

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

New Substances Notification 19965: Alkanedioic acid, polymer with alkanediol, α -hydro- ω -hydroxypoly[oxy(alkyl alkanediyl)], alkanebis[isocyanato carbomonocycle] and alkyloxirane polymer with oxirane ether with 2-ethyl-2-(substituted methyl)-1,3-propanediol (3:1) (Confidential Accession No. 19415-3)

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 alkanedioic acid, polymer with alkanediol, α -hydro- ω -hydroxypoly[oxy(alkyl alkanediyl)], alkanebis[isocyanato carbomonocycle] and alkyloxirane polymer with oxirane ether with 2-ethyl-2-(substituted methyl)-1,3-propanediol (3:1) (Confidential Accession No. 19415-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because they contain isocyanate 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 an adhesive. Potential uses may include manufacture of polyurethane polymers, or in the production of paints, coatings and adhesives for industrial, commercial or consumer use.

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 solid with limited bioavailability. The substance is not expected to bioaccumulate based on its high molecular weights, which will limit its ability to cross biological membranes.

Ecological assessment

Based on its high molecular weight and solid state, it is unlikely that the substance would become available to aquatic organisms. A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 not expected as the substance will be chemically reacted into a stable matrix once cured and will be unavailable for release. For potential activities such as industrial paints and coatings, adhesives, and polyurethane foam, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified activity. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

Based on the low potential for ecotoxicity and for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance is expected to have low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance contains isocyanate groups, which are a concern for potential skin sensitization.

When the notified substance is used industrially as an adhesive, 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 the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water or air is not expected given the low potential for environmental release. Potential uses of the substance include consumer adhesives and coatings, where direct 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 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.