

Proposed Registration Decision

PRD2018-02

Hydrogen Peroxide and Peroxyacetic Acid and OxiDate 2.0

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Overview

Proposed Registration Decision for Hydrogen Peroxide and Peroxyacetic Acid

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 OxiDate 2.0 Technical and OxiDate 2.0, containing the technical grade active ingredients hydrogen peroxide and peroxyacetic acid, for the suppression or partial suppression of fungal and bacterial diseases on labeled crops grown in greenhouse, field and hydroponic systems, as well as a sanitizer for greenhouse surfaces and equipment.

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 OxiDate 2.0 Technical and the end-use product OxiDate 2.0.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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 hydrogen peroxide and peroxyacetic acid, the PMRA will consider any comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on hydrogen peroxide and peroxyacetic 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 Hydrogen Peroxide and Peroxyacetic Acid?

Hydrogen peroxide and peroxyacetic acid are the two active ingredients in OxiDate 2.0, a new fungicidal and bactericidal end-use product intended for foliar applications for the suppression or partial suppression of fungal and bacterial disease on various field and greenhouse-grown crops and for cleaning greenhouse surfaces and equipment. These active ingredients are known general biocides with a broad spectrum of activity against fungal and bacterial pathogens.

Health Considerations

Can Approved Uses of Hydrogen Peroxide and Peroxyacetic Acid Affect Human Health?

Hydrogen peroxide and peroxyacetic acid are unlikely to affect human health when OxiDate 2.0, containing hydrogen peroxide and peroxyacetic acid, is used according to label directions.

Potential exposure to hydrogen peroxide and peroxyacetic acid may occur when handling and applying the product, but dietary (food and water) exposure is unlikely. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The available information on hydrogen peroxide and peroxyacetic acid was assessed for their potential to cause acute and short-term toxicity, developmental effects, genotoxicity, and various other effects. Due to the rapid degradation of hydrogen peroxide and peroxyacetic acid to water and oxygen, there is no concern for carcinogenicity, developmental or other long-term effects. Due to the corrosive nature of these chemicals, the hazard posed by the product containing these active ingredients is mostly of an acute nature.

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*.

OxiDate 2.0 is expected to be slightly acutely toxic by the oral and dermal routes and moderately acutely toxic by the inhalation route. It is also expected to be corrosive to the eyes and severely irritating to the skin but is not expected to be a skin sensitizer. Consequently, signal words are required to be on the product label highlighting the skin irritation and eye corrosivity hazards.

Residues in Water and Food

Dietary risks from food and water are not of concern

Due to the rapid degradation of hydrogen peroxide and peroxyacetic acid and the low application rate, the residues from treated crops are not expected to be of concern to human health.

It is expected that the uses of hydrogen peroxide and peroxyacetic acid in Canada on food crops for the proposed uses will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops.

Exposure to hydrogen peroxide and peroxyacetic acid is not expected in drinking water from the proposed uses and therefore, risk due to exposure from drinking water is not anticipated.

Risks in Residential and Other Non-Occupational Environments

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

There are no residential uses for OxiDate 2.0. The label has necessary mitigation measures to prevent bystander exposure, such as to prevent spray drift from application. To avoid bystander exposure in fields or greenhouses, the end-use product label must state that unprotected persons should be kept out of the area for the duration of the treatment period. Entry or re-entry to the greenhouse is allowed only after thorough ventilation and mists or fog have dissipated and the treated surface has dried. Entry or re-entry to the field is allowed only after the treated surface has dried. Consequently, residential and bystander exposure is not of concern.

Occupational Risks from Handling OxiDate 2.0

Occupational risks are not of concern when OxiDate 2.0 is used according to the label directions, which include protective measures.

For the assessment of occupational exposure and risks, emphasis has been placed on hydrogen peroxide and peroxyacetic acid's potential for acute toxicity from the corrosive nature of these active ingredients.

Standard precautionary statements (for example, wearing of personal protective equipment (PPE)) and a restricted-entry interval (REI) are on the end-use product label to protect workers before, during and after product application.

Environmental Considerations

What Happens When Hydrogen Peroxide and Peroxyacetic Acid Are Introduced Into the Environment?

Hydrogen peroxide and peroxyacetic acid are not expected to pose risks of concern to the environment when used according to label instructions.

Hydrogen peroxide and peroxyacetic acid, the active ingredients in OxiDate 2.0, will enter the environment when used as a foliar-treatment fungicide and antimicrobial on agricultural field crops and in greenhouses. Hydrogen peroxide and peroxyacetic acid mix readily in water and are expected to break down rapidly to water, acetic acid and oxygen. Hydrogen peroxide and peroxyacetic acid do not remain in soil for a long time because they are broken down by soil bacteria. The movement of hydrogen peroxide and peroxyacetic acid in the environment is expected to be minimal due to their very short half-lives in natural soils. Hydrogen peroxide and peroxyacetic acid are not expected to be found in air and are not expected to move through the soil into groundwater. Hydrogen peroxide and peroxyacetic acid will not accumulate in animals.

Hydrogen peroxide and peroxyacetic acid are not expected to pose risks of concern to earthworms, birds or small wild mammals. Under controlled laboratory conditions, hydrogen peroxide and peroxyacetic acid can be toxic to fish, aquatic invertebrates, amphibians and algae. Hydrogen peroxide and peroxyacetic acid may affect sensitive plants that are not pests if concentrations are high enough. Risk reduction measures are required to mitigate the exposure and potential risks to aquatic organisms, terrestrial plants, bees and other beneficial arthropods. When hydrogen peroxide and peroxyacetic acid are used in accordance with the label statements, and the required measures to reduce adverse effects are applied, risks of concern to the environment are not expected.

Value Considerations

What Is the Value of OxiDate 2.0?

OxiDate 2.0 provides an alternative product that will potentially reduce the need for conventional fungicides under low disease pressure.

OxiDate 2.0 is a product applied as a foliar spray or in hydroponic systems to suppress or partially suppress fungal and bacterial diseases of various crops grown under field and greenhouse conditions. OxiDate 2.0 will help address a need expressed by growers for a greater diversity in non-conventional alternatives to manage diseases. This also represents a first registration for the management of slip-skin maceration disorder in sweet cherry. In addition, the product can be used as an effective sanitizer to clean greenhouse surfaces and equipment.

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 OxiDate 2.0 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The OxiDate 2.0 label must include the signal words "WARNING –POISON. DANGER–CORROSIVE TO EYES, DANGER SKIN IRRITANT".

The label requires workers to wear personal protective equipment (PPE), including goggles or a face shield, coveralls over long-sleeved shirt and long pants, boots, chemical resistant gloves and NIOSH approved respiratory protection during mixing loading and applications, clean–up and repair activities. An REI of "4 hours or until sprays are dry" is also required to minimize exposure of workers. When applied as a mist or fog in greenhouses, the greenhouses must be thoroughly ventilated afterwards before workers are allowed to enter. If early entry into areas treated with OxiDate 2.0 is necessary, the above-mentioned PPE is required.

For outdoor uses, standard drift statements are required on the OxiDate 2.0 label to minimize bystander exposure: "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Environment

The following label amendments are required:

- Label statements informing users of the toxicity to plants and aquatic organisms are required.
- Label statement informing users of possible toxicity to bees and other beneficials when exposed to direct contact with the end-use product.
- Spray buffer zones are required for the protection of terrestrial and aquatic habitats.
- Label statements, informing users that effluent from greenhouses containing hydrogen peroxide and peroxyacetic acid should not be allowed to enter the environment, are also required.

