Health Canada Santé Canada

Evaluation Report for Category A, Subcategory 2.0 Application

Application Number: 2013-0335
Application: Major New Use
Product: VigorOx 15/23 Antimicrobial Agent
Registration Number: 31329
Active ingredients (a.i.): Hydrogen Peroxide (HPX) and Peroxyacetic Acid (PCA)
PMRA Document Number : **2396955**

Purpose of Application

The purpose of this application was to register the technical grade active ingredient, VigorOx 15/23 Antimicrobial Agent (Registration Number 31329), containing hydrogen peroxide (guarantee 23%) and peroxyacetic acid (guarantee 15%) to be used for manufacturing, formulating or repacking into end-use products that can be used for the treatment of wastewater and sewage effluent antimicrobial agents in public and private treatment facilities. An application for the associated end-use product, VigorOx WWT II, was reviewed concurrently under application number 2013-0346.

Chemistry Assessment

The Active Ingredient, Its Properties and Uses

Identity of the Active Ingredient

Active substances	Hydrogen peroxide Peroxyacetic acid
Function	Slimicide
Chemical names	
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 + $C_2H_4O_3$

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Molecular weight	Hydrogen peroxide: 34.014 Peroxyacetic acid: 76.051
Structural formula	
Purity of the active ingredient	23.0% hydrogen peroxide 15.0% peroxyacetic acid

Physical and Chemical Properties of the Active Ingredient

Technical Product—VigorOx 15/23 Antimicrobial Agent

Property	**Result**
Colour and physical state	Colourless liquid
Odour	Sharp, pungent, vinegar-like odour
Melting range	N/A
Boiling point or range	Hydrogen peroxide: 126ºC Peroxyacetic acid: 105ºC Hydrogen peroxide and peroxyacetic acid will decompose upon heating.
Density	1.14-1.17 g/mL
Vapour pressure	Hydrogen peroxide: 0.047-0.177 kPa at 20ºC (varies depending on concentration) Peroxyacetic acid: 1.87 kPa at 25ºC
Ultraviolet (UV)-visible spectrum	A mixture of hydrogen peroxide and peroxyacetic acid absorbs below 300 nm
Solubility in water at 20°C	Completely soluble in water
Solubility in organic solvents at 20°C	Miscible with polar organic solvents
n-Octanol-water partition coefficient (K_{ow})	Hydrogen peroxide: Log K_{ow} = 0.3 Peroxyacetic acid: Log K_{ow} = -50 (calculated)
Dissociation constant (pK_a)	Hydrogen peroxide: 8.2 Peroxyacetic acid: 8.2 at 19.5ºC
Stability (temperature, metal)	Hydrogen peroxide: stable up to 1 year; stable in high purity aluminum and 304/2316 series stainless steel; decomposition is catalyzed by transition metal ions, solid metals or metal oxides, pH 7 or greater, heat or sunlight. Peroxyacetic acid: Stable to sunlight and metal/metal ions. At high temperatures, hydrogen peroxide and peroxyacetic acid will decompose.

Methods of Analysis

Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredients and the impurities in VigorOx 15/23 Antimicrobial Agent have been assessed to be acceptable for the determinations.

Method for Formulation Analysis

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

Health Assessment

Impact on Human and Animal Health

Toxicology Summary

A detailed review of the toxicological databases for the active ingredients hydrogen peroxide and peroxyacetic acid consisting of waiver rationales was conducted. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure resulting from the intended use of this pest control product.

The submitted waivers referred to toxicity information submitted previously for other products registered by the applicant containing hydrogen peroxide and peroxyacetic acid, and the US Registration Eligibility Decision (RED) document on Peroxy Compounds. Reviews by the European Centre for Ecotoxicology of Chemicals (ECETOC) were also utilized for this review.

The acute toxicity of both hydrogen peroxide and peroxyacetic acid has been well characterized in publicly available scientific literature. The main mode of action of both active ingredients is based on their strong oxidizing and corrosive properties, with their oral, dermal and inhalation toxicities being secondary to corrosivity. VigorOx 15/23 Antimicrobial Agent and VigorOx WWT II are considered to be slightly acutely toxic by the oral and dermal route, and moderately acutely toxic by the inhalation route. They are not likely to be skin sensitizers.

