Proposed Registration Decision PRD2018-21

Hydrogen peroxide; Peroxyacetic acid; AdvaCare D

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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 registration for the sale and use of Hydrogen Peroxide and PAA 11/15% and AdvaCare D, containing the technical grade active ingredients hydrogen peroxide and peroxyacetic acid (PAA), as a commercial and industrial laundry sanitizer.

The active ingredients are currently registered in Canada. Hydrogen peroxide is an algaecide, bactericide, fungicide, slimicide, sanitizer and acaricide, with uses in aquaculture, agriculture, industry and as a hard and soft surface sanitizer. For details, please see Proposed Re-evaluation Decision PRVD2017-12, *Hydrogen Peroxide and Its Associated End-use Products*, and Re-evaluation Decision RVD2018-09, *Hydrogen Peroxide and Its Associated End-use Products*. Peroxyacetic acid is a slimicide co-formulated with hydrogen peroxide for the control of algal, bacterial, fungal and yeast growth in pulp and paper mills; it also controls bacterial growth in recirculating cooling water systems and sewage, wastewater effluents in treatment plants, and on-shore oil and gas field well operations. For details, please see Proposed Re-evaluation Decision PRVD2017-13, *Peroxyacetic acid and Its Associated End-use Products*, and Re-evaluation Decision RVD2018-10, *Peroxyacetic acid and Its Associated End-use Products*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product are acceptable.

This summary describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of hydrogen peroxide, peroxyacetic acid, and AdvaCare D.

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.

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

The *Pest Control Products Act* also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

Before making a final registration decision on hydrogen peroxide, peroxyacetic acid, and AdvaCare D, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on hydrogen peroxide, peroxyacetic acid, and AdvaCare D, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

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

What Are Hydrogen Peroxide and Peroxyacetic Acid?

Hydrogen peroxide and peroxyacetic acid are the two active ingredients in AdvaCare D, a new sanitizer end-use product intended for application to soiled laundry from institutions such as hospitals and long-term care facilities to kill bacteria and viruses. These active ingredients kill microorganisms by oxidizing cellular components such as lipids, proteins and nucleic acids.

Health Considerations

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

Hydrogen peroxide and peroxyacetic acid are unlikely to affect your health when AdvaCare D is used according to label directions.

Potential exposure to hydrogen peroxide and peroxyacetic acid may occur when handling and using AdvaCare D, 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

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

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

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

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.

AdvaCare D is expected to be highly acutely toxic by the oral, dermal, and inhalation routes and is corrosive to eyes and skin, but is not likely to be a skin sensitizer. Consequently, signal words are required on the product label highlighting the hazards associated with corrosivity of the end-use product.

Residues in Water and Food

Dietary risks from food and water are not of concern.

There are no food or feed uses proposed for AdvaCare D; therefore, there is no dietary exposure to residues of hydrogen peroxide and peroxyacetic acid.

Exposure to hydrogen peroxide and peroxyacetic acid is not expected in drinking water from the proposed use; therefore, there is no drinking water exposure concern.

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 AdvaCare D. Given the nature of the proposed use, there is no bystander exposure. Consequently, residential and bystander exposure are not of concern.

Occupational Risks From Handling AdvaCare D

Occupational risks are not of concern when AdvaCare D 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) are present on the end-use product label to protect workers during handling of the product.

Environmental Considerations

An environmental assessment was not required for this evaluation based on the use pattern.

Value Considerations

What Is the Value of AdvaCare D?

AdvaCare D is used to kill bacteria and viruses in soiled laundry.

Laundry sanitizers are important for commercial operations that clean laundry from hotels or institutions such as hospitals and long-term care facilities. Heavy-duty laundering is required for items such as towels and bed sheets that are used by multiple people over a short time. The laundry sanitizer is used to ensure bacteria and viruses are killed to prevent pathogens from cross-contamination. Laundering with detergent alone can reduce the bacteria present on fabric, but does not achieve the level of control provided by a sanitizer. There are several laundry sanitizers currently registered, but all of these are based on one active ingredient, sodium hypochlorite. AdvaCare D will add alternative active ingredients for this use.

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 Hydrogen Peroxide and PAA 11/15%, and AdvaCare D to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The hazard signal words “DANGER–POISON and CORROSIVE TO EYES AND SKIN” are required on the principal display panels of the labels of Hydrogen Peroxide and PAA 11/15% and the end-use product AdvaCare D.

The requirements of personal protective equipment on the end-use product AdvaCare D label include protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves when handling.

