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

New Substances Notification 19628: Poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-, polymer with 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, oil, polymer with diethylene glycol, phthalic anhydride and polypropylene glycol ether with glycerol (3:1) and 1,1'-methylenebis[4-isocyanatobenzene] (Confidential Accession Number 19366-4)

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 substances and have determined that they are 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.

Substances identities

The notified polymer is poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-, polymer with 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, oil, polymer with diethylene glycol, phthalic anhydride and polypropylene glycol ether with glycerol (3:1) and 1,1'-methylenebis[4-isocyanatobenzene] (Confidential Accession No. 19366-4). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains aromatic isocyanate groups.

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 in industrial adhesives. Potential uses may include consumer adhesives or other industrial applications.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to react in the presence of moisture to form insoluble, high molecular weight compounds. The environmental products of hydrolysis are expected to partition to sediment and soil and are expected to be persistent in these compartments because the high molecular weight, insoluble species are expected to be highly resistant to biodegradation. The substance and its products of hydrolysis 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 (median lethal 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 given the high level of removal during wastewater treatment and the fact that the substance will be chemically reacted into a stable matrix once the product is cured and unavailable for release. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. 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). Based on the high molecular weight of the substance, toxicity concerns associated with isocyanate groups are not expected.

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 the product is 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. Potential uses of the substance include consumer adhesives, where direct exposure of the general population is expected to be mainly by contact with the skin at very low levels given the high molecular weight of the substance which will limit its ability to cross biological membranes, the infrequent use of consumer products containing the substance and the small quantities of product expected to be in contact with the skin. Indirect exposure of the general population from environmental media such as drinking water is not expected since there is little or no release to the environment. Direct and indirect exposure of the general population is not expected for potential use of the substance for industrial applications other than the notified use, for reasons 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 the 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.