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

New Substances Notification 21545: 1,3-Benzenedicarboxylic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, hexanedioic acid, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene] and 1,2-propanediol, polyalkoxymetalloid-*N*-[(polyalkoxymetalloid)alkyl]-1-propanamine-blocked (Confidential Accession Number 19725-3)

**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 1,3-benzenedicarboxylic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, hexanedioic acid, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene] and 1,2-propanediol, polyalkoxymetalloid-*N*-[(polyalkoxymetalloid)alkyl]-1-propanamine-blocked (Confidential Accession Number 19725-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains terminal 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 in flexible packaging applications. Potential uses may include adhesives, paints, coatings and production of polyurethane foams.

**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 sediment. The substance will rapidly react with water to form high molecular weight compounds that are highly insoluble in water. However, the environmental products of hydrolysis are expected to be persistent in soil and sediment. The substance and its products of hydrolysis are not expected to bioaccumulate based on lack of bioavailablity due to their high molecular weight and water insolubility, which limit their ability to cross biological membranes.

**Environmental risk assessment**

Based on the low water extractability (< 2%), the substance is expected have low bioavailability. Therefore, a predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 activity is expected to be mainly by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities that 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 harm to the environment in Canada.

**Human health risk assessment**

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). It is expected to have a high acute toxicity by the inhalation route (median lethal concentration 0.5-1 mg/L). It is expected to be a moderate dermal sensitizer (estimated concentration of 1-10% required to produce a stimulation index of 3 in a local lymph node assay). It is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in flexible packaging applications, direct exposure of the general population is not expected due to the industrial nature of the use and 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 adhesives, paints and coatings formulations available to consumers, where direct exposure will be mainly by contact with the skin at low levels. Exposure will be limited by the large size of the polymer which will limit its ability to cross biological membranes, the infrequent use of products containing the substance and small anticipated surface area of skin exposed. Once the product has cured, the substance will be chemically reacted into a stable matrix and will be unavailable for uptake. Indirect exposure of the general population is expected to be at levels that do not pose a human health concern, similar to 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

**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 the *Hazardous Products Regulations* for products intended for the workplace.