.3.2 Mixer, Loader and Applicator Exposure and Risk Assessment

The proposed use of White Vinegar 12% may result in exposure to workers during handling of the product, including mixing, loading, and application, as well as clean-up and maintenance activities. Workers will be primarily exposed by dermal and ocular routes. Inhalation exposure from vapours and spray mist are also likely.

Review of toxicological information on acetic acid indicates that acute toxicity from acetic acid solutions ~10% (v/v) is low. However, based on its low pH, acetic acid is considered slightly acutely toxic by the dermal route and dermal irritation is expected due to its corrosive nature. It is considered corrosive to eyes. Irritation to the respiratory tract is also likely from inhalation of the vapours.

The end-use product label has a number of exposure reduction statements (for example, the wearing of personal protective equipment, including long clothing, as well as hygiene and precautionary statements) to protect workers against any unnecessary risk from exposure. The persons handling the end-use product, including those involved in clean-up and maintenance activities, must wear: a long-sleeved shirt and long pants, shoes, socks, chemical resistant gloves, and protective eyewear. Also, the label instructs individuals to avoid contact of the product with skin, eyes or clothing and avoid breathing dust or spray mist. When workers follow these exposure reduction measures, occupational exposure resulting from product handling is not expected to raise a toxicological concern.

3.3.3 Bystander Exposure

As the commercial application involves only authorized personnel, bystander exposure is expected to be negligible when the end-use product is used according to the label directions.

3.3.4 PostApplication Exposure

Postapplication exposure for persons entering the treated fields after the applications is negligible since the product is applied directly into the soil where it is expected to degrade rapidly. A restricted-entry interval is not required.

4.0 Impact on the Environment

The fate characteristics of acetic acid are well documented in the open literature. Acetic acid is known to biotransform readily under aerobic and anaerobic conditions (HSDB, 2004) in soil (half-life in soil <14 days; HSDB, 2004). It is, therefore, not expected to be persistent in the environment. Acetic acid is toxic to plants and slightly toxic to aquatic organisms. However, due to the nature of the use of White Vinegar 12%, as a spot soil injection targeting the pest plant directly, the potential for exposure of terrestrial and aquatic non-target organisms is expected to be negligible and, therefore, a quantitative risk assessment was not required.

5.0 Value

The value-related information submitted for review consisted mainly of efficacy data presented in research reports and trial summaries. The trials were carried out in Quebec and New Brunswick. A summary of trials undertaken in the United States was also submitted. White Vinegar 12% was applied postemergence to weeds; food-grade acetic acid was used in a 12% concentration except in certain trials conducted in the United States. Weed control was assessed visually on three or four occasions after treatment.

5.1 Acceptable Efficacy Claims

The application of acetic acid (12%) by injection near the roots of weeds showed adequate control (greater than 80%) of certain species in the Juncaceae, Cyperaceae (Scirpus and Carex) and Gramineae families. Since it is quite difficult to identify species of weeds belonging to these families and since acetic acid is a non-selective herbicide, it is acceptable to specify only the family names in the list of weeds controlled by White Vinegar 12%.

5.2 Effects on Host Organisms

5.2.1 White Vinegar 12%

White Vinegar 12%, consisting of acetic acid, is a non-selective herbicide that can damage cranberry plants if it comes into contact with them. Applying the herbicide by injection into the soil in the root zone of weeds minimizes contact between the acetic acid and the cranberry plants. Treatments of 12% acetic acid injected into the soil have shown only slight phytotoxicity to cranberry plants; however, cranberry vines were more severely affected when applications were made in dry soil as compared to moist soil. The label on White Vinegar 12% specifies that it is important to avoid applying the product when the soil is very dry or during periods of extreme heat.

5.2.2 Rotational Crop Claims

Crop rotation testing was not carried out following acetic acid treatments because cranberry is a perennial plant that can live for about one hundred years. Therefore, no other crop would be seeded the year after an application of White Vinegar 12% is made.

