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

New Substances Notification No. 18658: 1,3-Propanediol, 2,2-bis(hydroxymethyl)-, polymer with oxirane

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, 1,3-propanediol, 2,2-bis(hydroxymethyl)-, polymer with oxirane (Chemical Abstracts Service Registry No. 30599-15-6), can be classified as a poly(ether). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains a high percentage of low molecular weight components.

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 as a binder resin. Other industrial and consumer uses are also possible.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water because it is considered inherently biodegradable. The substance is not expected to bioaccumulate based on its very high water solubility (>10 000 mg/L) and very low octanol-water partition coefficient ($\log K_{ow} \leq 0$).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L) and is expected to have low chronic toxicity in aquatic invertebrates (no-observed-effect concentration >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological risk.

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 not expected. The substance will only be used in industrial settings and will be already chemically reacted into the coating matrix once cured and therefore will not be bioavailable. Potential uses of the substance could include industrial as well as consumer applications. These potential uses would result in different environmental release scenarios than the notified use; however, due to the low ecotoxicity of the substance no increased ecological risk is expected from these potential uses. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

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

Human Health Assessment

Based on the available hazard information on the substance and structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight), and a low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). It does not cause skin sensitization. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an industrial binder resin, direct exposure of the general population is not expected. Consumers may come into contact with end-use products coated with the substance, however direct exposure is not expected because the substance will be chemically reacted in the coating matrix once cured and therefore it will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the industrial use of the substance, which results in little or no release to the environment.

Other potential industrial uses of the substance are expected to result in the same low potential for direct and indirect exposure as was described for the notified use. If the substance is used in consumer products, direct exposure of the general population is expected to be mainly by the dermal route. The size of the substance, its non-ionic nature and expected surface active properties indicate that the substance has the potential for dermal absorption if used in consumer applications where direct dermal contact occurs. However, given the low acute and subchronic toxicity, 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.