Next Steps

Before making a final registration decision on hydrogen peroxide, peroxyacetic acid, and AdvaCare D, Health Canada’s PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all

comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other Information

When the Health Canada makes its registration decision, it will publish a Registration Decision on hydrogen peroxide, peroxyacetic acid, and AdvaCare D (based on the Science Evaluation section of this consultation document). In addition, the relevant 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, Peroxyacetic acid, AdvaCare D

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredients

Active substance	Hydrogen peroxide Peroxyacetic acid
Function	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
CAS number	Hydrogen peroxide: 7722-84-1 Peroxyacetic acid: 79-21-0
Molecular formula	$H_2O_2 + C_2H_4O_3$
Molecular weight	Hydrogen peroxide: 34.014 Peroxyacetic acid: 76.051
Structural formula	
Purity of the active ingredients	11.2% hydrogen peroxide 15.2% peroxyacetic acid

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

Technical Product—Hydrogen Peroxide and PAA 11/15%

Property	Result
Colour and physical state	Colourless liquid
Odour	Strong acetic acid odour
Melting range	Not applicable
Boiling point or range	105–110°C
Density at 20 °C	1.114 g/mL
Vapour pressure at 20 °C	1.3–2.6 kPa

Property	Result
Ultraviolet-visible spectrum	No significant absorbance expected at $\lambda > 300$ nm
Solubility in water	Completely miscible in water
Solubility in organic solvents	May react with organic solvents
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 5 — -0.46 7 — -0.60 9 — -0.66 neutral — -0.23 (calculated)
Dissociation constant (pK_a)	8.24 (25 °C)
Stability (temperature, metal)	Stable under normal conditions; heat and exposure to heavy metals causes decomposition; may react with organic materials.

End-Use Product—AdvaCare D

Property	Result
Colour	Colourless
Odour	Strong acetic acid odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	11.2% hydrogen peroxide 15.2% peroxyacetic acid
Container material and description	Plastic jug, pail, drum, bulk (15–1200 L)
Density at 20 °C	1.114 g/mL
pH of 1% dispersion in water	2.83
Oxidizing or reducing action	Oxidizing agent
Storage stability	Stable for 1 year when stored in plastic (high-density polyethylene) containers; the peroxyacetic acid and hydrogen peroxide content decreases steadily but remains within specifications.
Corrosion characteristics	Non-corrosive to the packaging material
Explodability	Not potentially explosive

1.3 Directions for Use

The end-use product AdvaCare D is added to the laundry in the bleach rinse step at a rate of 119 to 237 mL of product per maximum 227 L of rinse water. This rate is sufficient to sanitize a maximum of 45 kg of dry laundry. The laundry should be treated with AdvaCare D for a minimum of five minutes at temperatures of 32 to 71 ºC. For further bleaching action, an additional dose of product up to 11 mL/kg (17 oz/cwt) may be added in the bleach or rinse step.

1.4 Mode of Action

Both hydrogen peroxide and peroxyacetic acid are strong oxidizing agents with unpaired electrons in their molecular structure. This makes them highly reactive to cellular macromolecules including lipids, proteins and nucleic acids, leading ultimately to cell death.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredients

The methods provided for the analysis of the active ingredients in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredients in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The toxicological databases for hydrogen peroxide and peroxyacetic acid, consisting of waiver rationales and published data, are considered to be adequate 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 for formulation. Instead, in the final formulated solution, it exists as an equilibrium mixture of peroxyacetic acid, acetic acid, and hydrogen peroxide.

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*. 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.* These previous reviews are considered relevant to the toxicological effects of hydrogen peroxide and peroxyacetic acid in the integrated system product (ISP).

The applicant submitted data waiver requests based on the following rationales with scientific support: 1) The ISP, containing the active ingredients hydrogen peroxide (11.2%) and peroxyacetic acid (15.2%), is proposed as a laundry product; 2) PAA exists as an equilibrium solution containing PAA, acetic acid, and hydrogen peroxide (H_2O_2) dissolved in water; 3) Solutions of PAA are widely utilized in commerce as antimicrobials, and their human health effects are well characterized; 4) Since PAA solutions containing ≥ 10% PAA are considered to be corrosive, and the ISP contains 15.2% PAA, the ISP is expected to be corrosive in nature.

The rationales provided in support of the data waiver request regarding acute toxicity, irritation, and sensitization studies were found to be justifiable, and the data waiver requests were accepted.

Hydrogen Peroxide and PAA 11/15% is expected to be highly acutely toxic by the oral, dermal and inhalation routes and is corrosive to eyes and skin, but is not likely to be a skin sensitizer.

In view of the rapid decomposition of Hydrogen Peroxide and PAA 11/15% to water and oxygen on contact with the aqueous systems, the active ingredients are unlikely to accumulate in mammalian organs/tissues long enough to exert significant effects. Consequently, there is no concern for short- or long-term toxicity, including carcinogenicity, prenatal developmental toxicity, reproductive toxicity or genotoxicity.