Due to the rapid degradation of hydrogen peroxide and peroxyacetic acid, the hazard posed by VigorOx WWT II is mostly of an acute nature. However, several short-term toxicity studies have been conducted with hydrogen peroxide and peroxyacetic acid, with the test substances administered in the diet or drinking water. The main effect observed from hydrogen peroxide administration over three to ten weeks was decrease in body weight gain and reduced water consumption. Reduced food and water consumption was also observed in studies conducted with peroxyacetic acid, likely due to the odour and irritant properties of the compounds. Stability of the peroxy compounds in either drinking water or feed was also an issue during the tests.

Developmental toxicity information for hydrogen peroxide and peroxyacetic acid was not available at the time of evaluation. However, based on the toxicological information that was

available, coupled with a long history of human exposure as commodity chemicals around the world and their uses as pesticides in the United States, it appears unlikely that treatment related effects will result from maternal exposure to hydrogen peroxide or peroxyacetic acid.

Hydrogen peroxide has been shown to be mutagenic in vitro, but is not genotoxic in vivo due to its rapid decomposition to water and oxygen. Since hydroxyl radicals and singlet oxygen are capable of damaging DNA directly, the genotoxic potential of hydrogen peroxide depends on the accessibility of the hydroxyl radical to target DNA. Based on the limited information available, peroxyacetic acid is considered to be non-mutagenic.

Chronic exposure to 0.4% hydrogen peroxide in drinking water has been shown to cause duodenal tumours in mice; however there is limited or insufficient evidence of carcinogenicity for hydrogen peroxide (PRDD2000-02). There is no available chronic toxicity or carcinogenicity data on peroxyacetic acid.

Occupational Exposure and Risk Assessment

Use Description Scenario

The proposed commercial use for VigorOx WWT II is as an antimicrobial product for wastewater disinfection. The product is to be applied to the final effluent at a rate of 0.5 – 4 ppm peroxyacetic acid. VigorOx WWT II will be packaged in bulk containers (55 gallon drums or greater) which will be connected to a manifold system which applies the product to the effluent. Metering pumps continuously dose the product to the effluent, which minimizes worker exposure to the end-use product.

Occupational Exposure Risk Assessment

Occupational exposure to VigorOx WWT II may occur when the end-use product containers are connected to the manifold system, and is expected to be by the dermal or inhalation route, or through accidental splash to the eyes. Personal protective equipment (PPE) requirements on the end-use product label will instruct workers to wear goggles, face shield, protective coveralls, boots and chemical resistant gloves while transferring and handling the product. In addition, precautionary statements instruct workers to ensure that air concentrations of peroxyacetic acid and hydrogen peroxide in the workplace do not exceed exposure levels established by Occupational Health and Safety Authorities in their jurisdiction, and that if values do exceed those levels, that they are to wear NIOSH approved respiratory protection. Other precautionary and hygiene statements on the end-use product label include instructions to not breathe the vapor, to not enter an enclosed area without proper respiratory protection, and to wash thoroughly with soap and water after handling. Exposure of workers to VigorOx WWT II will be appropriately mitigated through the requirements for PPE, observing exposure levels of the active ingredients, observing precautionary and hygiene statements, and the nature of the closed system where the end-use product will be used. Therefore, occupational exposure to VigorOx WWT II is expected to be minimal when workers follow the label directions.

Bystander Exposure and Risk Assessment

As VigorOx WWT II is to be used in a closed system in a wastewater treatment plant where bystanders are not expected to be present, no bystander exposure to the end-use product is expected to occur.

Post-Application Exposure

There is a potential for worker exposure to VigorOx WWT II during post-application activities such as removing the spent container from the manifold system. However, post-application exposure to VigorOx WWT II is expected to be minimal when workers follow the required PPE and precautionary and hygiene statements on the product label.

Incident Reports Related to Human and Animal Health

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Two incident reports for products containing hydrogen peroxide have been received by PMRA, which were aquaculture related and involved fish deaths. As of December 2013, there were no incident reports for end-use products containing peroxyacetic acid.

Environmental Assessment

Impact on the Environment

Fate and Behaviour in the Environment

Under the intended use pattern, VigorOx WWT II is injected into water and therefore the aquatic environment will be the primary compartment exposed. Terrestrial environments are unlikely to be exposed to this product and as such data specific to terrestrial fate and toxicity were not considered.

