

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

Ministerial Condition No: 17799: Poly(oxy-1,2-ethanediyl), α -[2-(tetrahydro-1 (2H)-pyrimidinyl) alkyl]- ω -hydroxy-, N-tallow alkyl derivs., di-Me 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 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 or import is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 17799](#) published in the *Canada Gazette* Part I, Vol. 148, No. 47, November 22, 2014.

Substance Identity

The substance is a polymer that can be classified as a poly(ether) cycloalkylamine salt. Dimethylsulfate is used as a methylating agent, and the resulting monomethylsulfate is left as a counter ion. The substance does not meet the [Reduced Regulatory Requirement criteria](#).

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/year for use as a surfactant in corrosion inhibitor formulations for oilfield 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 modelled bioaccumulation factor (BAF) and bioconcentration factor (BCF).

Ecological Assessment

Based on available hazard information on an acceptable analogue, the substance is expected to have high acute toxicity to fish and algae ($LC_{50} < 1 \text{ mg/L}$) and moderate acute toxicity to daphnia ($EC_{50} 1\text{-}10 \text{ mg/L}$). The predicted no effect concentration was based on analogue data and was calculated to range between 1 and 10 $\mu\text{g/L}$ using the 72h- EC_{50} 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 and the cleaning of transportation vessels by release of the substance to surface water in quantities $> 1 \text{ kg/day}$. The predicted environmental concentration for the notified activity is estimated to be $> 1 \mu\text{g/L}$.

Based on the potential for aquatic exposures to exceed the predicted no-effect concentration, it is suspected that the substance is capable of causing ecological harm in Canada. The risks have been identified with the formulation of the substance and the cleaning of transportation vessels.

Human Health Assessment

Based on the available hazard information on the substance, it has a low to moderate potential for acute toxicity by the oral route of exposure. The substance is expected to be a dermal irritant and to cause serious damage to eyes.

When used as a raw material additive in corrosion inhibitor formulations in the oil and gas sector, direct exposure of the general population is expected to be negligible, as there are no consumer applications identified. Releases of the substance to the environment are expected to be negligible from an oil and gas site. Levels of releases from formulation and from the cleaning of transportation vessels do not trigger concerns for human health. Therefore, indirect exposure of the general population from environmental media such as drinking water is also not expected. Based on the low potential for direct and indirect exposure of the substance when used as notified, it is unlikely to be 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.

Due to the identified risk to the environment related to the aquatic toxicity if the substance is used in corrosion inhibitor formulations for oilfield applications, a [Ministerial Condition No. 17799](#) was published in the Canada Gazette Part I, Vol. 148, No. 47 on November 22, 2014 to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use, handling, and disposal in order to mitigate these potential risks.

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.