5.3 Consideration of Benefits

5.3.1 Social and Economic Impact

The presence of weeds in cranberry bogs is a problem for cranberry growers, which requires effective management solutions. Weeds compete with cranberry plants for water, light, space and nutrients. A high density of weeds can be a nuisance and can slow down harvest operations, as well as cause post-harvest yield losses in terms of both fruit quantity and quality. There are no registered herbicides for use in fields under organic production, particularly new plantings. In conventional production, it would be beneficial to have alternatives to sprout inhibitors to control perennial weeds. Access to an effective localized treatment method could minimize applications over larger areas.

The registration of acetic acid could help both organic and conventional cranberry growers improve weed management.

5.3.2 Survey of Alternatives

The weed control options available for cranberry are described below.

1) Cultural practices such as the use of excavated coarse sand, which by definition is free of weeds, to prepare a new field and to sand existing fields; the use of cuttings (for planting) from a field containing minimal weeds; maintenance of a suitable pH level higher than 5.5; proper fertilization and drainage to promote the growth of cranberry plants; and removal of floating debris on the bog surface after harvest in order to eliminate weed seeds that may be present in the debris;

2) Mechanical control methods: given cranberry growing conditions, no mechanical control methods can be considered as a solution except for hand weeding. Hand weeding of perennials is difficult and labour-intensive. It is the only method that can be used for weed control in organic cranberry production;

3) Herbicides registered for conventional cranberry production: Table 2, Appendix I, lists the herbicides registered for use on cranberry crops. These herbicides differ depending on whether they can be used in newly planted fields and/or existing fields and in terms of whether they are pre-emergent or postemergent. There are no herbicides registered for use in organic production.

5.3.3 Compatibility with Current Management Practices, Including Integrated Pest Management

White Vinegar 12% is a weed control option for cranberry that can be alternated with, or used at the same time as, other conventional herbicides with a different mode of action, in order to control weeds that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families. White Vinegar 12% is a product that can be applied to localized areas, thereby potentially reducing the preventive use of conventional herbicides.

5.3.4 Information on the Occurrence or Possible Occurrence of the Development of Resistance

There are no reported cases of weed resistance to acetic acid, and the use of White Vinegar 12% can help to reduce the risk of development of resistance to conventional herbicides by decreasing the amount used. Furthermore, given the small number of herbicides registered for use in cranberry production, the addition of acetic acid to the existing arsenal of weed control methods will aid in resistance management.

5.3.5 Contribution to Risk Reduction

White Vinegar 12% targets weeds that are already present in cranberry fields, and its use can therefore reduce the postemergence application of conventional herbicides for prevention purposes. At present, there are no herbicides registered for use in organic cranberry production. White Vinegar 12% provides a weed control tool for organic growers as well as an alternative weed control option for conventional growers.

5.3.6 Health, Safety and Environmental Benefits

Acetic acid is generally accepted around the world as a substance authorized for weed control in organic vegetable production.

5.4 Accepted Uses

Please consult Table 3, Appendix 1 for the list of accepted uses.

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), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, White Vinegar 12% Technical and the related end-use product, White Vinegar 12%, were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track-1 criteria. It has been determined that the technical active substance does not meet TSMP Track-1 criteria:

- White Vinegar 12% Technical does not meet the Track 1 criteria because it is not persistent, and is not considered a Track 1 substance.

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.*[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- White Vinegar 12% Technical and White Vinegar 12%, do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

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

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

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

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

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[9]

7.0 Summary

7.1 Human Health and Safety

The applicant submitted toxicology information collected from databases and published sources. Acetic acid is of low acute toxicity in the rat by the oral and inhalation routes. It is slightly acutely toxic by the dermal route in rats and in rabbits. Based on its low pH, it is considered corrosive to the eyes, and mildly to moderately irritating to the skin and respiratory tract. It is not likely to be a skin sensitizer. There is no evidence to indicate that acetic acid is carcinogenic, genotoxic or that it is a developmental or reproductive toxicant.

