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

New Substances Notification No. 18605: 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with butyl 2-propenoate, 2-ethylhexyl 2-propenoate and 2-propenoic acid, ester with alpha-[[[3-(substituted amino)methylphenyl]amino]carbonyl]-omega-methoxypoly(oxy-1,2-ethanediyl), 2,2'-azobis[2-methylbutanenitrile]-initiated

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, 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with butyl 2-propenoate, 2-ethylhexyl 2-propenoate and 2-propenoic acid, ester with alpha-[[[3-(substituted amino)methylphenyl]amino]carbonyl]-omega-methoxypoly(oxy-1,2-ethanediyl), 2,2'-azobis[2-methylbutanenitrile]-initiated (Confidential Accession No. 18888-6), can be classified as a poly(alkyl). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it is expected to substantially degrade.

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 coating additive. Potential uses may include ink, engine oils, concrete and cement formations, and de-inking fluids.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, sediment and soil. The substance is not expected to be persistent in these compartments because it is expected to biodegrade under environmental conditions. 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 algae (median effective concentration >100 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 expected to be mainly from the cleaning of transportation and formulation vessels by release of the substance to water at low levels. Other potential activities, that may include manufacturing, could result in environmental release of the substance to water. Significant environmental exposure is not expected from notified or potential activities. A predicted environmental concentration for notified and other potential activities was not estimated given the low potential for environmental exposure.

Based on the low ecotoxicity and low potential for environmental exposure, 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 low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight). It is expected to be of low concern for skin sensitization and genotoxicity.

When the notified substance is used as an additive in coatings industrially or commercially, direct exposure of the general population is not expected. The general population may come into contact with end-use products treated with the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. There is potential for dermal contact when applying consumer coatings; however, dermal uptake can be mitigated by the large molecular size and the ionic nature of the substance. Other potential uses include ink, engine oils, concrete and cement formations, and de-inking fluids; direct exposure of the general population is not expected due to the commercial or industrial nature of these uses. The substance could find use in consumer cleaners and detergents but dermal uptake is not expected. The potential for indirect exposure of the general population from environmental media such as drinking water is expected to be low for notified and potential uses.

Based on the low potential for direct or indirect exposure and the low 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.