Next Steps

Before making a final registration decision on hydrogen peroxide and peroxyacetic acid and OxiDate 2.0, 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 hydrogen peroxide and peroxyacetic acid and OxiDate 2.0 (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

Hydrogen Peroxide and Peroxyacetic Acid

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredients

Ac	tive substances	Hydrogen peroxide Peroxyacetic acid				
Function		Bactericide, fungicide, sanitizer				
Chemical name						
1. International Union of Pure and Applied Chemistry (IUPAC)		Hydrogen peroxide Ethaneperoxoic acid				
2.	Chemical Abstracts Service (CAS)	Hydrogen peroxide Peroxyacetic acid				
CA	AS number	Hydrogen peroxide: 7722-84-1 Peroxyacetic acid: 79-21-0				
Mo	olecular formula	$\begin{array}{l} H_2O_2\\ C_2H_4O_3 \end{array}$				
Molecular weight		Hydrogen peroxide: 34.014 Peroxyacetic acid: 76.051				
Str	ructural formula	но—он				
		о он				

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Purity of the active ingredient

27.0% hydrogen peroxide 2.5% peroxyacetic acid

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

Technical Product—OxiDate 2.0 Technical

Property	Result
Colour and physical state	Colourless liquid
Odour	Pungent
Melting range	Not applicable
Boiling point or range	Decomposes at temperatures above 55°C
Density	1.091 g/mL
Vapour pressure at 25°C	0.14-0.15 kPa for 20-35% hydrogen peroxide
	1.9 kPa for peroxyacetic acid
Ultraviolet (UV)-visible	Does not absorb at $\lambda > 300 \text{ nm}$
spectrum	
Solubility in water at 20°C	Completely soluble
Solubility in organic solvents at 20°C	Miscible with many polar organic solvents
<i>n</i> -Octanol-water partition $coefficient(K_{n})$	$K_{\rm ow} = 0.3; \log K_{\rm ow} = -0.52$
Dissociation constant (pK_a)	pK_a 11.65 for hydrogen peroxide
	$pK_a 8.2$ for peroxyacetic acid
Stability (temperature, metal)	Unstable in heat and direct sunlight; incompatible with acids,
	bases, reducing agents, organic materials, metals and metal
	salts.

End-Use Product—OxiDate 2.0

Property	Result
Colour	Colourless
Odour	Pungent
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	Hydrogen peroxide 27.0%
	Peroxyacetic acid 2.5%
Container material and	Plastic (HDPE) drums, totes or bulk (1 L–1050 L)
description	
Density	1.091 g/mL
pH of 1% dispersion in water	1.05
Oxidizing or reducing action	Oxidizing

Property	Result
Storage stability	Stable for up to 1 year when stored in commercial packaging at room temperature; unstable when stored for 30 days at 50°C.
Corrosion characteristics	Not corrosive to the packaging material
Explodability	Not explosive

1.3 Directions for Use

For suppression or partial suppression of labelled fungal and bacterial diseases on various indoor or outdoor grown horticultural and field crops, Oxidate 2.0 may be applied by foliar spray at concentrations of 1.0-2.5% or through hydroponic systems at a concentration of 0.3%. Oxidate 2.0, diluted to a concentration of 0.16-1.0%, can also be used in greenhouses as a sanitizer on wood and non-porous hard surfaces and equipment.

1.4 Mode of Action

Neither hydrogen peroxide nor peroxyacetic acid are currently classified in any of the mode of action groups established by the Fungicide Resistance Action Committee (FRAC). These actives are well known general biocides with a non-specific mode of action that kill pathogenic organisms through rapid oxidation and degradation of cellular structures.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulation have been assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

Based on the structure of peroxyacetic acid, the major degradation products expected are oxygen and water. Acetic acid and hydrogen peroxide are intermediary degradates which react to form peroxyacetic acid. Any excess hydrogen peroxide in the solution is presumed to be rapidly degraded into oxygen and water.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The toxicological databases for hydrogen peroxide and peroxyacetic acid, consisting of animal studies, waiver rationales and published data, are considered to be sufficiently complete and of sufficient scientific quality to define the potential toxic effects associated with the two active ingredients. It should be noted that peroxyacetic acid is not manufactured as a pure compound in the final formulation; instead the solution exists as an equilibrium mixture of peroxyacetic acid and hydrogen peroxide.

Hydrogen Peroxide (27%v/v)

A detailed review of the toxicological database for hydrogen peroxide was conducted previously and is summarized in the Evaluation Report ERC2010-10, *Hydrogen Peroxide*, and more recently in the Proposed Re-evaluation Decision PRVD2017-12, *Hydrogen Peroxide and Its Associated End-use Products*. These previous reviews evaluated the toxicity of technical grade hydrogen peroxide at 35% and are considered relevant to the toxicological effects expected of the 27% solution in the end-use product OxiDate 2.0.

The main mode of action of hydrogen peroxide is associated with its strong oxidizing and corrosive properties, with its oral, dermal and inhalation toxicities being secondary to its corrosivity. Hydrogen peroxide is an oxidizing agent that is highly reactive, but also rapidly decomposes to water and oxygen upon contact with moisture. Due to the highly corrosive nature of hydrogen peroxide following acute exposure, the anticipated intermittent exposure associated with the proposed new uses of OxiDate 2.0, and the rapid decomposition of hydrogen peroxide to oxygen and water, long-term effects are not expected.

Peroxyacetic acid (2.5% v/v)

An overview of the toxicological database for peroxyacetic acid was recently summarized in the Proposed Re-evaluation Decision, PRVD2017-13 *Peroxyacetic Acid and Its Associated End-use Products*. Previously submitted toxicology data consisted primarily of acute studies, conducted with peroxyacetic acid (17% with use dilutions to 0.15%). Acceptable scientific waiver rationales were submitted to satisfy all other toxicology data requirements. The rationales were predominantly based upon the rapid degradation of peroxyacetic acid and its corrosive properties, similar to those of hydrogen peroxide.

The hazard posed by the proposed use of products containing peroxyacetic acid is mostly of an acute nature. A 2.5% solution of peroxyacetic acid is considered to be slightly acutely toxic by the oral and dermal routes, and moderately acutely toxic by the inhalation route. It is corrosive to both skin and eyes, but it is not a dermal sensitizer. Although several short-term toxicity studies were attempted with peroxyacetic acid administered in the diet or drinking water, results were considered equivocal due to intake avoidance likely from the odour and irritant properties of the test compounds.

Based on the concentrations of hydrogen peroxide and peroxyacetic acid in the end-use product, OxiDate 2.0 is expected to be slightly acutely toxic by the oral and dermal routes, and moderately acutely toxic by the inhalation route. It is also expected to be corrosive to the eyes and a skin and eye irritant, but not a dermal sensitizer.

Incident Reports

As of 7 September 2017, no human incidents involving the actives hydrogen peroxide or peroxyacetic acid were submitted to the PMRA.

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

Dermal absorption of hydrogen peroxide and peroxyacetic acid is not expected to be of concern due to the rapid decomposition of hydrogen peroxide and peroxyacetic acid.

3.2.2 Use Description

The end-use product OxiDate 2.0 is intended for foliar application to various greenhouse and field crops using conventional ground equipment, including backpack sprayer, ground boom, and fogging or misting equipment. The diluted product is applied to the point of run-off to achieve full and even coverage. Up to eight applications may be used at 7-day spray intervals.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

Occupational exposure to OxiDate 2.0 is characterized as short-term and intermediate in duration and is primarily by the dermal route and inhalation routes, but accidental ocular exposure is also possible while mixing, loading, and applying the product, as well as during clean-up and equipment maintenance. The major concern is while handling the concentrated product at the time of loading and mixing. The application rate for the proposed uses is low as only a diluted (0.3-2.5%) solution will be applied.

