

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

New Substances Notification No. 19063: Hexanedioic acid, polymer with hydroxylalkyl alkanediol, alkanoate, polymer with polymethylenepolyphenylene isocyanate

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 hydroxylalkyl alkanediol, alkanoate, polymer with polymethylenepolyphenylene isocyanate (Confidential Accession No. 19185-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains terminal and pendant 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 a component of polyurethane products used in industrial settings. Potential uses may include use as a component of polyurethane products in other industrial settings and some commercial products.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will rapidly react with moisture to form insoluble, high molecular weight polyureas which will tend to partition to soil and sediment. The substance is not expected to be persistent based on its rapid hydrolysis. However, the hydrolysis products are expected to be persistent in soil and sediment as the high molecular weight, insoluble species are expected to be highly resistant to biodegradation. The substance and its hydrolysis products are not expected to bioaccumulate based on their high molecular weight which will limit their ability to cross biological membranes.

Ecological assessment

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 (LC₅₀) and median effective concentration (EC₅₀) >100 mg/L), low chronic toxicity in algae (EC₅₀ >100 mg/L) and low chronic toxicity in aquatic invertebrates (21-day EC₅₀ >10 mg/L). 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. Because the substance reacts with water or moisture in the air, special conditions of transportation, processing, use and disposal designed to mitigate potential releases are used. Therefore, environmental exposure from the notified and potential activities are not expected. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and low ecotoxicity.

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 potential for acute toxicity by the oral, dermal and inhalation routes of exposure (oral and dermal median lethal dose >2000 mg/kg body weight; inhalation LC₅₀ >5 mg/L/4hr).

When the notified substance is used as a component of a polyurethane system, 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 is expected to be low as significant environmental releases are not expected.

If the substance is used in other industrial applications, direct and indirect exposure of the general population is expected to be similar to that of the notified use. If the substance is used in consumer products, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation at low levels. Inhalation exposure is expected to be mitigated by the conditions of use. Dermal exposure is expected to be mitigated by the large molecular weight of the substance which will limit its ability to cross biological membranes, infrequent use of products containing the substance, small area for skin contact during use, and the unavailability of the substance for uptake once cured. Indirect exposure of the general population from environmental media such as drinking water is not expected.

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.

Assessment conclusion

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

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.