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

New Substance Notification 19841: Hexanedioic acid, polymer with α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene] and 2,2'-oxybis[ethanol], reaction products with alkyl alcohol (Confidential Accession No. 19360-8)

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 α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene] and 2,2'-oxybis[ethanol], reaction products with alkyl alcohol (Confidential Accession No. 19360-8). The notified polymer does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains a high percentage of low molecular weight components and terminal isocyanates.

Notified and potential activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial adhesives. No other activities 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 soil and sediments. The substance is expected to be persistent in soil and sediments because it reacts with water to form high molecular weight, insoluble complexes that are resistant to degradation. The substance and its reaction products are not expected to bioaccumulate based on their high molecular weight and reactivity with water.

Ecological assessment

Based on the available hazard information on structurally related polymers, the substance is expected to have low acute toxicity in fish (median lethal concentration > 100 mg/L) and low acute toxicity in aquatic invertebrates (median effective loading rate > 100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified 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 not expected. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity. No potential activities which could significantly increase ecological risk 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 polymers, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). Based on information on residual reactants, the substance may also elicit carcinogenicity, respiratory effects, and dermal sensitization.

When the notified substance is used in industrial adhesives, 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.

Assessment conclusion

When used as notified, the substance is not suspected 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.