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

New Substances Notification No. 19754: 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 1,1'-methylenebis[isocyanatobenzene] (Chemical Abstracts Service No. 113184-29-5)

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-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 1,1'-methylenebis[isocyanatobenzene] (Chemical Abstracts Service No. 113814-29-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals & Polymers)* because its number average molecular weight is less than 1000 daltons with a high percentage of low molecular weight components, and it contains 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 the notified use in industrial coatings. Potential uses may include industrial coatings for other applications, adhesives, and polyurethane foam. No consumer uses were identified.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it is not expected to be bioavailable in the water column. The substance is expected to react with water to form higher molecular weight, insoluble complexes that will be resistant to degradation. As a result, some partitioning of these complexes to soil and sediment may occur. 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, the substance has low acute toxicity in aquatic organisms (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified and 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 not expected as the substance will be highly removed during wastewater treatment, and will be chemically reacted into a stable matrix once the product is cured and will be unavailable for release. For potential activities such as industrial coatings for other applications, adhesives, and polyurethane foam, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

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 for two 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). However, as a methylenediphenyl diisocyanate (MDI) polymer, aerosol inhalation of the substance at high concentrations may be of concern for adverse health effects including irritation and sensitization.

When the notified substance is used as an industrial coating, 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 such as air and drinking water is expected to be low. If the substance is used in industrial uses such as coatings for other applications, adhesives, and in polyurethane foam, direct and indirect exposure of the general population is expected to be similar to that of the notified use. No potential consumer uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for direct and 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 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 *Hazardous Products Regulations* for products intended for the workplace.