The toxicity profile of AdvaCare D is the same as that of the ISP.

Incident Reports

As of 2 February 2018, no human incidents involving the active ingredients 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

AdvaCare D is intended for use in an indoor commercial laundry operation, in a laundry machine, in the oxidation zone of the wash process. A computerized system controls the product dispensing system and determines when the product is being dispensed, at what amount, and for which program. One person controls and selects the correct wash program for the soiled linen to be washed. AdvaCare D is dispensed into the washing machines via a closed-loop system. Upon entering the washing machine, the product is immediately diluted with water in the wash process and is utilized to wash the soiled linen. The application rate is 119–237 mL of the end-use product per 227 L of rinse water to sanitize a maximum of 45 kg dry laundry. The laundry is treated for a minimum of 5 minutes at 32 °C to 71 °C. For further bleaching action, an additional dose of product up to 11 mL/kg (17 oz/cwt) may be added in the bleach or rinse step. After the end-use product is consumed in the wash process through the oxidation zone, it is discarded through the drain into the wastewater system.

3.2.3 Mixer, Loader and Applicator Exposure and Risk

As the whole operation is automated, there is no mixer, loader, or applicator exposure.

Worker exposure is expected only in case of an accidental spill and during clean-up tasks, which will be rare and only caused by human error or mechanical failure. The label has necessary exposure mitigation measures in case of a spill. The personal protective equipment requirements on the end-use product label include protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves when handling the end-use product.

Due to the nature of the closed system where the end-use product will be used, and the exposure mitigation measures and precautionary statements present on the label, the risk due to occupational exposure of AdvaCare D is acceptable when workers follow the label directions.

3.2.4 Postapplication Worker Exposure and Risk

There are no postapplication activities where workers are exposed directly to the product. Post-application activities include removing the laundry after treatment/rinsing or removing the empty container when the dispensing system signals it as empty; therefore, no postapplication exposure is expected from such activities.

3.2.5 Residential and Bystander Exposure and Risk

There are no residential uses for AdvaCare D. As the end-use product is to be used in a closed system in a laundry machine, no bystander exposure to the end-use product is expected to occur. Consequently, residential and bystander exposure is not of concern.

3.3 Food Residue Exposure Assessment

3.3.1 Food

There are no food or feed uses proposed for AdvaCare D; therefore, there is no dietary exposure to residues of hydrogen peroxide and peroxyacetic acid.

3.3.2 Drinking Water

There is no drinking water exposure concern from the proposed laundry sanitizer use of AdvaCare D. Due to the rapid degradation of hydrogen peroxide and peroxyacetic acid, they are unlikely to persist in the environment to the extent that they could be consumed in drinking water. Moreover, the label has necessary mitigation measures to prevent drinking water contamination.

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 non-food use of AdvaCare D.

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.

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. For the current evaluation, the PMRA did not identify the potential for dietary or residential exposure for hydrogen peroxide and peroxyacetic acid as a pesticide. Therefore, there is no requirement for a cumulative health risk assessment at this time.

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 sets science-based MRLs to ensure the food Canadians eat is safe.

There are no proposed food or feed uses for the end-use product. 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

An environmental assessment was not required for this evaluation based on the use pattern.

5.0 Value

5.1 Consideration of Benefits

Currently, all registered laundry sanitizers are based on one active ingredient, sodium hypochlorite (Appendix I, Table 1). The registration of AdvaCare D provides alternative active ingredients for laundry sanitizers. While sodium hypochlorite is effective at sanitizing laundry, it has the potential to react with organic matter and form undesirable chlorinated disinfection by-products. The active ingredients in AdvaCare D, peroxyacetic acid and hydrogen peroxide, break down into acetic acid and water, respectively.

5.2 Effectiveness Against Pests

Data were provided from ten standard laboratory efficacy trials. These trials were scientifically sound and representative of typical laundry sanitizer use. AdvaCare D was tested against a broad range of human pathogens. These data demonstrated the ability of AdvaCare D to reduce levels of bacteria and viruses within laundry samples by levels of 99.9% or greater, when used according to the label directions.

5.3 Non-Safety Adverse Effects

No non-safety adverse effects were identified for the use of AdvaCare D as a laundry sanitizer.

5.4 Supported Uses

The use of AdvaCare D as a laundry sanitizer is supported (Appendix I, Table 2).

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

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

During the review process, hydrogen peroxide and peroxyacetic acid and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] 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 Track 1 substances.
- 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 product are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[5].

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5 *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 1Formulants 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 list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including DIR99-03[7] 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:

- The Integrated System Product Hydrogen Peroxide and PAA 11/15% and the end-use product AdvaCare D do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

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

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 AdvaCare D from the proposed use. Both peroxyacetic acid and hydrogen peroxide are highly reactive and subject to rapid decomposition.

