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

New Substances Notification No. 18648: Hexanedioic acid, polymer with 1,2-ethanediol and 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene

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, hexanedioic acid, polymer with 1,2-ethanediol and 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene (Chemical Abstracts Service Registry No. 925206-99-1), can be classified as a poly(alkylester)-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 industrial polyurethane elastomer formulations. Potential uses may include other polyurethane foam and elastomer applications, as well as coatings, adhesives and sealants for industrial use in the furniture, construction and automotive sectors.

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 because it reacts with water to form high molecular weight insoluble complexes that are resistant to degradation. 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 hazard information on structurally related chemicals, the substance has low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solution) due to its insolubility. A predicted no-effect concentration was not calculated given the low potential for ecological risk.

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 activity is expected to be low because it will be contained to industrial settings and the substance will be consumed during use. A predicted environmental concentration for notified activities was not estimated given the low potential for ecological risk.

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

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg). The substance contains isocyanate functional groups. Some isocyanates are of concern for potential respiratory irritation, and dermal and respiratory sensitization.

When the notified substance is used in industrial polyurethane elastomer formulations, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is expected to be low because the substance will be used in an industrial environment and is consumed in the manufacturing process.

Based on the uses of similar substances, potential uses of the notified substance include manufacturing of polyurethane foam, elastomers, coatings, adhesives and sealants for industrial use in the furniture, construction and automotive sectors. The potential for direct and indirect exposure of the general population from these potential uses is expected to be low due to their industrial nature, similar to that of the notified use.

Based on the low potential for direct or indirect 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 expected 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.