The risk due to occupational exposure of OxiDate 2.0 from mixing, loading, applying, clean-up, and maintenance of spraying equipment for workers is considered to be acceptable if mitigative measures are followed as described on the label. This includes wearing goggles or face shield, coveralls over long-sleeved shirt and long pants, boots, chemical-resistant gloves and a NIOSH-approved respirator during mixing, loading, application, clean-up and repair activities.

The precautionary (for example, wearing of personal protective equipment) and standard hygiene statements on the end-use product label aimed at minimizing worker exposure are considered protective.

3.2.4 Postapplication Exposure and Risk

There is a potential for exposure to workers re-entering areas treated with OxiDate 2.0. Postapplication exposure is possible when people enter the treated area soon after the application. The primary route of exposure for workers/individuals entering or re-entering a treatment site is dermal from contact with freshly treated surfaces. As the applied spray material is a dilute solution, postapplication exposure is not expected to be of concern when entry/re-entry to recently treated areas is restricted until sprays have dried, as has been specified on the label. In greenhouses, postapplication exposure is of concern when workers enter a treated area immediately after fogging and are exposed by inhalation routes to aerosols if the area is not thoroughly ventilated or sufficient time is not given to let the suspended particles settle out of the air. To mitigate such potential exposures, entry/re-entry of workers to treated areas is to be prohibited until sprays have dried, or greenhouses are thoroughly ventilated following fogging or workers wear personal protective equipment consisting of a NIOSH approved respirator, protective clothing, shoes plus socks, water-proof gloves and protective eyewear.

3.2.5 Residential and Bystander Exposure and Risk

There are no residential uses for OxiDate 2.0. Although the proposed agricultural uses can result in bystander exposure, it is expected to be much less than that for workers and is considered very low. The label has necessary mitigation measures to prevent bystander exposure, such as to prevent spray drift from application. To avoid bystander exposure in fields, the end-use product label must state that unprotected persons should be kept out of the field for the duration of the treatment period, and allows entry or re-entry after the treated surface has dried. To avoid bystander exposure in greenhouses, the end-use product label must state that unprotected persons should be kept out of the greenhouses for the duration of the treatment period, and allows entry or re-entry to greenhouse only after thorough ventilation and aerosols have cleared and the treated surface has dried. Consequently, residential and bystander exposure is not of concern.

3.3 Food Residue Exposure Assessment

3.3.1 Food

Because of the proposed low application rate of the end-use product and the anticipated rapid decomposition of hydrogen peroxide and peroxyacetic acid to oxygen and water, there is low dietary exposure from residues (if any) expected from the proposed uses of OxiDate 2.0. Therefore, the proposed food crop uses are not expected to increase the risk to human health from the consumption of treated produce.

Furthermore, while good hygiene practices such as washing of produce are not considered in the assessment for the registration of a food-use pesticide, any remaining residues of either active ingredient in OxiDate 2.0 is likely to be further decreased by washing (and possible cooking) of treated crop prior to consumption.

3.3.2 Drinking Water

Drinking water exposure to residues from the application of the end-use product is expected to be low because of the low rates of application and the anticipated non-persistence of hydrogen peroxide and peroxyacetic acid in the environment. Moreover, the label has necessary mitigation measures to prevent contamination of drinking water from the proposed use of OxiDate 2.0. 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 hydrogen peroxide and peroxyacetic acid. Because of the proposed low application rate of the end-use product and the anticipated rapid decomposition of hydrogen peroxide and peroxyacetic acid to oxygen and water, there is no dietary concern from the proposed use. The available literature suggests that there are no significant treatment related effects from exposure to low residue levels expected from the proposed uses.

3.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of hydrogen peroxide or peroxyacetic acid 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) for which there is reliable information.

3.3.5 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. While hydrogen peroxide and peroxyacetic acid may share a common moiety with other peroxy compound active ingredients, the potential risks from cumulative exposure to peroxy compounds are not of concern given the low application rate and rapid degradation of the active ingredients to water and oxygen.

3.3.6 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

No methods are required to quantify residues of hydrogen peroxide and peroxyacetic acid due to their rapid decomposition to water and oxygen. The dietary risks from food and drinking water are expected to be low and not of concern given that the active ingredients rapidly degrade to water and oxygen once applied. Consequently, the specification of an MRL for either hydrogen peroxide or peroxyacetic acid under the *Pest Control Products Act* is not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Hydrogen peroxide and peroxyacetic acid are very short lived in the environment with reported half-lives ranging from several minutes to 15 hours in soil and up to 2.5 days in aquatic environments. Peroxyacetic acid undergoes hydrolysis, spontaneous decomposition, and metal-catalyzed decomposition in the aquatic environment. Adsorption to soil or sediment particles is not expected for either of these active ingredients. As such, movement of hydrogen peroxide and peroxyacetic acid with runoff water in natural soils is only expected for very short distances due to the very fast degradation half-life of these substances in natural soils. The transformation products from the degradation of hydrogen peroxide and peroxyacetic acid are water, oxygen and acetic acid. Hydrogen peroxide and peroxyacetic acid are not expected to leach to ground water. Hydrogen peroxide and peroxyacetic acid are expected to stay in solution; partitioning to sediment is not expected. Volatilization into the atmosphere is expected to be low and neither are expected to accumulate in the tissues of organisms. Environmental parameters for hydrogen peroxide have been summarized and were published in Evaluation Report ERC2010-10, *Hydrogen Peroxide*.

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. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

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

quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A summary of toxicity data for terrestrial organisms is presented in Appendix I, Table 1. The accompanying risk assessment is presented in Appendix I, Table 2.

Bees and other beneficial terrestrial invertebrates: No toxicity data on bees and other beneficial arthropods, or earthworms, were available. As hydrogen peroxide and peroxyacetic acid are proposed for use as a contact fungicide and bactericide, exposure to bees and beneficial arthropods from use on greenhouse and field crops may occur through direct contact with the spray or dried residues on food sources. Exposure to non-target organisms through dried residues on soil or food sources is, however, expected to be limited due to the short half-life of hydrogen peroxide and peroxyacetic acid in the natural environment. Therefore, no risks of concern are expected for earthworms, or to bees via exposure through residues in food. Bees may be contacted directly by the spray solution containing hydrogen peroxide and peroxyacetic acid if they are present in the treatment area at the time of application. To mitigate exposure, and potential risk, a precautionary statement will be required on the label informing the user to not apply the product directly to, or allow it to drift to, blooming crops or while bees and other beneficial arthropods are actively visiting the treatment areas.

Birds and mammals: An oral dose of 310.8 mg a.i./kg bw hydrogen peroxide caused no mortality in bobwhite quail (*Colinus virginianus*), but resulted in a transient loss of coordination. Hydrogen peroxide was moderately toxic to rats on an acute basis. No toxicity data for peroxyacetic acid was available. Given that hydrogen peroxide and peroxyacetic acid are contact fungicides and bactericides and are unstable (i.e. both have very short half-lives in the environment), the amounts of dried residues on food sources for wild birds and mammals, which includes foliage, are expected to be limited. Furthermore, birds and mammals would have to consume large quantities of treated food to reach the levels that were tested. For example, a bird would have to consume 15.2 L of spray solution as residues in food per kilogram of body weight to be equivalent to the dose tested in the study with bobwhite quail where minor effects from hydrogen peroxide were observed. Similarly, 7.6 L spray solution would have to be consumed by a small mammal to be equivalent to the LD₅₀ determined in the laboratory study with hydrogen peroxide.

Therefore, based on this, it is considered unrealistic that birds and mammals would be able to consume enough hydrogen peroxide as residues on food items that would be equivalent to the levels where effects were observed in toxicity studies. Therefore, risks of concern are not expected to wild birds and small mammals from exposure to hydrogen peroxide and peroxyacetic acid from agricultural use on field crops.