Peroxyacetic acid undergoes hydrolysis, spontaneous decomposition, and metal-catalyzed decomposition in the aquatic environment. Peroxyacetic acid hydrolyzes to acetic acid and water. Hydrolysis is a major route of transformation in the environment under neutral and alkaline conditions. Peroxyacetic acid also decomposes spontaneously and rapidly in aqueous solution to yield acetic acid and oxygen under slightly acidic to alkaline conditions. Decomposition, catalyzed by metal ions, is more pronounced at higher pH. Half-lives for peroxyacetic acid under acidic conditions range from seven to 12 days, and at neutral or alkaline conditions half-lives are less than one day.

Hydrogen peroxide is unstable in water and decomposes to oxygen and water. The hydrolysis half-life was 60 hours in sea water samples. Hydrogen peroxide is also subject to phototransformation in the aquatic environment with a half-life of 10 days, but is not considered a major route of transformation. Biotransformation of hydrogen peroxide is not a major route of transformation in the environment.

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 to 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 may 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. Toxicology endpoints 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). If the generation of quantitative data is not practical for a particular active ingredient/product, a qualitative assessment may be more appropriate.

The risk assessment for peroxyacetic acid and hydrogen peroxide is quantitative. Screening level and refined assessments (where further characterization of risk was required) were carried out for the aquatic environment only, as terrestrial exposure will not occur under the current use pattern for the end-use product VigorOx WWT II. An uncertainty factor of 0.5 and 0.1 was applied to invertebrate and fish acute endpoints, respectively, in order to account for differences in inter- and intra- species sensitivity and varying protection goals.

The maximum amount of peroxyacetic acid required at the injection point is 4 mg/L. Based on the ratio of the guarantee (1.5:1, hydrogen peroxide to peroxyacetic acid), the maximum rate for hydrodgen peroxide is 6 mg/L. Assuming these concentrations are inputted directly into the environment, mixing with surrounding water at or soon after entry would be expected. A previous review by Environment Canada and Health Canada (Priority Substances List Assessment Report, Ethylene Glycol, 2000) utilized a conservative dilution factor of 10 (river flow/total effluent discharge rate) when conducting a similar risk assessment of industrial effluent discharge into the aquatic environment. This value was determined based on a literature review of appropriate data, and is also applicable to the current use pattern. In addition, the Environment Canada and Health Canada review reported from the literature an overall median dilution factor of 100 for large water bodies. Therefore, for the current review, the dilution factor of 10 was applied towards a screening level risk assessment to represent a conservative scenario, and 100 was applied towards a refined risk assessment to represent a more realistic scenario for most Canadian aquatic receiving environments. The concentration of the active ingredients at the point of injection is divided by the dilution factors to provide the estimated exposure concentrations (EECs), and assumes no decomposition.

Risks to Terrestrial Organisms

No data were submitted on toxicity of peroxyacetic acid and hydrogen peroxide to non-target terrestrial organisms. Under the intended use pattern, the exposure of terrestrial organisms to VigorOx WWT II will be very limited and, therefore, the risk to these organisms was not assessed.

Risks to Aquatic Organisms

Peroxyacetic acid:

Peroxyacetic acid has been shown to cause acute adverse effects to aquatic organisms (Appendix 1, Table 2). Using the most conservative endpoint for each group of organisms, as well as a conservative estimated exposure concentration in aquatic systems, the screening level risk quotient exceeded the level of concern for freshwater invertebrates, fish, and algae (Appendix 1, Table 3).

Since the level of concern was exceeded at the screening level for invertebrates, fish, and algae, a refined risk assessment was carried out utilising the dilution factor of 100 and the same conservative endpoints (Appendix 1, Table 4). The risk quotients from the refined assessment were below the level of concern. Therefore, based on the refined risk assessment, the use of VigorOx WWT II under the intended use pattern is not expected to pose a risk to fish and algae when considering a more realistic dilution factor of 100.

Hydrogen peroxide:

The toxicity of hydrogen peroxide to aquatic organisms is summarized in Appendix 1, Table 2. Using the most conservative endpoint for each group of organisms, as well as a conservative estimated exposure concentration in aquatic systems, the screening level risk quotient exceeded the level of concern for freshwater algae (Appendix 1, Table 3). The level of concern was not exceeded for any other non-target aquatic organism.

