

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

New Substance Notification 20438: Hexanedioic acid, polymer with (chloromethyl)oxirane, ethyl(hydroxymethyl)alkanediol, (alkylalkylidene)bis[phenol] and oxirane, 2-propenoate (Confidential Accession No. 19531-9)

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 hexanedioic acid, polymer with (chloromethyl)oxirane, ethyl(hydroxymethyl)alkanediol, (alkylalkylidene)bis[phenol] and oxirane, 2-propenoate (Confidential Accession No. 19531-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because the number average molecular weight is less than 1 000 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 industrial coatings. 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 water. The substance is expected to be persistent in water because it is neither readily hydrolyzed nor biodegradable. The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (<250 L/kg) and its low octanol/water partition coefficient ($\log K_{ow} < 3$).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute ecotoxicity to fish (median lethal effective concentration and median effective concentration (EC_{50}) 1-100 mg/L) and moderate chronic toxicity to algae (median effective loading rate 1-10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 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 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, with the exact value being below the PNEC value. For potential activities such as manufacturing or formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L, also below the PNEC.

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 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 an extreme dermal sensitizer (100% response (guinea pig maximization test)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, consumers may come into contact with end-use products containing the substance. However, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the 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 Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.