Non-target terrestrial plants: Non-target terrestrial vascular plants can be exposed to hydrogen peroxide and peroxyacetic acid through spray drift following application to field crops. In a study of vegetative vigour, a variety of plants (for example, apple trees, onion, cabbage crops, and others) were sprayed with hydrogen peroxide and peroxyacetic acid at the single application rate of 5524 g a.i./ha (based on the concentration of hydrogen peroxide). Applications at this rate took place on three consecutive days followed by three weekly sprays for a total dose of 33,144 g a.i./ha over 24 days (based on hydrogen peroxide). Although no adverse effects were noted at any time during the study period, the maximum application rate on the proposed label for Oxidate 2.0 is approximately five times the single application rate tested in the toxicity study (for example, 5524 vs 27,540 g a.i./ha). In addition, as stated on the proposed label, OxiDate 2.0 may result in leaf necrosis for some plants. For example, a single US incident report indicated damage to potato plants. Thus, there is uncertainty regarding the potential for toxicity to terrestrial plants at the rates proposed, and a conservative risk assessment approach was used. This was based on an EEC equal to the maximum cumulative application rate and using a 10-d foliar half-life for the active ingredient. The endpoint for vegetative vigour (ER₂₅>5524 g a.i. hydrogen hydroxide/ha) was adjusted by multiplying it by six to take into consideration that multiple applications were employed. The calculated risk quotient for the screening level assessment (RQ<2.67) marginally exceeded the LOC for plants. The risk to terrestrial vascular plants was further characterised by looking at off-field exposure from ground boom and airblast spray drift and the LOC was not exceeded for either method of application. As a result, a default spray buffer zone will be required to protect sensitive non-target terrestrial plants.

4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data is presented in Appendix I, Table 3. Various studies were available for each active ingredient separately and for a mixture of the two active ingredients, and were used to characterize the toxicity of hydrogen peroxide and peroxyacetic acid. Given the complexity of interpreting results where a mixture of active ingredients is the test substance, only the most sensitive test end-points resulting from individual active ingredients were used for the risk assessment (Appendix I, Tables 4-6).

Freshwater and marine invertebrates: Hydrogen peroxide and peroxyacetic acid were moderately toxic to highly toxic to *Daphnia magna*, mysid and bivalve embryo larvae (*Mytilus* sp.) on an acute basis. The screening level assessment identified a risk to freshwater invertebrates (maximum RQ of 3.83) on an acute basis and, therefore, the risk assessment was further characterised (see Section 4.2.3). Based on two endpoints for aquatic-phase life-stages of two insect species, hydrogen peroxide is not toxic to these organisms.

Freshwater and marine fish: Peroxyacetic acid was moderately toxic to bluegill sunfish and rainbow trout. Hydrogen peroxide, tested as sodium percarbonate, was slightly toxic to rainbow trout, *Oncorhynchus mykiss*, but the mixture of hydrogen peroxide and peroxyacetic acid was shown to be of moderate to high toxicity to rainbow trout, bluegill sunfish, fathead minnow and inland silverside on an acute basis. The screening level risk quotients from acute exposure to hydrogen peroxide and peroxyacetic acid exceeded the LOC (RQ values up to 3.87). Therefore the risk assessment was further characterised (see Section 4.2.3).

Amphibians: To assess the risk to amphibians, the most sensitive fish toxicity endpoints are used as surrogate data, when amphibian data are not available, to represent aquatic life-stages of amphibians. The difference between fish and amphibian risk assessments is related to the water depth used for the estimated environmental concentrations (water depth of 15 cm for amphibians). The screening level risk quotient for acute exposure of amphibians to hydrogen peroxide exceeded the LOC (RQ=14.94) and, therefore, the risk assessment was further characterised (see Section 4.2.3). The risk quotient for peroxyacetic acid was lower; therefore, only the higher RQ was reflected in the risk assessment.

Freshwater and marine algae: Hydrogen peroxide and peroxyacetic acid, tested together on freshwater diatoms, green and blue green algae, indicated EC_{50} values ranging from 0.44 mg a.i./L to 1.5 mg a.i./L. Chlorophyll reduction was observed in algae exposed to hydrogen peroxide for 24 and 48 hours; most significant was a reduction to < 6% chlorophyll for *Microcystis* at a concentration of 1.7 mg/L hydrogen peroxide. The most sensitive endpoint for freshwater algae was 0.18 mg a.i./L for peroxyacetic acid and *Selenastrum capricornutum*. The most sensitive endpoint for marine algae was 0.85 g a.i./L (growth) for hydrogen peroxide and *Nitzchia closterium*. The screening level RQ exceeded the level of concern for freshwater algae (RQ = 4.73) and for marine algae (RQ = 8.02) and, therefore, the risk assessment was further characterised (see Section 4.2.3).

Freshwater vascular plants: Hydrogen peroxide and peroxyacetic acid, tested together, affected the biomass of freshwater vascular plant duckweed *Lemna gibba* with an EC₅₀ of 230 mg proxitane/L. In non-guideline toxicity studies, hydrogen peroxide caused necrosis in *Ceratophyllum demmersum* and caused necrosis, chlorosis and growth inhibition in *Hydrilla verticillata*. Although a quantitative risk assessment was not conducted for aquatic plants, aquatic EECs of 4.6 and 0.426 mg a.i./L for hydrogen peroxide and peroxyacetic acid, respectively, are not expected to cause risks of concern. For example, the EEC for hydrogen peroxide in 80 cm of water is approximately 7 to 30 times lower than the concentration where necrosis was noted in toxicity studies. Sensitivity of aquatic plants to hydrogen peroxide is likely to vary; however, spray buffer zones, being required for aquatic habitats, are expected to mitigate exposure of aquatic vascular plants.

4.2.3 Risk of spray drift to Aquatic Organisms

The level of concern was exceeded at the screening level for amphibians, fish, algae and freshwater and marine invertebrates. A refined EEC for a broadcast application was calculated using a maximum percent drift deposition at one metre downwind of the site of application. The maximum spray drift deposition at one meter downwind from the point of application is 6% for

ground boom spray (ASAE droplet medium size), 74% for early season airblast spray (ASAE droplet fine size) and 59% for late season airblast spray (ASAE droplet fine size) for both an 80 cm and 15 cm depth of water.

The refined RQ values for ground boom spray drift indicate that the LOC is not exceeded for all species on an acute basis (RQ < 1). For both early and late season airblast sprays, the refined RQ values indicate that the level of concern is exceeded for freshwater species including amphibians (RQ=4.45), fish (RQ=1.14), algae (RQ=1.40) and marine algae (RQ=2.32). Spray buffer zones for agricultural uses will be required for the protection of aquatic habitats.

4.2.4 Risk from runoff / greenhouse effluent

Risk to aquatic organisms resulting from run-off is not expected given the very short half-life of hydrogen peroxide and peroxyacetic acid in natural soils (half-life of less than 1 day). However, uses in greenhouse (aerosol/fog treatment in hydroponic growing systems, sanitizing of hard surfaces and equipment) could result in some exposure to the environment if washwaters containing hydrogen peroxide and peroxyacetic acid are released to aquatic environments through discharge of effluents. Statements, informing users that effluent from greenhouses containing hydrogen peroxide and peroxyacetic acid should not be allowed to enter the environment, are also required.

4.2.5 Incident Reports

As of 7 September 2017, the PMRA received three incident reports involving the active hydrogen peroxide. Two of these incidents were associated with farmed atlantic salmon while, the third involved bees.