Since the level of concern was exceeded at the screening level for algae, a refined risk assessment was carried out utilising the dilution factor of 100 and the same conservative endpoints (Appendix 1, Table 5). The risk quotient from the refined assessment was below the level of concern. Therefore, based on the refined risk assessment, the use of VigorOx WWT II under the intended use pattern is not expected to pose a risk to algae when considering a more realistic dilution factor of 100.

Pest Control Product Policy Considerations

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, peroxyacetic acid and hydrogen peroxide were assessed in accordance with the PMRA Regulatory Directive DIR99-03[1] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

> Peroxyacetic acid and hydrogen peroxide do not meet Track 1 criteria, and are not considered Track 1 substances. These substances are not persistent and do not bioaccumulate.

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*[2]. The list is used as described in the PMRA Notice of Intent NOI2005-01[3] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[4], 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:

> Technical grade peroxyacetic acid and hydrogen peroxide and the end-use product VigorOx WWT II 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[5].

Value Assessment

Directions for Use

- VigorOx WWT II is added to effluent water at a concentration of 0.5 ppm to 4 ppm with a contact time of approximately 30 to 45 minutes.
- May be applied to effluent water discharged from secondary, or tertiary treatments; and to effluent water discharged from trickle bed or percolating fluidized bed filters.

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

[2] *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.*

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

[4] DIR2006-02, PMRA Formulants Policy.

[5] DIR2006-02, PMRA Formulants Policy.

Mode of Action

Both hydrogen peroxide and peroxyacetic acid are strong oxidizing agents. They will oxidize the outer cell membrane of bacteria leading to cell lysis.

Effectiveness Against Pests

The laboratory test and the three operational trials provided have shown that 1.5 ppm peroxyacetic acid was usually sufficient for effective control of various types of bacteria such as fecal coliforms. One trial has also shown that concentrations up to 4 ppm could provide additional reduction of bacterial counts if required. The range of rates will allow flexibility in the treatment depending on the various factors that may influence the amount of biocide needed for effective control such as seasonal variations, weather and treatment plant location.

Acceptable Efficacy Claims

VigorOx WWT II is acceptable for use as a disinfectant in the treatment of sewage and wastewater effluent related to public and private wastewater treatment plants at rates of 0.5-4 ppm peroxyacetic acid.

Economics

Wastewater treatment plants may receive financial penalties when exceeding the provincial bacterial discharge limit. Moreover, some municipalities using chlorine treatment have been required to install dechlorination systems in order to address disinfection by-products present in the water. Upgrading an existing plant to include a dechlorination process typically results in significant costs and operational complexity. Therefore, the availability of an alternate disinfection method not requiring dechlorination such as VigorOx WWT II may alleviate the financial burden of wastewater treatment plants.

Sustainability

Survey of Alternatives

Sodium hypochlorite is the only other active ingredient currently registered for the treatment of municipal wastewater effluent; however, this active is not permitted for this use by all provinces or municipalities. UV light can be used as a non-chemical alternative, but its performance is directly related to wastewater opacity. If the wastewater contains high concentration of suspended solids, inefficient disinfection of the wastewater is likely to occur (Appendix 1, Table 6).

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

No information has been provided. However, since this product is a strong oxidant which affects different targets in the cell, it is not expected that the development of resistance will be a problem or concern.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of VigorOx 15/23 Antimicrobial Agent containing hydrogen peroxide and peroxyacetic acid, to be used for manufacturing, formulating or repacking into end-use products that can be used for the treatment of wastewater and sewage effluent antimicrobial agents in public and private treatment facilities.

List of Abbreviations

a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
DACO	Data Code
DNA	deoxyribonucleic acid
EC_5	effective concentration on 5% of the population
EC_{50}	effective concentration on 50% of the population
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EEC	estimated environmental exposure concentration
EP	End-use product
g	gram(s)
h	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
kP_a	kilopascal(s)
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
mg	milligram(s)
mL	millilitre(s)
N/A	not applicable
nm	nanometre(s)
NIOSH	National Institute for Occupational Safety and Health
NOEC	no observed effect concentration
pH	potential of hydrogen
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RED	Reregistration Eligibility Decision
TGAI	Technical Grade Active Ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight for weight

Appendix I Tables and Figures

Table 1 Summary of acute toxicity, irritation and sensitization of hydrogen peroxide and peroxyacetic acid

