

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

Ministerial Condition Nos: 17554 and 16954: Oxirane, 2-methyl-, polymer with oxirane, mono-C11-14-alkyl ethers, branched, sulfates, sodium salts, Chemical Abstracts Service Registry No. 78355-51-8

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), and pursuant to section 83 of that 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 or import is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 17554](#) published in the *Canada Gazette* Part I, Vol. 148, No. 16, April 19, 2014 and in [Ministerial Condition No. 16954](#) published in the *Canada Gazette* Part I, Vol. 146, No. 40, October 6, 2012.

Substance Identity

The substance is a polymer that can be classified as an alkyl polyethoxylate/propoxylate sulfate polymer. The substance meets the [Reduced Regulatory Requirements criteria](#).

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10,000 kg/yr for use as a surfactant in enhanced oil recovery 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 a surfactant which is expected to be persistent in this compartment. It has limited potential for abiotic and biotic degradation. The substance is not expected to be bioaccumulative based on its very high water solubility and high number average molecular weight (greater than 1,000 daltons).

Ecological Assessment

Based on the available hazard information on the substance, the substance has high acute toxicity to fish ($LC_{50} < 1$ mg/L) and moderate acute toxicity to daphnia (EC_{50} 1-10 mg/L). The predicted no effect concentration was based on analogue data and was calculated to range between 1 and

10 µg/L using the 72h-EC₅₀ from the most sensitive organism (algae), which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from formulation activities and the cleaning of transportation vessels by release of the substance to surface water in quantities > 1 kg/day. The predicted environmental concentration for the notified activity is estimated to be > 1 µg/L.

Based on the potential for transportation and formulation exposures, in conjunction with the high ecotoxicity, the substance is anticipated to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on surrogate data from structurally related chemicals, the substance is expected to have low potential for acute toxicity by the oral and dermal routes of exposure (LD₅₀ > 2000 mg/kg bw) and moderate potential for subchronic toxicity following repeated dosing via the oral and dermal routes of exposure in mammalian test animals (NOAEL=30-300 mg/kg bw). It is a moderate to severe eye and skin irritant at high doses but a mild irritant at lower doses. It is not expected to be a dermal sensitizer. It is not mutagenic *in vitro*, therefore the substance is unlikely to cause genetic damage.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

When used as a surfactant in enhanced oil recovery applications, direct exposure of the general population is expected to be negligible. Indirect exposure of the general population from environmental media such as drinking water is expected to be low as a result of the notified use. However, if the substance is used as a surfactant in personal care products and household cleaning products, an increased potential for direct dermal exposure may exist.

Based on the low potential for both direct and indirect exposure from its notified use, the substance is not likely to pose a significant health risk to the general population. However, based on the high potential for direct dermal exposure of the general population and the potential for both subchronic and cutaneous toxicity, the use of the substance in personal care products and household cleaning products may result in the substance becoming harmful to human health.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(a) of CEPA 1999 and may constitute a danger in Canada to human life or health according to the criteria under paragraph 64(c) of CEPA 1999.

Due to the identified risk to the environment related to the aquatic toxicity if the substance is used as a surfactant in enhanced oil recovery applications, two ministerial conditions were issued to restrict the manner in which the notifiers may manufacture, import use, handle, or dispose of

the substance in order to mitigate the potential risk. The potential risk to the general population related to subchronic toxicity and cutaneous effects if the substance is used in personal care products or household cleaning products will also be mitigated by these Ministerial Conditions, as the only permitted use of the substance is as a surfactant in enhanced oil recovery applications.

A conclusion under CEPA 1999, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.