The incidents with farmed salmon involved mortality, which was reported during a bath treatment for sea lice with hydrogen peroxide. One incident was likely due to factors other than the pesticide. The second incident was considered to be related to the reported pesticide exposure. A delayed flushing of hydrogen peroxide from the well tank and the exposure of fish to a treatment duration longer than that specified on the product label likely resulted in fish mortality. The hydrogen peroxide product involved in the incidents has a different use pattern than the proposed product. The reported exposure scenarios are therefore, not relevant to the proposed product which is proposed for use on horticultural and field crops.

In the bee incident, abnormal behaviour and a small number of dead bees were reported in front of multiple hives, after two neighboring bean fields were treated with a fertilizer and a product containing hydrogen peroxide. This incident report was determined to be inconclusive for hydrogen peroxide.

The US EIIS database was also queried for environment incidents. There was one environment incident involving use of hydrogen peroxide on potato plants where damage to the plants was reported.

The exposure scenario reported in the incident involving farmed Atlantic salmon is not relevant to the proposed product which is for use on crops, hence, no additional risk mitigation measures are being proposed.

No incidents involving peroxyacetic acid were located in the Canadian or U.S. EIIS databases.

5.0 Value

No value information was required to support the use of Oxidate 2.0 on greenhouse surfaces and equipment since the value of this use was based on a precedent registration with identical use directions.

Efficacy of the product against labeled pathogens on agricultural crops was demonstrated through a combination of small-scale efficacy trials, extrapolations from precedent registrations through scientific rationales, and statements of use history from the U.S.

Although symptoms of crop phytotoxicity were not reported in any of the trials where Oxidate 2.0 was applied in accordance with label directions, adverse effects, such as leaf burn could occur from strong oxidizers like hydrogen peroxide and peroxyacetic acid if label directions are not followed or if the product is used on untested sensitive varieties. A detailed warning statement appears on the label to inform users of this potential.

As a general biocide, target pathogens are unlikely to develop resistance to OxiDate 2.0. Under conditions of low disease pressure, this product may also be of value to integrated pest management in conventional agricultural systems by reducing reliance on synthetic fungicides or in other agricultural systems intended to avoid such products entirely.

Oxidate 2.0 will be an alternative product for the management of many bacterial and fungal plant pathogens on various field and greenhouse-grown crops under low disease pressure. It represents an additional non-conventional option for the suppression or partial suppression of numerous economically damaging diseases of indoor and outdoor crops. It will also provide Canadian cherry producers with a first registration to help manage the emerging problem of slip-skin maceration disorder. A number of the other labeled diseases currently have no other non-conventional alternatives including black rot on grape and apple, *Phomopsis* on blueberry and grape, leaf mould on tomato, tan spot and brown leaf spot on potato, and downy mildew on celery. Moreover, there are a very limited number of registered options for the management of any of the bacterial diseases on the Oxidate 2.0 label, where these are generally limited to various copper-based active ingredients and very few biological products.

The reviewed value information was sufficient to support the claims detailed in the supported uses provided in Appendix I, Table 7.

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, i.e., 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, hydrogen peroxide and peroxyacetic acid and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Hydrogen peroxide and peroxyacetic acid do not meet Track 1 criteria, and are not considered a Track 1 substance. See Table 8 for comparison with Track 1 criteria.
- Hydrogen peroxide and peroxyacetic acid are 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*.⁶ The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,⁸ and takes 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:

- 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.

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.

• The technical grade active ingredient OxiDate 2.0 Technical and the end-use product OxiDate 2.0 do not contain any formulants 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.

7.0 Summary

7.1 Human Health and Safety

The toxicology database for hydrogen peroxide and peroxyacetic acid is adequate to define the majority of toxic effects that may result from exposure to OxiDate 2.0 containing the two active ingredients, from the proposed uses. Both peroxyacetic acid and hydrogen peroxide are highly reactive and subject to rapid decomposition.

OxiDate 2.0 is expected to be slightly acutely toxic by the oral and dermal route routes and moderately acutely toxic by the inhalation route. It is also expected to be corrosive to the eyes severely irritating to the skin and is not expected to be a skin sensitizer.

Available information on short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of hydrogen peroxide and peroxyacetic acid to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. There are no reports indicating short- or long-term effects resulting from either active ingredient's long history of use as a commodity chemical in the food industry. This is to be expected as hydrogen peroxide and peroxyacetic acid do not accumulate in animal tissues due to their rapid decomposition.

Handlers and workers are not expected to be exposed to levels of OxiDate 2.0 that will result in a health risk of concern when OxiDate 2.0 is used according to label directions. Although the proposed field crop uses can result in bystander exposure, the label includes appropriate mitigative measures to minimize the potential for exposure. To avoid bystander exposure in fields, the end-use product label requires that unprotected persons be kept out of the field for the duration of the treatment period, and allow entry or re-entry only after treated surfaces have dried. To avoid bystander exposure in greenhouses, the end-use product label requires that unprotected persons be kept out of the greenhouses for the duration of the treatment period, and allow entry or re-entry only after treated surfaces have dried. To avoid bystander exposure in greenhouses for the duration of the treatment period, and allow entry or re-entry only after treated surfaces have dried. To avoid bystander exposure in greenhouses for the duration of the treatment period, and allow entry or re-entry to greenhouse only after thorough ventilation and aerosols have cleared and treated surfaces have dried. There are no residential uses for OxiDate 2.0.

The dietary risks from food and drinking water are expected to be very low from the proposed uses. Consequently, the specification of an MRL under the *Pest Control Products Act* is not being recommended.

7.2 Environmental Risk

Hydrogen peroxide and peroxyacetic acid enter the environment when applied as a foliar spray and aerosol/fog to control diseases on certain crops in the field and in greenhouses, respectively. When used according to label directions, hydrogen peroxide and peroxyacetic acid are not expected to pose risks of concern to earthworms, birds and mammals. Hydrogen peroxide and peroxyacetic acid may pose a risk to non-target terrestrial plants and aquatic organisms including fish, amphibians, invertebrates and algae.

Also, hydrogen peroxide and peroxyacetic acid may pose a risk to bees and beneficial insects when they are exposed directly to the spray solution. Risks to non-target organisms can be mitigated through label statements and spray buffer zones to protect sensitive habitats. Label statements are required on the product labels to inform the users of the potential risks.

7.3 Value

OxiDate 2.0 is a fungicidal and bactericidal product that has value as a greenhouse surface and equipment sanitizer while also providing an alternative for the suppression or partial suppression of fungal and bacterial diseases on various crops grown indoors and outdoors. It also represents a first Canadian registration to reduce symptoms associated with slip-skin maceration disorder in sweet cherry.

Under low disease pressure, OxiDate 2.0 may reduce or delay the need for synthetic fungicides in conventional agricultural systems or, in non-conventional systems aiming to avoid the use of such fungicides, its registration represents a valuable addition to currently limited disease management options.

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 OxiDate 2.0 Technical and OxiDate 2.0, containing the technical grade active ingredient ingredients hydrogen peroxide and peroxyacetic acid, for the suppression or partial suppression of fungal and bacterial diseases on labeled crops grown in greenhouse, field and hydroponic systems, as well as a sanitizer for greenhouse surfaces and equipment.

