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

New Substances Notification No. 18902: 1,4-Benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, alkanediol, hexanedioic acid, 1,6-hexanediol, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,3-isobenzofurandione, 1,1'-methylenebis[4-isocyanatobenzene], 2-oxepanone and 2,2'-oxybis[ethanol]

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 polymer, 1,4-benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, alkanediol, hexanedioic acid, 1,6-hexanediol, α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,3-isobenzofurandione, 1,1'-methylenebis[4-isocyanatobenzene], 2-oxepanone and 2,2'-oxybis[ethanol] (Confidential Accession No. 19108-1), can be classified as a poly(arylester, ether, ester, arylurethane). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because of the presence of 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 use in 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 tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment due to its structure, size and low water solubility. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (no significant adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low ecotoxicity.

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 low as the substance is consumed upon use and will not be available for further exposure. The substance could potentially be used in other industrial or consumer adhesive applications, which are expected to result in similar environmental exposure to the notified activities. A predicted environmental concentration for notified or potential activities was not estimated given the low bioavailability and ecotoxicity of the substance.

Based on the low potential for environmental release, the low bioavailability and low ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available surrogate data on structurally related chemicals, the substance is expected to have a low to moderate potential for acute toxicity by the oral route of exposure (median lethal dose >300 mg/kg-bw with no mortality and lack of gross pathological findings). The substance contains terminal isocyanate groups which have been associated with dermal sensitization.

When the notified substance is used as an industrial adhesive, direct exposure of the general population is expected to be low. The substance will be chemically reacted into the polymer matrix of end-use products and unavailable for dermal uptake. If the substance is used in consumer adhesive applications, an increased direct exposure to the skin may exist. However, the anticipated application method will limit exposure and dermal absorption is not expected to be significant due to the size of the polymer. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low potential for direct or indirect human 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 the *Hazardous Products Regulations* for products intended for workplace use.