

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

Ministerial Condition No: 17718: Oxirane, 2-methyl-, polymer with oxirane, mono(hydrogen sulfate), alkyl ethers, sodium salts

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 environment or human health in Canada, its manufacture and import is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 17718](#) published in the *Canada Gazette* Part I, Vol. 148, No. 35, August 30, 2014.

Substance Identity

The substance is a polymer that can be classified as an alkyl polyethoxylate/propoxylate sulfate polymer. The substance does not meet the [Reduced Regulatory Requirements criteria](#).

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10,000 kg/year to be used as a component of a surfactant blend at oil and gas drilling sites.

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 expected to experience limited biodegradation, however it is anticipated to be persistent in the aquatic compartment. The substance is not expected to be bioaccumulative based on its very high water solubility and low octanol-water partition coefficient.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has high acute toxicity to algae and fish ($(L(E)C_{50} < 1 \text{ mg/L})$) and moderate toxicity to daphnia ($LC_{50} 1\text{-}10 \text{ mg/L}$). The predicted no effect concentration was calculated to range between 1 and 30 $\mu\text{g/L}$ using the 72h- EC_{50} from the most sensitive organism (algae).

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 activities is expected to be mainly from releases to water at levels > 1 kg/day resulting from manufacturing, offshore use and cleaning of transportation vessels. The predicted environmental concentrations for notified activities are estimated to range 3 - 40 µg/L.

Based on potential aquatic exposure in conjunction with high acute aquatic toxicity, the substance is anticipated to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on two structurally related chemicals, the substance has a low potential for acute toxicity by the oral route of exposure (LD50>2000 mg/kg bw), and a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (higher liver weight, NOAEL>100 mg/kg bw/day). It is expected to be a skin and eye irritant. It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used in an industrial setting for 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. Based on the negligible direct exposure and low indirect exposure, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

However, the potential use of the substance in personal care products and household cleaning products may significantly alter the exposure of the general population to the substance, primarily via the dermal route. Given its moderate sub-chronic oral toxicity (elevated liver weight), these potential uses may therefore result in the substance becoming harmful to human health.

Assessment Conclusion

The substance is suspected to be toxic to the environment according to the criteria under paragraph 64(a) of CEPA 1999 and to have the potential to be harmful to human health according to the criteria under paragraph 64(c).

Due to the identified risk to the environment related to the aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture and import, use, handle, and dispose of the substance in order to mitigate these potential risks, as described in [Ministerial Condition No. 17718](#), published in the *Canada Gazette* Part I, Vol. 148, No. 35, August 30, 2014. The potential risk to the general population related to subchronic toxicity if the substance is used in personal care products or household cleaning products will also be mitigated by this Ministerial Condition.

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