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

λ	wavelength
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
С	Celsius
CAS	Chemical Abstracts Service
CBI	confidential business information
CEPA	Canadian Environmental Protection Act
cm	centimetres
d	day(s)
DACO	data code
EC ₂₅	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
EIIS	Ecological Incident Information System
ER_{25}	effective rate for 25% of the population
ERC	evaluation report
FRAC	Fungicide Resistance Action Committee
g	gram
ĥ	hour(s)
ha	hectare(s)
HDPE	high-density polyethylene
HPX	hydrogen peroxide
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
$K_{ m ow}$	<i>n</i> –octanol-water partition coefficient
kPa	kiloPascal
L	litre(s)
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOC	level of concern
mg	milligram(s)
mL	millilitre(s)
MRL	maximum residue limit
NA	not applicable
NIOSH	National institute for Occupational Safety
nm	nanometre
NOEC	no observed effect concentration
NR	not reported
PCA	peroxyacetic acid
pН	measure of the acidity or basicity of an aqueous solution

dissociation constant
Pest Management Regulatory Agency
personal protective equipment
Proposed Re-evaluation Decision
restricted-entry interval
risk quotient
solution
Toxic Substances Management Policy
United States
United States Environmental Protection Agency
ultraviolet
volume per volume dilution

Appendix I Tables and Figures

Table 1 Effects of hydrogen peroxide and peroxyacetic acid on terrestrial organisms

Organism		Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#			
Invertebrate	Invertebrates								
No toxicity d	ata were available	for earthworms	, bees, and benefici	al arthropods.		1059569			
Birds									
Bobwhite qua	ail, <i>Colinus</i>	14-d Acute	GreenClean	LD ₅₀ >310.8 mg	No adverse	1403012			
virginianus		oral	(42.5% Sodium	a.i. equivalent	effects at single				
			percarbonate) ^b	/kg bw	dose tested				
Mammals									
Rat		Acute	H ₂ O ₂ 70%	LD ₅₀ : 56.25 mg	Moderately	1384173			
				a.i./ kg bw	toxic	1059592			
Vascular pla	ints								
Fruit trees	apple, pear	24-d	ZeroTol ^c	No phytotoxic effects were 22 observed $EC_{25} > 5524$ g a.i./ha, the highest tested rate		2260563			
	Cherry, peach	Vegetative vigor	OxiDate 2.0 ^d						
Vegetable	broccoli,	11501							
crops	onions, garlic								
cabbage				Note: products were applied for 3 consecutive days followed by 3					
Ornamental White rose, red			ZeroTol						
shrubs rose,									
	rhododendrons			weekly sprays for a total of					
	pittosporum			33,114 g a.i./ha.					

^a USEPA classification for others, where applicable

^b Sodium percarbonate contains 32.5% hydrogen peroxide; thus, GreenClean contains 13.8% hydrogen peroxide.

^c ZeroTol contains 27 % hydrogen peroxide and 2.5% peroxyacetic acid

^d OxiDate 2.0 contains 27 % hydrogen peroxide and 2.5% peroxyacetic acid

Table 2Risk to terrestrial vascular plants

Organism	Exposure	Endpoint value	EEC	RQ	Risk
Vascular plants					
Vascular plant	Vegetative	EC ₂₅ > 33,114 g	88,355 g a.i./ha	< 2.67	Yes
	vigour	a.i./ha ^a	5301 g a.i./ha (6 % drift)	< 0.16	No
			26,153 g a.i./ha (airblast	< 0.79	No
			early season) ^b		
			20,851g a.i./ha (airblast	< 0.63	No
			late season) ^b		

^abased on total tested application rate; ^bBased on maximum accumulative rate of 35,342 g a.i/ha (11,040 g a.i./ha, 8 times with 5 days interval)

Table 3Effects of hydrogen peroxide and peroxyacetic acid on aquatic organisms

Organism	Exposure	Substance	Endpoint value (mg/L)	Degree of toxicity ^a	Reference
Invertebrates					
Daphnia magna	NR	HPX	LC ₅₀ :7.7 (immobilized)	Moderately toxic	PMRA 1059372
	48-h Acute	HPX (Sodium percarbonate)	EC ₅₀ : 4.5		PMRA 1403010
	48-h Acute	PCA	EC ₅₀ : 0.73	Highly toxic	PMRA 1175557

Organism	Exposure	Substance	Endpoint value (mg/L)	Degree of toxicity ^a	Reference
	48-h Acute	PCA, 15% HPX, 22%	LC ₅₀ :0.67		PMRA 2266545
		PCA, 15% HPX, 14%	EC ₅₀ : 3.3	Moderately toxic	PMRA 2266545
Daphnia pulex	48-h Acute	HPX	LC ₅₀ :2.4 (immobilized)		PMRA 1059372
Amphipod crustaceans	96-h Acute	HPX	LC ₅₀ :4.4		
Mysid, Mysidopsis	96-h Acute	PCA, 15%	LC ₅₀ : 0.65	Highly toxic	PMRA 2266545
bahia	7-d Chronic	HPX, 22%	NOEC: 0.14		
Bivalve, Mytilus	Embryo	PCA, 15%	IC ₅₀ : 0.36		
edulus (<4 hr old)	larval	HPX, 22%	NOEC: 0.23		
Bivalve, Blue mussel, <i>Mytilus</i>	Embryo larval (48h)	PCA, 15% HPX, 14%,	EC ₅₀ : 3.7	Moderately toxic	PMRA 2266545
galloprovincialis	48-h Acute	PCA, 15% HPX, 14%	EC ₅₀ : 3.68	Moderately toxic	PMRA 2266545
Snails (Physa sp)	96-h Acute	HPX	LC ₅₀ :17.7	Moderately toxic	PMRA 1059372
Red Abalones, Haliotis rufescens	NR	HPX	Induced spawning	g at 170 mg/L	PMRA 1059372
Insects	•				
Stratiomyd fly (Diptera)	NR	HPX	No effect at 217.6	mg/L	PMRA 1059372
Dragonfly naiads	NR	HPX	No effect at 170 n	ng/L	
Fish				0	
Rainbow trout, Oncorhynchus	48-h Acute	HPX	Mortality increase mg/L	ed linearly at>40	PMRA 1059372
mykiss	96-h Acute	HPX (Sodium percarbonate)	LC ₅₀ : 48.7	Slightly toxic	PMRA 1403011
	96-h Acute	PCA	LC ₅₀ : 1.6	Moderately	PMRA 1175557
	96-h Acute	PCA, 15% HPX, 14%	LC ₅₀ : 13.4	toxic	PMRA 2266545
	96-h Acute	PCA, 15% HPX, 22%	LC ₅₀ : 0.72	Highly toxic	PMRA 2266545
Bluegill sunfish.	96-h Acute	PCA	LC ₅₀ : 1.1	Moderately	PMRA 1175562
Lepomis macrochirus		PCA, 15% HPX, 22%	LC ₅₀ : 1.21	toxic	PMRA 2266545
Catfish	96-h Acute	HPX	LC ₅₀ :37.4	Slightly toxic	PMRA 1059372
Ictalurus punctatus	24-h Acute	HPX	No effect at 9.8 m	g/L	
Carp Cyprinus carpio	48-h Acute	НРХ	LC ₅₀ :42	Slightly toxic	
Rabbitfish Siganus punctatus	24-h Acute	HPX	LC ₅₀ :224	Practically non toxic	
Striped goby Gobius vittatus	24-h Acute	HPX	LC ₅₀ :155		
Jack mackerel Trachurus symmetricus	24-h Acute	HPX	LC ₅₀ :89 Slightly toxic		
Yellowtail Seriola lalandi	3 min	HPX	Slight anemia due to		
Red sea bream Pagrus major	3 min	HPX	Slight anemia due methemoglobinen	to nia at 300 and	

