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

New Substances Notification No. 19081: 1,3-Benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, hexanedioic acid, 1,6-hexanediol, 1,6-hexanederivative, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione, 1,1'-methylenebis[isocyanatobenzene] and α,α',α''-1,2,3-propanetriyltris[ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)]]

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 that 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 1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, hexanedioic acid, 1,6-hexanediol, 1,6-hexanederivative, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione, 1,1'-methylenebis[isocyanatobenzene] and α,α',α''-1,2,3-propanetriyltris[ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)]] (Confidential Accession No. 19180-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains terminal aromatic isocyanate groups.

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. Potential uses are expected to be similar to those notified.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will react with moisture to form insoluble, high molecular weight polyurea compounds 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 insoluble high molecular weight species are expected to be resistant to degradation. 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 and median effective concentration >100 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. Environmental exposure from the notified activities is not expected as the substance will cross-link to form an insoluble, high molecular weight polyurea if exposed to water, and the substance will be unavailable for release once cured. For potential activities such as manufacturing, environmental exposure is not expected, similar to that of the notified use. 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 due to limited bioavailability and low potential for 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 moderate potential for acute toxicity by the oral route of exposure (median lethal dose 300-2000 mg/kg body weight).

When the notified substance is used in industrial adhesives, direct exposure of the general population is not expected because the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. If the substance is used in consumer applications, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Uptake from 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 and low quantities of products containing the substance, and small area of skin available for dermal contact during use. Additionally, the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. If the substance is used for other industrial applications, direct exposure of the general population is expected to be similar to that of the notified use. Indirect exposure of the general population from environmental media such as drinking water is expected to be low for notified and potential uses as significant environmental release is not expected.

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 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.