

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

New Substances Notification 19713: Poly(oxy-1,4-butanediyl), α -hydro- ω -hydroxy-, polymer with 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene (Chemical Abstracts Service registry number 914981-07-0)

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-1,4-butanediyl), α -hydro- ω -hydroxy-, polymer with 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene (Chemical Abstracts Service registry number¹ 914981-07-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains aromatic isocyanates.

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 as an industrial additive. Potential uses may include a variety of industrial coating and manufacturing applications.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent based its ability to hydrolyze rapidly in the presence of moisture. The initial hydrolysis products may further hydrolyze to form insoluble polyurea compounds which will tend to settle to sediment. The environmental products of hydrolysis are expected to be persistent in this compartment as the high molecular weight, insoluble species are expected to be highly resistant to degradation. The substance and its products of hydrolysis are not expected to bioaccumulate based on their high molecular weights which will limit their ability to cross biological membranes.

Ecological assessment

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Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective loading rate >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for 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 such as transportation, formulation and use is not expected as the substance will be consumed during processing and trapped within a stable matrix during use from which it will not be released. A predicted no-effect concentration was not calculated given the low potential for ecological hazard. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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

Human health assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight).

When the notified substance is used as an industrial additive, 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. Potential uses of the substance include industrial coating applications, where direct exposure is not expected, similar to that of the notified use. Potential use in consumer coating applications could lead to direct exposure of the general population mainly by contact with the skin but at low levels given the high molecular weight of the substance which will limit its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern for notified and potential activities given the low potential for environmental release.

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.