Organism	Exposure	Substance	Endpoint value (mg/L)	Degree of toxicity ^a	Reference
			1500 mg/L	· · · · · ·	
Squawfish P. lucius	24-h Acute	HPX	No mortality at 10 mg/L	NA	
Coho salmon	24-h Acute	HPX		NA	-
Oncorhynchus					
kisutch					-
Mosquito fish	Field study	HPX	Unharmed at	NA	
Gambusia affinis	ND		2.38-9.86 mg/L	N7.4	-
Guppy Poecilia	NR	HPX	Unharmed at 34 m_{α}/I	NA	
<i>Feliculaia</i> Golden orfe	24 h Acute	НРУ			-
Leuciscus idus	24-II Acute		LC50.33		
Fathead minnow,	24-h Acute	HPX	LC ₅₀ :16.4		
Pimephales	96-h Acute	PCA, 15%	LC ₅₀ :0.99	Highly toxic	PMRA 2266545
promelas		HPX, 22%			
Aholehole, Kuhlia sandvicensis	NR	HPX	No behaviour effe	ect at 20 mg/L	PMRA 1059372
Inland silveside,	96-h Acute	PCA, 15%	LC ₅₀ :2.17	Moderately	PMRA 2266545
Menidia beryllina		HPX, 22%		toxic	
	7-day Acute	PCA, 15% HPX, 14%	LC ₅₀ : 35.6	NA	PMRA 2266545
Freshwater algae					
Diatom, Navicula	96-h Acute	Proxitane:	EC ₅₀ : 0.56	NA	PMRA 2266545
pelliculosa		PCA, 12% HPX, 18.5%			
Blue green algae,	96-h Acute	Proxitane:	EC ₅₀ : 1.5	NA	PMRA 2266545
Anabaena flos-		PCA, 12%			
aquae	24.1	HPX, 18.5%		1	DMD A 1050272
	24-h	НРХ	9.86 mg/L	ced to 5% at	PMRA 1059372
Selenastrum	120-h	Vigor Ox	Cell density;	NA	PMRA 2266545
capricornutum	061.4	PCA, 5.22%	EC ₅₀ : 0.18	NT A	PMRA 1175566
	96-fi Acute	Perasan: PCA 15%	EC_{50} : 0.44	NA	PMIKA 2200343
		HPX, 22%			
Ankistrodesmus	24-h	HPX	Chlorophyll reduc	ced to <5% at 17	PMRA 1059372
Raphidiopsis	24-h	HPX	Chlorophyll reduc	ced to <5% at	-
Tupmatopolo			6.8 mg/L		
Microcystis	48-h	HPX	Chlorophyll reduc	ced to <6% at	
			1.7 mg/L		
Marine algae	I	T		1	
Nitzchia closterium	NR	HPX	EC ₅₀ : 0.85 (growth)	NA	PMRA 1059372
Marine Diatom,	96-h Acute	Proxitane:	EC ₅₀ : 27	NA	PMRA 2266545
Skeltonema		PCA, 12%			
costatum		HPX, 18.5%			
Freshwater plants	7 1	Duenite	Diamag		DMD A 2266545
gibba	/-days - Dissolved	Proxitane: PCA, 12% HPX 18.5%	B10mass EC ₅₀ : 230	NA	PMKA 2266545
Ceratonhyllum	Continious	HPX	34 (80 % necrosis	;)	PMRA 1059372
demmersum	Commous				1

Organism	Exposure	Substance	Endpoint value (mg/L)	Degree of toxicity ^a	Reference
Hydrilla	1-h	HPX	34 (30% necrosis)		
verticillata	NR	HPX	136 (80% necrosis	s, chlorosis,	
			growth inibition)		

^aUSEPA classification, where applicable; NA: not applicable; NR: not reported; HPX: hydrogen peroxide; PCA: peroxyacetic acid.

Table 4Screening risk to aquatic organisms

Organism	Exposure	Substance	Adjusted endpoint value (mg a i $/L$) ^a	EEC (mg a i/L) ^b	RQ	LOC
Freshwater spec	ies		(ing unit)	un(2)		Checcucu
Daphnia magna	48-h Acute	PCA	EC ₅₀ : 0.365	0.426	1.17	Yes
Daphnia pulex	48-h Acute	HPX	EC ₅₀ :1.2	4.6	3.83	Yes
Rainbow trout, Oncorhynchus mykiss	96-h Acute	PCA	LC ₅₀ : 0.16	0.426	2.66	Yes
Bluegill sunfish Lepomis macrochirus	96-h Acute	PCA	LC ₅₀ : 0.11	0.426	3.87	Yes
Fathead minnow Pimephales promelas	24-h Acute	HPX	LC ₅₀ : 1.64	4.6	2.80	Yes
Amphibians (Fish data as surrogate)	24-h Acute	НРХ	LC ₅₀ : 1.64°	24.5	14.94	Yes
Freshwater algae (Selenastrum capricornutum)	120-h Acute	Vigor Ox: PCA	EC ₅₀ : 0.09	0.426	4.73	Yes
Marine species					_	
Marine algae Nitzchia closterium	Acute	HPX	EC ₅₀ : 0.43	3.45	8.02	Yes

HPX: hydrogen peroxide; PCA: peroxyacetic acid.

a EC₅₀ aquatic invertebrates/algae divided by 2; LC50 fish/amphibians divided by 10.

b EECs in water are calculated for either a 15 cm (amphibian) or 80 cm water depth and the maximum cumulative rate of HPX or PCA.

c The RQ for HPX fish endpoint and EEC for 15 cm body of water (amphibian assessment) was higher than for PCA, therefore, only HPX was used for the amphibian assessment.

Table 5Refined risk to aquatic organisms (Ground boom spray)

Organism	Exposure	Substance	Adjusted endpoint	EEC (mg	RQ	LOC
			value (mg a.i./L)	a.i./L)		exceeded
Freshwater spec	ies					
Daphnia magna	48-h Acute	PCA	EC ₅₀ : 0.365	0.025	0.07	No
Daphnia pulex	48-h Acute	HPX	EC ₅₀ :1.2	0.27	0.22	No
Rainbow trout, Oncorhynchus mykiss	96-h Acute	PCA	LC ₅₀ : 0.16	0.025	0.16	No

			-			
Bluegill sunfish	96-h Acute	PCA	LC ₅₀ : 0.11	0.025	0.23	No
Lanomia						
Lepomis						
macrochirus						
Fathead	24-h Acute	HPX	LC ₅₀ : 1.64	0.27	0.16	No
minnow			- 50			
miniow						
Pimephales						
promelas						
Amphihians	24-h Acute	НРХ	EC roi 1 64	1.47	0.90	No
Ampinotans	24-II Acute	III A	LC50.1.04	1.7/	0.70	140
(Fish data as						
surrogate)						
Algae	120 -h	Vigor Ox:	EC ₅₀ : 0.09	0.025	0.28	No
(Selenastrum	Acute	PCA				
capricornutum)		-				
eupricomunity						
Marine species						
Algae Nitzchia	Acute	HPX	EC ₅₀ : 0.43	0.21	0.49	No
closterium						
ANDAY 1 1	11 DOL					

HPX: hydrogen peroxide; PCA: peroxyacetic acid.

Table 6Refined risk to aquatic organisms (Airblast spray)

Organism	Exposure	Substance	Adjusted	Seasonal EEC (mg	ŀ	RQ	LOC
			endpoint value (mg a i /L)	a.i./L)	Early spray	Late	exceeded
Freshwater spec	ies		uni(2)		Spray	spray	
Daphnia magna	48-h Acute	PCA	EC ₅₀ : 0.365		0.34	0.27	No
Daphnia pulex	48-h Acute	HPX	EC ₅₀ :1.2		1.17	0.91	Yes
Rainbow trout, Oncorhynchus mykiss	96-h Acute	РСА	LC ₅₀ : 0.16	Early Late HPX 1.4 1.1	0.79	0.62	No
Bluegill sunfish Lepomis macrochirus	96-h Acute	PCA	LC ₅₀ : 0.11	PCA 0.126 0.10	1.14	0.91	Yes
Fathead minnow Pimephales promelas	24-h Acute	HPX	LC ₅₀ : 1.64		0.85	0.67	No
Amphibians (Fish data as surrogate)	24 h Acute	HPX	EC ₅₀ : 1.64	EarlyLateHPX7.35.8	4.45	3.53	Yes
Freshwater algae (Selenastrum capricornutum)	120 -h Acute	Vigor Ox: PCA	EC ₅₀ : 0.09	EarlyLatePCA0.1260.10	1.4	1.1	Yes
Marine species				1			
Marine algae Nitzchia closterium	Acute	НРХ	EC ₅₀ : 0.43	EarlyLateHPX1.00.8	2.32	1.86	Yes

HPX: hydrogen peroxide; PCA: peroxyacetic acid.