Occupational exposure and the potential for irritation to skin and respiratory tract as well as for corrosive effects to eyes from the proposed use of White Vinegar 12% is of concern during handling of the end-use product; however, occupational exposure is not expected to present an unacceptable risk when workers follow label directions.

As the end-use product contains food-grade acetic acid and it is applied as localized injections into the soil surrounding cranberry plants, dietary exposure to acetic acid from the proposed use of the end-use product is considered negligible. The PMRA did not establish an MRL for acetic acid.

7.2 Environmental Risk

Acetic acid is known to biodegrade rapidly. It is, therefore, not expected to be persistent in the environment. Also, due to the nature of the use of White Vinegar 12%, as a soil injection, the potential for exposure of non-target organisms is not expected to occur. Therefore, the risk to non-target organisms in the environment following the use of White Vinegar 12% according to the label directions is expected to be negligible.

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

7.3 Value

White Vinegar 12% is a new herbicide with a 12% acetic acid concentration for use in controlling perennial weeds that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families, in cranberry production, including organic production. Reports on research and testing were submitted in support of the application, and the results showed that an application of White Vinegar 12% by injection into the soil provides effective control of target weeds and does not pose an excessive risk of phytotoxicity for cranberry plants. Given that there are currently no registered herbicides for use in organic cranberry growing, White Vinegar 12% provides a weed control tool for organic growers as well as an alternative weed control option for conventional growers.

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 White Vinegar 12% Technical and White Vinegar 12%, containing the technical grade active ingredient acetic acid, for the control of perennial weeds in cranberry crop.

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
bw	body weight
C	carbon
CAS	Chemical Abstracts Service
CH_3COOH	acetic acid
cm	centimetres
cm^3	centimetre(s) cubed
CO_2	carbon dioxide
DACO	data code
g	gram
H	hydrogen
H_2O	water
HDPE	high-density polyethylene
Hg	mercury
hr	hour(s)
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
kPa	kilopascal
L	litre
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
mg	milligram
mL	millilitre
mol	mole(s)
mm	millimole(s)
MRL	maximum residue limit
N/A	not applicable
NOAEL	no observed adverse effect level
O_2	oxygen
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
REI	restricted-entry interval
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Toxicity Profile of Technical Acetic Acid

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES
Oral Toxicity	Rat (>10%)	LD_{50}[1] = 3310–3530 mg/kg bw	Low toxicity	2273267
Dermal Toxicity	Rat/Rabbit	1060 mg/kg bw	Slightly toxic CAUTION-SKIN IRRITANT	2273301
Inhalation	Rat	11.4 mg/L (4 hr)	Mild to moderate irritation via the pulmonary route. Low toxicity	2273301
Primary Eye Irritation	Based on the low pH of acetic acid at 12% (v/v) it is considered corrosive to eyes. No study required. DANGER – CORROSIVE TO EYES			N/A
Primary Skin Irritation	Based on the low pH of acetic acid at 12% (v/v) it is considered to be mild to moderately irritating to the skin. No study required. Mild to moderate skin irritation.			N/A
90-day oral toxicity	Rat	NOAEL[1] = 195 mg/kg bw LOAEL[1]= 390 mg/kg bw	No toxicological effects	2273301
Pre-natal Developmental toxicity	Mouse Rat Rabbit	NOAEL= 1600 mg/kg bw LOAEL= 1600 mg/kg bw	No significant treatment -related reproductive effects	2273301
Mutagenicity - Reverse mutation assay	0– 10, 000 µg/plate (with and without metabolic activation)	Negative	Not mutagenic	2273301
Carcinogenicity	Acetic acid is a naturally occurring intermediary metabolite found in all plants and animals including humans and it has a history of use as a food ingredient (vinegar), it is not likely to be a carcinogen. No study required.			N/A
Genotoxicity	Ames test- with or without metabolic activation		Negative	2273267

