

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

Ministerial Condition No. 18420; Poly(oxy-1,2-ethanediyl), α , α' -(iminodi-2,1-ethanediyl) bis[ω -hydroxy-, *N*-[3-(C₁₀₋₁₆-alkyloxy)propyl] derivatives, di-Et sulfate-quaternized

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and determined that the substance is anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and/or import are authorized subject to conditions on its use, handling, and disposal as described in Ministerial Condition No. 18420 published in the *Canada Gazette* Part I, Vol. 150, No. 6, February 6, 2016.

Substance Identity

The chemical, poly(oxy-1,2-ethanediyl), α , α' -(iminodi-2,1-ethanediyl) bis[ω -hydroxy-, *N*-[3-(C₁₀₋₁₆-alkyloxy)propyl] derivatives, di-Et sulfate-quaternized (Chemical Abstracts Service Registry No. 70983-58-3), can be classified as a quaternary ammonium compound.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as an antistatic agent. Potential uses include other industrial and consumer applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water because it is anticipated to biodegrade. The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors of <250 L/kg.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate to high (median lethal concentration, median effective concentration and no-observed-effect concentration (NOEC) <10 mg/L) acute toxicity in aquatic organisms. The predicted no-effect concentration was calculated to be 1-10 μ g/L

using the NOEC from the most sensitive organism (aquatic invertebrates), which was used to estimate the ecological risk.

The notified and other potential (releases associated with increased transportation and cleaning of storage totes) activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. The predicted environmental concentration for notified activities is estimated to be 0.001-1000 mg/L.

Based on the predicted range of environmental concentrations in conjunction with the moderate to high acute toxicity, the substance is anticipated to cause ecological harm in Canada. The risks have been identified as release of the substance to water when used as notified and through transport and manufacture.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a moderate potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose 300-2000 mg/kg body weight), and a low to moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg bw/day; 90-day NOAEL >100 mg/kg bw/day). It is a moderate skin irritant but not a dermal sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as notified, direct exposure of the general population is not expected. Indirect exposure of the general population is expected to be minimal. If potential uses of the substance were to include consumer applications, it is anticipated that there would be increased potential for direct human exposure.

Assessment Conclusion

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64(a) of CEPA.

Due to the identified risk and potential risks to the environment and human health if the substance were released to water or used in consumer application, Ministerial Condition No. 18420 was published in the *Canada Gazette* Part I, Vol. 150, No. 6 on February 6, 2016. The Ministerial Condition restricts the manner in which the notifier may manufacture or import the substance, as well as imposes restrictions on use, handling or disposal in order to mitigate the risks that have been identified.