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

New Substances Notification No. 18647: Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 5-isocyanato-1-(isocyanatomethyl-1,3,3-trimethylcyclohexane

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, oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with α-hydro-ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 5-isocyanato-1-(isocyanatomethyl-1,3,3-trimethylcyclohexane (Chemical Abstracts Service Registry No. 85784-12-9), can be classified as a branched polyether polyurethane, isocyanate terminated. 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 polyurethane sealants. Potential uses may include use in coatings, adhesives, elastomers, fibers, binders and use in polymer reactions.

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 the substance is expected to react 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 that will limit its 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 (no adverse effects were observed in saturated

solution). Due to its high molecular weight and insolubility, it is unlikely that the substance will be available to aquatic organisms and therefore will be unable to elicit any toxic effects. 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 not expected. The substance is consumed upon use, and once cured it will be chemically bound to a polymer matrix and unavailable for release. If released to the aquatic environment, the substance is expected to react with water to form large, insoluble polymers which will be efficiently removed during waste water treatment. No other potential activities were identified. A predicted environmental concentration for notified activities was not estimated given that no environmental releases are expected.

Based on the low potential for environmental release, lack of bioavailability in the aquatic environment and low ecotoxicity, 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 potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight).

When the notified substance is used in commercial or industrial polyurethane sealants, direct exposure of the general population is not expected. When the notified substance is used as a prepolymer in do-it-yourself products, direct exposure of the general population is expected to be mainly by contact with the skin. However, significant dermal uptake is not expected given the fast curing time and high molecular weight of the substance which inhibits its ability to cross biological membranes. Once cured, the substance will be chemically reacted into a stable polymer matrix and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible. Other potential uses of the notified substance include use in coatings, adhesives, elastomers, fibers, binders and use in polymer reactions. These uses are mainly industrial and commercial in nature, and direct and indirect exposure to the general population is not likely to change significantly from that of the notified use.

Based on the low toxicity and 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 the *Hazardous Products Regulations* for products intended for workplace use.