[1] LD_{50} = Lethal dose 50%; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level

Table 2 Herbicides Registered for Use in Cranberry Production

Registered Herbicides	Application New Planting / Production Field	Application Timing	Application Method	Weeds Controlled
Devrinol (napropamide)	New planting	Pre-emergence	Broadcast	Annuals: grasses and a few broadleaf weeds
Casoron (dichlobenil)	Production field	Pre-emergence	Broadcast or localized	Annuals and perennials: grasses and broadleaf weeds
Callisto (mesotrione)	Production field	Pre-emergence, Early postemergence and late postemergence	Broadcast	Annual broadleaf weeds
Select / Centurion (clethodim)	New planting and production field	Postemergence	Broadcast	Annuals and perennials: grasses
Poast (sethoxydim)	New planting and production field	Postemergence	Broadcast and localized	Annuals and perennials: grasses
Roundup and other glyphosate herbicides	New planting and production field	Postemergence	Localized	Annuals and perennials: grasses and broadleaf weeds
Lontrel (clopyralid)	New planting and production field	Postemergence	Localized	Tufted vetch
2,4-D amine	Production field	Postemergence	Localized	Annuals and broadleaf perennials

Table 3 List of Supported Uses

Proposed Use Pattern	Accepted Use Pattern
- Control of perennials that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families, through a localized application of White Vinegar 12% near the crowns of weeds. - The product is injected into the soil using a specially designed injector calibrated to inject between 35 and 40 mL of 12% acetic acid. - A single injection for a tuft of 7 cm, and 2 to 3 injections for a larger tuft. - A second application may be made.	Accepted as proposed.
- Localized application in cranberry production, for new plantings as well as production fields.	Accepted as proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2273244	MAQT_Vinaigre blanc 12%, DACO: 2.1,2.10,2.11,2.11.1,2.11.2,2.11.3, 2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11 ,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.1
2273245	Aliments Reinhart limitee, La fabrication du vinaigre, DACO: 2.11,2.13
2273246	Aliments Reinhart Limitee, 2002, Le vinaigre blanc 12% (Fiche technique), DACO: 2.0,2.11,2.13
2273247	Aliments Reinhart Limitee, 2003, Information nutritionnelle, DACO: 2.11,2.13

2.0 Human and Animal Health

PMRA Document Number	Reference
2273244	CODO Partie 2-MAQT_Vinaigre blanc 12%., DACO: 2.1,2.10,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2 .13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2 .14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9,4 .5.2
2273254	Centre canadien d`hygiene et de securite au travail (CCHST), 1996, Cheminfo: acetic acid (solutions of 10% or less), DACO: 2.0,4.2,4.8
2273256	Centre canadien d`hygiene et de securite au travail (CCHST), 1996, Cheminfo: acetic acid (solutions greater than 10%), DACO: 2.0,4.2,4.8
2273258	Commission de la sante et de la securite du travail (CSST), 2005, Acide acetique en solution aqueuse de 3 a 10%, DACO: 2.0,4.8
2273259	Munger Landscape Distribution, 2009, Material safety data sheet: Munger horticultural vinegar plus, DACO: 2.0,4.2,4.8
2273261	Sigma Aldrich, 2012, Material safety data sheet: acetic acid solution (5-10%), DACO: 2.0,4.2,4.8
2273262	Sigma Aldrich, 2012, Material safety data sheet: acetic acid solution (10-25%), DACO: 2.0,4.2,4.8
2273263	Sigma Aldrich, 2012, Material safety data sheet: glacial acetic acid, DACO: 2.0,4.2

2273264 Aggregated Computational Toxicology Ressource (ACToR), Chemical summary: Acetic acid (64-19-7), DACO: 12.5.2,12.5.4,4.8