Table 7List of Supported Uses

Supported label claims
Partial suppression of mummy berry (<i>Monilinia vacinii-corymbosi</i>) on blueberry with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of phomopsis twig blight (<i>Phomopsis vaccinii</i>) on blueberry with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of black rot (<i>Guignardia bidwellii</i>) on grape with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of downy mildew (<i>Plasmopara viticola</i>) on grape with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of cane and leaf spot; fruit rot (<i>Phomopsis viticola</i>) on grape with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of powdery mildew (<i>Uncinula nacator</i>) on grape with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of botrytis fruit rot (<i>Botrytis cinerea</i>) (field) on strawberry with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of fire blight (<i>Erwinia amylovora</i>) on apple and pear with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of scab (<i>Venturia inaequalis</i>) on apple with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of powdery mildew (<i>Podosphaera leucotricha</i>) on apple with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of black rot (<i>Botryosphaeria obtusa</i>) on apple with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Reduction of slip-skin maceration disorder symptoms at harvest (associated yeast species: <i>Aureobasidium pullulans, Candida railenensis, Cryptococcus victoriae and Hanseniaspora uvarum</i>) on sweet cherry with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of bacterial blight (<i>Xanthomonas campestris pv. phaseoli</i>) on beans with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of cerospora leaf spot (<i>Cercospora beticola</i>) on sugar beet with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of gummy stem blight (<i>Didymella bryoniae</i>) on watermelon with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of leaf mould (<i>Fulvia fulva</i> syn. <i>Cladosporium fulvum</i>) on tomato with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of botrytis grey mould (<i>Botrytis cinerea</i>) on tomato with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of downy mildew (<i>Pseudoperonospora cubensis</i>) on cucumber with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Suppression of bacterial wilt <i>(Erwinia tracheiphila)</i> on cucumber with foliar applications at a rate of 1.0% (v:v) to the point of run-off
Partial suppression of powdery mildew (<i>Podosphaera fusca</i>) on pumpkin with foliar applications at a rate of 2.5% (v:v) to the point of run-off
Partial suppression of powdery mildew (<i>Erysiphe cichoracearum</i>) on zucchini with foliar applications at a rate of 2.5% (v:v) to the point of run-off

Supported label claims

Suppression of downy mildew (*Bremia lactucae*) on lettuce with foliar applications at a rate of 1.0% (v:v) to the point of run-off

Suppression of Downy mildew (*Peronospora parasitica*) on cauliflower, broccoli with foliar applications at a rate of 1.0% (v:v) to the point of run-off

Suppression of downy mildew (*Peronospora umbellifarum*) on celery with foliar applications at a rate of 1.0% (v:v) to the point of run-off

Partial suppression of powdery mildew (*Erysiphe cichoracearum*) on lettuce in hydroponic system /0.3% (v:v) to the point of run-off

Partial suppression of botrytis tan spot (*Botrytis cinerea*) / Potato with foliar applications at a rate of 2.5% (v:v) to the point of run-off

Suppression of white mold (*Sclerotinia sclerotiorum*) on potato with foliar applications at a rate of 2.5% (v:v) to the point of run-off

Suppression of brown leaf spot (*Alternaria alternata*) on potato with foliar applications at a rate of 1.0-2.5% (v:v) to the point of run-off

Aerosol/Fog Treatments For Control of Foliar Diseases in Crops Grown In Greenhouses and Hydroponic Growing Systems

Application of OxiDate 2.0 with a non-ionic surfactant

Table 8Toxic Substances Management Policy (TSMP) Considerations-Comparison
to Toxic Substances Management Policy

Track 1 Criteria			
TSMP Track 1 Criteria	TSMP Trac va	k 1 Criterion lue	Endpoints for Hydrogen Peroxide and Peroxyacetic Acid
CEPA toxic or CEPA toxic equivalent ¹	Yes		Yes
Predominantly anthropogenic ²	Yes		No
Persistence ³ :	Soil	Half-life ≥ 182 days	< 1 Day
	Water	Half-life ≥ 182 days	<1-12 Days
	Sediment	Half-life \geq 365 days	< 12 Days
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life and volatilisation are not important routes of dissipation and long-range atmospheric transport is unlikely to occur.
Bioaccumulation ⁴	$\text{Log } K_{\text{ow}} \ge 5$		No
	$BCF \geq 5000$		not available
	$BAF \ge 5000$		not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria.	

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

²The 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. ⁴Field data (exempli gratia, BAFs) are preferred over laboratory data (exempli gratia, BCFs) which, in turn, are preferred over chemical properties (exempli gratia, log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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Document	
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	CBI
2733867	2017, Product Chemistry for ZeroTol 2.0 (OxiDate 2.0, OxiDate 2.0
	Technical), DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2733868	2017, Chemistry-2.13.1-4-oxidate-5-batch-final-Preliminary Analysis of
	Oxidate 2.0 Technical, DACO: 2.13.1,2.13.2,2.13.3 CBI
2733869	2016, PMRA-[CBI Removed] calculation-5-Batch 2% PAA
	formulation18nov2016, DACO: 2.13.3 CBI
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2733873	2004, [CBI Removed]-Ambient Water Quality Guidelines - Overview, DACO:
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2.0 Human and Animal Health

PMRA	References
Document	
Number	
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	12.5.4, 12.5.6, 12.5.7, 4.8, 6.4, 7.8
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1059540	2000, Chronic Rodent Study, DACO: 4.4.1
1059541	2000, Oncogenicity (rodent species 1) Study, DACO: 4.4.2
1059542	2000, Oncogenicity (rodent species 2) Study, DACO: 4.4.3
1059543	2000, Multigeneration-Reproduction (Rodent) Study, DACO: 4.5.1
1059544	2000, Teratogenicity Study (Rodent) - Waiver Request, DACO: 4.5.2
1059545	2000, Teratogenicity Study (non-Rodent) - Waiver Request, DACO: 4.5.3
1059546	2000, In Vitro Chromosomal Aberrations Study, DACO: 4.5.6
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1059553	2000, Acute Inhalation Study - Waiver Request, DACO: 4.2.3
1059554	2000, Primary Eye Irritation Study - Waiver Request, DACO: 4.2.4
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3.0 Environment

PMRA	References
Document	
Number	
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	Under Static Conditions, DACO: 9.3.5
1403011	2001, GreenClean-Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss)
	Under Static Conditions, DACO: 9.5.4
1403012	2006, An Acute Oral Toxicity Study with the Northern Bobwhite, DACO: 9.6.4

4.0 Value

PMRA	References
Document	
Number	
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2600149	2012, Evaluation of fungicide allowed for organic production on foliar diseases
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2600150	2008, Evaluation of composted dairy manure and biorational products for the
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2600153	2009, Evaluating biofungicides for control of mummyberry and anthracnose
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2600154	2014, Evaluation of fungicide programs for potato early blight, brown leaf spot
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B. Additional Information Considered

i) Published Information

1.0 Environment

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