

# **Evaluation Report for Category B, Subcategory 1.2 Application**

Application Number:	2015-1975
Application:	New TGAI or ISP Product Chemistry - New source (site) new
	registrant
Product:	High Purity Grade 70% H <sub>2</sub> O <sub>2</sub>
<b>Registration Number:</b>	31776
Active ingredients (a.i.):	Hydrogen peroxide
<b>PMRA Document Number:</b>	2662663

# **Purpose of Application**

The purpose of this application was to register a new use site category, aquaculture, for the hydrogen peroxide technical grade active ingredient product, High Purity Grade 70%  $H_2O_2$ , with the associated commercial end-use product Aquaparox 50.

#### **Chemistry Assessment**

Common Name:	Hydrogen peroxide
IUPAC* Chemical Name:	Hydrogen peroxide
CAS <sup>†</sup> Chemical Name:	Hydrogen peroxide

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Property	Result
Colour and physical state	Colourless liquid
Nominal concentration	70.5%
Odour	Slightly sharp or pungent acidic, irritating odour
Density	1.29 g/mL
Vapour pressure at 20°C	0.1 kPa
pH	1.0-2.0
Solubility in water	Completely soluble
n-Octanol/water partition	$Log K_{ow} = -1.57$ (estimated)
coefficient	

High Purity Grade 70%  $H_2O_2$  has the following properties:

The required chemistry data for High Purity Grade 70%  $H_2O_2$  have been provided, reviewed, and found to be acceptable.



#### Health Assessments

The acute toxicity of products containing 50% hydrogen peroxide has been previously assessed based on published scientific literature. The associated end-use product, Aquaparox 50, is considered to be highly acutely toxic via the oral route, of low acute toxicity via the dermal route, and of moderate acute toxicity via the inhalation route. The product is expected to be severely corrosive or irritating to the eyes, corrosive to the skin, but not a skin sensitizer. The label contains appropriate hazard statements and precautionary statements on avoiding eye and skin contact and the inhalation of fumes.

It is expected that potential exposures and risks from hydrogen peroxide from loading the bulk Aquaparox 50 into holding tanks on well boats or barges/vessels used for tarpaulin applications will not be of concern provided that the label precautionary and personal protective equipment (i.e., chemical resistant coveralls, face shield, long-sleeved shirt, pants, socks, boots, gloves) statements are followed.

The use of the well boat method for applying Aquaparox 50 represents essentially a closed system. As a result, exposures and risks from hydrogen peroxide during application, clean-ups, and repairs are not expected to be of concern provided that the label precautionary and personal protective equipment statements are followed.

The tarpaulin method does not have the same closed system characteristics as the well boat method and greater amounts of hydrogen peroxide could be handled on a daily basis. Therefore, there is a greater potential for occupational dermal, ocular and inhalation exposures. However, if workers involved in application, clean-ups, and repairs for Aquaparox 50 using the tarpaulin method follow similar label precautionary and PPE statements as those for the well boat method, with the additional use of a NIOSH-approved respirator, potential exposures and risks are not expected to be of concern.

Divers entering sea cages to retrieve any dead fish a few hours after Aquaparox 50 treatments or the next day are not expected to be exposed to or experience risks from hydrogen peroxide in sea water. Well boat wells are flushed with clean sea water before fish are returned to the sea cages and hydrogen peroxide used in tarpaulin treatments is expected to degrade and disperse once the tarpaulins are removed.

Given the anticipated decomposition and dissipation of hydrogen peroxide in sea water following treatments with the associated end-use product Aquaparox 50 and label statements on restricting entry to fish farms for bystanders until treatments are complete and tidal flushing occurs, bystander exposures and risks are not expected to be of concern.

Food residue exposure to hydrogen peroxide from the proposed use of Aquaparox 50 is not expected to be of concern. The use of Aquaparox 50 to treat sea lice on farmed Atlantic salmon according to label directions is not expected to increase the levels of hydrogen peroxide in the edible tissues of the salmon beyond endogenous background levels due to the rapid decomposition of the compound in sea water and the natural degradation in fish blood and tissues. There is no withdrawal period post treatment prior to harvesting the fish (i.e., no pre-harvest interval).

The use pattern for the associated end-use product involves direct application to salmon in well boat wells or tarpaulins in aquaculture sea cages in the open ocean. Consequently, hydrogen peroxide is not expected to contaminate drinking water sources or supplies.

# **Incident Reports:**

As of June 17, 2016, no human incidents involving the active ingredient hydrogen peroxide were reported to the PMRA.

# Maximum Residue Limit

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

Since hydrogen peroxide is naturally occurring in fish tissues and use of the associated end-use product is not expected to increase concentrations beyond endogenous levels, a maximum residue limit (MRL) is not specified for the proposed use.

### **Environmental Assessment**

Hydrogen peroxide is highly reactive in natural waters and breaks down rapidly to form water and oxygen. It is not expected to accumulate over time in either sediment or in the water column. Hydrogen peroxide is highly toxic to marine algae. However, based on its rapid transformation, it is not expected to pose a risk of concern to algae populations when used according to label instructions. Hydrogen peroxide is not expected to pose a risk of concern to any other non-target aquatic organisms. Environmental concerns have been mitigated through adequate label statements.

### Value Assessment

A value assessment was not required for this application.

# Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of the new use site category, aquaculture, on the technical grade active ingredient product High Purity Grade 70%  $H_2O_2$ .

#### References

PMRA	Reference
Document	
Number	
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	2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.2,2.3,2.3.1,2.4,2.5,2 .6,2.7,2.8,2.9 CBI
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	greater than 35%), DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13, 2.14.2,2.14.3,
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	DACO: 8.1,8.2.2.3,8.2.3.3.2,8.2.3.5.4,8.2.4.1,8.2.4.2
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#### ISSN: 1911-8082

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