2273266 The Finnish Environment institute (SYKE), Data bank of environmental chemicals, DACO: 12.5.2,12.5.4,4.8

2273269 Hazardous substances data bank (HSDB), 2005, Acetic acid, DACO: 12.5.2,12.5.4,4.8

2273270 Institut nationale de recherche et de securite (INRS), France, 2011, Fiche toxicologique: acide acetique, DACO: 12.5.2,12.5.4,4.8

2273272 National Institute for Occupational Safety and Health (NIOSH), 1978, Occupational health guideline for acetic acid, DACO: 12.5.2,12.5.4,4.8

2273274 National Institute for Occupational Safety and Health (NIOSH), 1992, Occupational safety and health guideline for acetic acid, DACO: 12.5.2,12.5.4,4.8

2273275 International Program on Chemical Safety (IPCS), Commission of the European Communities (CEC) et National Institute for Occupational safety and health (NIOSH), 2006, Acetic acid, International chemical safety cards: 0363, DACO: 12.5.2,12.5.4,4.8

2273276 National Pollutant Inventory, Acetic acid, DACO: 12.5.2,4.8

2273278 US National Library of Medicine, Wireless information system for emergency responders, Hazmap, National toxicology program, DACO: 12.5.2,12.5.4,4.8

2273280 SKC, 2011, Material safety data sheet: dilute acetic acid 4 to 10%, DACO: 12.5.2,4.8

2273285 CODO Partie 4-MAQT_Vinaigre blanc 12%., DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.4,4.5.5

2273286 CODO Partie 4_Annexe 1.1., DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.4,4.5.5

2273290 CODO Partie 4_Annexe 1.2., DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.4,4.5.5

2273292 CODO Partie 4_Annexe 1.3, DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.4,4.5.5

2273302 Autres etudes_toxicit humaine., DACO: 4.8

2273303 Centers for Disease Control and Prevention et National Institute for Occupational Safety and Health (NIOSH), 1994, Documentation for immediately dangerous to life of health concentrations (IDLHs), DACO: 4.8

2273304 Centre Canadien d`hygiene et de securite au travail (CCHST), 2005, Qu`est ce que la LD50 et la LC50?, DACO: 4.8

2273305 US Environmental Protection Agency (EPA), EPA toxicity category, DACO: 4.8

2273306 Sante Canada, 2009, Le systeme general harmonise (SGH) de classification et d`etiquetage des produits chimiques, DACO: 4.8

3.0 Value

PMRA Document Number	Reference
2273309	CODO Partie 10-PC (Rens. valeur)_Vinaigre blanc 12%., DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.2.3.3(B),10.3,10.3.1
2273310	CODO Partie 10-PC (Annexe 1_Produits Homologues Canada), DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.2.3.3(B),10.3,10.3.1
2273311	2007, Resume: Experimentation de l`utilisation du vinaigre pour lutter contre les mauvaises herbes dans la production biologique de la canneberge, DACO: 10.2.3.1
2273312	Drolet I et Lavallee S, 2007, Experimentation de l`utilisation du vinaigre pour lutter contre les mauvaises herbes dans la production biologique de la canneberge, DACO: 10.2.3.3,10.2.3.3(B)
2273313	Drolet I., 2003, Rapport dtude prliminaire:Utilisation du vinaigre blanc (12%) pour lutter contre les mauvaises herbes en production de canneberges, DACO: 10.6
2273315	Graham G.L., Bertheleme C. et Tremblay R., 2006, valuation de lacide actique pour le dsherbage dans les systemes de production de canneberges (Vaccinium macrocarpon Ait.) biologiques, DACO: 10.6
2273316	Graham G.L., Bertheleme C., Tremblay R et Thebeau G., 2007, Perfectionnement des modalites de pulverisation de l`acide acetique pour lutter contre les mauvaises herbes dans la production biologique et conventionnelle de canneberge, DACO: 10.6

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number	Reference
2398944	2014-03-05, ACETIC ACID - National Library of Medicine HSDB Database, http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB, DACO: 8.1.