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

New Substances Notification No. 18755: Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl, polymer with diisocyanato-1-methylbenzene, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, polyalkylene glycol mono-Bu ether-blocked

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, propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl, polymer with diisocyanato-1-methylbenzene, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, polyalkylene glycol mono-Bu ether-blocked (Confidential Accession No. 19095-6), can be classified as a polycationic polymer. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains potentially cationic amine groups.

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 wetting and dispersing additive in industrial coatings. No other activities are anticipated in Canada.

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 based on its expected low biodegradability due to its large size, and complex chemical composition and structure. The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient (log K_{ow} 0-3) and 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 algae and aquatic invertebrates (median effective concentration >100 mg/L) and moderate acute toxicity in fish (median lethal concentration 1-100 mg/L). Toxicity will be mitigated by the presence of

dissolved organic carbon which is expected to be present under environmental conditions. A predicted no-effect concentration was not calculated given the low ecotoxicity.

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. The substance will be bound to the polymer matrix once cured and will not be available for further exposure, and any unreacted substance is expected to be efficiently removed by wastewater treatment processes via adsorption. A predicted environmental concentration for notified activities was not estimated given the low ecotoxicity. No other potential activities were identified.

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

Human Health Assessment

Based on the available information, the substance has a low potential for toxicity based upon its high molecular weight, which precludes it crossing biological membranes. Functional groups of the substance have not been associated with human toxicity.

When the notified substance is used in industrial coatings, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is not expected. No other potential uses for the notified substance were identified.

Based on the low potential for exposure in conjunction with the low potential for toxicity based upon its structure and functional groups, 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.