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

New Substances Notification No. 18423: Alkanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with 1,6-diisocyanatohexane, 1,2-ethanediamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol triacrylate-blocked, compounds with triethylamine

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, Alkanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with 1,6-diisocyanatohexane, 1,2-ethanediamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol triacrylate-blocked, compounds with triethylamine (Confidential Accession No. 18941-5, can be classified as a poly(urea, cycloalkylurethane). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains pendant acrylates.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a resin in industrial and commercial ultraviolet (UV) curing coatings for wood and polyvinyl chloride plastics. 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 water and sediment. The substance is expected to be persistent in water and sediment based on reduced degradability of the urea and urethane bonds due to the overall size and structure of the polymer. 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 the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration 1-100

mg/L). Using the lowest-observed-effect-concentration from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 100-1000 µg/L, which was used to estimate the 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 activities is expected to be low. The substance is imported into Canada. Drums used to transport the substance are rinsed after use and the rinsing liquids are added to the coating formulation mixing vessel. Once cured in coatings, leaching of the substance from final substrates is not expected. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10 µg/L. No other activities were identified.

Comparing the PEC with the PNEC, the ratio is less than 1. This along with other lines of evidence including environmental fate, hazard, and exposure indicates that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose 300-2000 mg/kg body weight).

When the notified substance is used industrially as a resin in UV curing coatings for wood and plastics, direct exposure of the general population is expected to be low. Although the general population may come into contact with coated products, the substance will already be chemically reacted into a stable matrix once cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. No other potential uses were identified.

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, 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.