

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

Ministerial Condition No. 17160: Amines, N,N,N'-trimethyl-N'- alkyltrimethylenedi, reaction products with sodium chloroacetate

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 and import is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 17160](#), published in the *Canada Gazette* Part I, Vol. 147, No. 24, June 15, 2013.

Substance Identity

The substance is a chemical that is an amphoteric surfactant.

Notified Activities

The substance is proposed to be manufactured in or imported into Canada in quantities greater than 10 000 kg/yr for use as a component of bitumen emulsions.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and sediment. The substance is not expected to be persistent in these compartments because of its short half-life (> 10 – 21 days). The substance is not expected to be bioaccumulative based on its very low log K_{ow} (≤ 0) and low bioconcentration/bioaccumulation factors (< 250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has high acute toxicity ($LC_{50} < 1$ mg/L) to fish, daphnids and algae. The predicted no effect concentration was calculated to be

< 10 µg/L using the LC₅₀ from the most sensitive organism (fish), which was used to estimate the environmental risk.

The notified and 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 release of the substance to water following cleaning of transportation vessels. The predicted environmental concentration for notified activities is estimated to be < 10 µg/L. In addition, potential activities for the substance, including manufacture, use in textile applications, and use in industrial laundry detergents, may result in significant ecological exposures through release of the substance to water.

Based on the potential for aquatic exposures exceeding its predicted no effect concentration, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with releases from transportation vessels. Potential risks have also been identified with manufacture of the substance and its use in textile applications and industrial laundry detergents.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low to moderate potential for acute toxicity by the oral route of exposure (oral LD₅₀ > 1000 mg/kg bw) and a low potential for acute toxicity by the dermal route of exposure (dermal LD₅₀ > 2000 mg/kg bw). While the subchronic oral NOAEL indicates a potential for moderate (10-1000 mg/kg bw/day) toxicity following repeated oral exposure, based on the severity of effects seen on the surrogate substances tested (observed mortality, forestomach effects and systemic effects in mammalian test animals), the substance is potentially moderately to highly toxic following repeated oral exposure. The substance is potentially a mild to moderate eye and skin irritant (maximum average score < 50; primary irritation index < 5) and a potential skin sensitizer (EC3 < 5%). The substance is not mutagenic *in vitro* and not likely to be clastogenic *in vitro*, therefore, the substance is unlikely to cause genetic damage.

When used as a component of bitumen emulsions, direct exposure of the general population is not anticipated. There is a potential for indirect exposure of the general population via drinking water if rinse water from the cleaning of transportation vessels is released to the environment (conservatively estimated to be less than 1 µg/kg bw/day). Exposure potential is not expected to change significantly when used in similar industrial applications. However, if the substance is used in household consumer products such as laundry detergents, household cleaners, lubricants, etc., an increased direct exposure potential to the skin may exist. Similarly, if the substance is manufactured in Canada, an increased indirect exposure potential from drinking water may exist.

Based on a low potential for direct exposure of the general population and that worst-case estimates of exposure from drinking water were significantly less than repeated oral doses that cause no effects in mammalian test animals, the substance is unlikely to be harmful to human health.

However, based on the potential for skin sensitization and moderate to high toxicity from repeat exposure, the use of the substance in consumer products such as detergents, cleaning products, personal care products and lubricant formulations may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Assessment Conclusion

The substance is suspected to be harmful 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 identified environmental risks related to the potential for aquatic exposures to exceed the predicted no effect concentration and human health risks related to the potential for skin sensitization and moderate to high toxicity from repeat exposure, a [Ministerial Condition](#) was imposed to authorize the notifier to manufacture and import the substance subject to conditions on its use, handling, and disposal in order to mitigate these potential risks. [Ministerial Condition No. 17160](#) was published in the *Canada Gazette* Part I, Vol. 147, No. 24 on June 15, 2013.