

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

New Substances Notification 21374: Poly[oxy(alkyl alkanediyl)], α,α',α'' -1,2,3-propanetriyltris[ω -(2-hydroxy-3-mercaptopropoxy)- (Confidential Accession No. 19665-3)]

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 poly[oxy(alkyl alkanediyl)], α,α',α'' -1,2,3-propanetriyltris[ω -(2-hydroxy-3-mercaptopropoxy)- (Confidential Accession No. 19665-3)]. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in adhesives. Potential uses may include use as a curing agent in coatings.

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 water. The substance is expected to be persistent in this compartment based on very low biodegradation (< 10% over 28 days). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and low predicted bioconcentration and bioaccumulation factors (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (no adverse effects observed at a loading rate of 100 mg/L) and moderate chronic toxicity to algae (no-observed-effect-concentration (NOEC) 1-10 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 $\mu\text{g/L}$, which was used to estimate the risk to the environment.

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 and cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-

100 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used in commercial adhesives, consumers may come into contact with end-use products containing the notified substance; however, direct exposure of the general population is not expected as the notified substance will be chemically reacted into a stable matrix and unavailable for uptake. When the notified substance is used in adhesives available to consumers, direct exposure of the general population will be mainly by contact with the skin; however, absorption through skin will be limited by the large molecular weight of the substance, the low frequency of use of products containing the substance, and the small amount of product containing the substance used during consumer applications. 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. Potential uses for the substance include use as a curing agent in coatings, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low 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.

The assumptions made in the assessment are considered to be adequately protective for the general population, as well as for subpopulations who may be more susceptible or highly exposed.

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 the Workplace Hazardous Materials Information System as specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.