AdvaCare D is expected to be highly acutely toxic by the oral, dermal and inhalation routes and is corrosive to eyes and skin, but is not likely 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.

As the end-use product is for indoor commercial laundry operation, in a laundry machine, with a computerized system control to dispense the product, there is no mixer, loader, or applicator exposure.

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

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

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

There are no postapplication activities where workers are exposed directly to the product. There are no residential uses for AdvaCare D. Because of the nature of the commercial use, no bystander exposure to the end-use product is expected. The risks to handlers and product-users of AdvaCare D are acceptable if the label directions are followed.

The proposed use is not for food. Consequently, the specification of an MRL under the *Pest Control Products Act* is not being recommended. There is no drinking water exposure concern. There were no human incidents involving hydrogen peroxide and/or peroxyacetic acid submitted to the PMRA.

7.2 Value

It is important to ensure that laundry from institutions such as hospitals and long-term care facilities is sanitized to prevent cross-contamination with any bacteria or viruses that may be present. Laundering with detergent alone can reduce the bacteria present on fabric, but does not achieve the level of control provided by a sanitizer. All of the currently registered laundry sanitizers are based on sodium hypochlorite. AdvaCare D would add important alternative active ingredients for this use.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Hydrogen Peroxide and PAA 11/15% and AdvaCare D, containing the technical grade active ingredients hydrogen peroxide and peroxyacetic acid, as a commercial and industrial laundry sanitizer.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product are acceptable.

List of Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
CAS	Chemical Abstracts Service
cwt	centum weight (hundredweight)
ISP	integrated system product
K_{ow}	*n*-octanol-water partition coefficient
MRL	maximum residue limit
PAA	peroxyacetic acid
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
SN	solution
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Tables and Figures

Table 1 Registered Alternatives

There are more than 20 alternative laundry sanitizers currently registered, however, they are all based on a single active ingredient.

Active Ingredient	Pest Control Product # examples of an end-use product with this active ingredient
Sodium hypochlorite	12419, 17363, 20643, 21674, 22749, 29182, 30242, 30243, 30206, 31293, 31600, 27397, 28279, 29183, 29243, 29852, 29876, 30045, 30174, 30514, 31684, 32162

Table 2 List of Supported Uses

Proposed label claim	Supported use claim
Laundry sanitizer (i.e., kills 99.9% of bacteria and viruses)	Accepted as proposed

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2744302	2013, AdvaCare 120 Sanitizer/Sour (Identical product), DACO: 2.14.13,2.14.8 CBI
2744305	2017, Chemistry Requirements for an ISP, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6, 2.7,2.8,2.9 CBI
2744307	1995, OXY-15 - Chemical Characterization EPA Registration No. 1677-164, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.14.1, 2.14.15, 2.14.2, 2.14.3, 2.14.6, 3.5.8, 3.5.9, 830.7000 CBI
2744308	1996, OXY-15 Long-term Storage Stability EPA Registration No. 1677-164, DACO: 2.14.14,3.5.14,3.5.5 CBI
2744309	2017, Environmental Chemistry and Fate Summary, DACO: 2.14.10,2.14.11, 2.14.12,2.14.4,2.14.5,2.14.7,2.14.9,8.1
2790300	2017, % Recent Certificate of Analysis for 15%, DACO: 2.13.3 CBI
2790301	2017, [CBI Removed] rationale, DACO: 2.13.4 CBI
2790302	2015, Quality Assurance Test Method Activity of Peracetic Acid by Acid-Base Titration, DACO: 2.13.1 CBI
2790303	2014, Quality Assurance Test Method Activity of Peracetic Acid by Acid-Base Titration, DACO: 2.13.1 CBI
2801001	2017, Clarification of the use of [CBI Removed], DACO: 2.11.2 CBI
2801002	2017, Listing of Starting Material Suppliers, DACO: 2.11.2 CBI
2745013	2017, Chemistry Requirements for an ISP, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2744343	2015, Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, DACO: 12.5.10
2744344	1993, Peroxy Compounds EPA RED Facts, DACO: 12.5
2744345	2008, SIDS Initial Assessment Profile, DACO: 12.5.2,12.5.4
2744346	2008, SIDS Dossier, DACO: 12.5
2745015	1995, Acute Oral Toxicity in Rats - Median Lethal Dosage Determination of Oxy-15, DACO: 4.6.1
2745016	2017, Scientific Rationale to Waive Requirements for EP Advacare Laundry Disinfectant, DACO: 4.6.2,4.6.4,4.6.5,4.6.6
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B. Additional Information Considered

Published Information

Human and Animal Health

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