PARAMETER	HYDROGEN PEROXIDE	PEROXYACETIC ACID
Acute oral LD_{50}	1193 mg/kg bw (male rat, 35% w/w) (PRDD2000-02) 1270 mg/kg bw (female rat, 35% w/w) (PRDD2000-02) 2000 mg/kg bw (mouse) (USEPA RED) **Slightly acutely toxic**	> 1000 mg/kg bw (rat, 17% w/w) (PRDD2000-02) 1540 mg/kg (rat, 100% w/w) (USEPA RED) **Slightly acutely toxic**
Acute dermal LD_{50}	4060 mg/kg bw (rat) (USEPA RED) > 2000 mg/kg bw (rabbit, 35% w/w) (PRDD2000-02) **Low acute toxicity**	1410 mg/kg bw (rabbit) (USEPA RED) **Slightly acutely toxic**
Acute inhalation LC_{50}	0.315 mg/L (mouse) (ERC2010-10) **Moderately acutely toxic**	0.45 mg/L (rat) (USEPA RED) **Moderately acutely toxic**
Primary eye irritation	**Corrosive** (rabbit) (PRDD2000-02)	**Corrosive** (rabbit) (PRDD2000-02)
Primary skin irritation	**Corrosive** (rabbit) (USEPA RED)	**Corrosive** (rabbit) (PRDD2000-02)
Skin sensitization	Not a sensitizer (guinea pig) (ECETOC, 1993)	Not a sensitizer (PRDD2000-02)

Table 2 Toxicity of peroxyacetic acid and hydrogen peroxide to aquatic organisms

Species	Toxicity end point (mg a.i./L)	Degree of Toxicity[a]
Peroxyacetic acid		

Invertebrates (water flea *Daphnia magna*)	48 h EC_{50}=0.73 (immobilization)	Highly toxic
Fish (Rainbow trout *Oncorhynchus mykiss*)	96 h LC_{50}=1.6	Moderately toxic
Fish (Bluegill sunfish *Lepomis macrochirus*)	96 h LC_{50}=1.1	Moderately toxic
Algae (green algae *Selenastrum capricornutum*)	120 h EC_{50}=0.18	Not applicable
Hydrogen peroxide		
Fathead minnow (*Pimephales promelas*)	NOEC=5 LC_{50}=16.4	Slightly toxic
Channel catfish (*Ictalurus punctatus*)	LC_{50}=37.4	Slightly toxic
Golden orfe (*Leuciscus idus melanotus*)	LC_{50}=35	Slightly toxic
Scud (*Gammarus* sp)	LC_{50}=4.42	Moderately toxic
Snail (*Physa* sp)	LC_{50}=17.7	Slightly toxic
Water flea *Daphnia pulex*	NOEC=1.0 LC_{50}=2.4	Moderately toxic
Water flea *Daphnia magna*	EC_{50}=7.7 (immobilization)	Moderately toxic
Freshwater algae *Mycrocystis* *Raphidiopsis* *Ankistrodesmus* *Anabaena*	EC_5=1.7 EC_5=6.8 EC_5=9.9 EC_5=17 (chlorophyll reduction)	Not applicable
Marine diatom (*Nitzchia closterium*)	EC_{50}=0.85	Not applicable
Coontail (*Ceratophyllum demersum*)	34 mg/L 80% (necrosis) 30% (necrosis)	Not applicable

[a]USEPA classification

Table 3 Summary of screening level risk assessment to aquatic organisms

Species	End point	EEC mg a.i./L	Risk quotient[a]
Peroxyacetic acid			
Invertebrates (water flea *Daphnia magna*)	½ EC_{50} = 0.37 mg a.i./L	0.4	**1.08**
Fish (Bluegill sunfish *Lepomis macrochirus*)	1/10th LC_{50} = 0.11 mg a.i./L	0.4	**3.64**
Algae (green algae *Selenastrum capricornutum*)	½ EC_{50} = 0.09 mg a.i./L	0.4	**4.44**
Hydrogen peroxide			
Invertebrates (water flea *Daphnia pulex*)	½ LC_{50} = 1.2 mg a.i./L	0.6	0.5
Fathead minnow (*Pimephales promelas*)	1/10th LC_{50} = 1.64 mg a.i./L	0.6	0.37
Algae (*Nitzchia closterium*)	½ EC_{50} = 0.43 mg a.i./L	0.6	**1.4**

