

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

New Substances Notification 20072: Alkanedioic acid, dialkyl ester, polymer with *N*1,*N*1-dimethyl-1,3-propanediamine and 1,1'-oxybis[2-chloroethane] (Confidential Accession Number 19438-6)

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 have determined that it is not 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, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified polymer is alkanedioic acid, dialkyl ester, polymer with *N*1,*N*1-dimethyl-1,3-propanediamine and 1,1'-oxybis[2-chloroethane] (Confidential Accession Number 19438-6). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic amine groups.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a petroleum processing aid. No other uses are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment because it is a high molecular weight substance with limited bioavailability and it does not contain any functional groups that are susceptible to hydrolysis or biodegradation. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish (median lethal concentration 1-100 mg/L) and moderate chronic toxicity to algae (no-observed-effect-concentration 0.1-10 mg/L), and is expected to have moderate acute toxicity to aquatic invertebrates (median effect concentration (EC₅₀) 1-100 mg/L). Using the EC₅₀, from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for acute to chronic extrapolation, species sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, 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 activities is expected to be mainly from formulation by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L and cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L. For potential activities such as industrial manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). No other mammalian toxicity data are available for the substance. The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used in petroleum processing, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low acute toxicity and low potential for 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.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, 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.