[a]bolded values indicate that the level of concern is exceeded (LOC = 1.0)

Table 4 Summary of refined risk assessment for peroxyacetic acid to aquatic organisms

Species	End point	EEC mg a.i./L	Risk quotient
Invertebrates (water flea *Daphnia pulex*)	½ LC_{50} = 0.37 mg a.i./L	0.04	0.11
Fish (Bluegill sunfish *Lepomis macrochirus*)	1/10th LC_{50} = 0.11 mg a.i./L	0.04	0.18
Algae (*Selenastrum capricornutum*)	½ EC_{50} = 0.09 mg a.i./L	0.04	0.22

Table 5 Summary of refined risk assessment for hydrogen peroxide to aquatic

organisms

Species	End point	EEC mg a.i./L	Risk quotient
Algae (*Nitzchia closterium*)	½ EC_{50} = 0.43 mg a.i./L	0.06	0.14

Table 6 Currently registered alternatives

Active Ingredient	Registration Number
Sodium hypochlorite	12419
Sodium hypochlorite	29852
Sodium hypochlorite	29876

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	References
2266533	Part 2 - Chemistry Requirements for TGAI, DACO: 2.1,2.10,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
2266535	2008, Product Identity, Composition, and Formulation, 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
2266536	2008, Product Identity, Composition, and Formulation, DACO: 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3 CBI
2266545	2009, Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for Hydrogen Peroxide, Peroxyacetic acid, and Potassium Peroxymonosulfate for Registration Review, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.
2320148	2013, VigorOx 15/23 Antimicrobial Agent Starting Materials, DACO: 2.11.3 CBI
2320149	2013, VigorOx 15/23 Antimicrobial Agent Certified Limits, DACO: 2.12.1 CBI
2320150	2013, VigorOx 15/23 Antimicrobial Agent Methodology/Validation, DACO: 2.13.1
2320151	2013, VigorOx 15/23 Antimicrobial Agent Batch Data, DACO: 2.13.3 CBI
2320152	2013, VigorOx 15/23 Antimicrobial Agent Density/Specific Gravity, DACO: 2.14.6
2266572	Part 3 - Chemistry Requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.5.1, 3.5.3, 3.5.4, 3.5.5
2266573	2008, Product Identity, Composition and Formulation, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.6, 3.5.7, 3.5.8
2266574	2008, Product Identity, Composition and Formulation (CBI), DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI

2266575 2008, 15% Peracetic Acid, 23% Hydrogen Peroxide: Determination of Viscosity for (Capillary Viscometer Method), DACO: 3.5.9

2266576 Part 3.5.10: Storage Stability and Part 3.5.14: Corrosion Characteristics, DACO: 3.5.10, 3.5.14

2320168 2013, VigorOx WWT II Establishing Certified Limits, DACO: 3.3.1 CBI

2320169 2013, VigorOx WWT II Enforcement Analytical Method, DACO: 3.4.1

2320170 2013, VigorOx WWT II Density/Specific Gravity, DACO: 3.5.6

2.0 Human and Animal Health

2266537 1993, US EPA RED Facts: Peroxy Compounds, DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6.

2266538 2009, US EPA Summary of Human Health Effects Data for the Peroxy Compounds Registration Review Decision Document, DACO: 4.3.1, 4.3.7, 4.4.2, 4.5.2, 4.5.4, 4.5.5.

2266578 Part 5 - Occupational Exposure Information Requirements, DACO: 5.2.

3.0 Environment

2119892 2007, United States Environmental Protection Agency. Ecological risk and fate assessment of Proxitane WW-12 microbiocide label amendment to add disinfection of sewage and wastewater effluent. PC codes: 000595 (hydrogen peroxide), 063201 (ethaneperoxoic acid); DP barcodes: D334873, D334954. DACO: 8.1, 8.2.3.1, 8.2.4.1, 8.3.1, 8.4.1, 9.1

4.0 Value

2266583 Part 10 - Value and Efficacy, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

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B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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2385673 Joint Assessment of Commodity Chemicals No. 40: Peracetic Acid and its Equilibrium Solutions, 2001, ECETOC 2001, ISSN-0773-6339-40, Brussels, Belgium.

2.0 Environment

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ISSN: 1911-8082