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

New Substances Notification No. 18022; Poly(oxy-1,2-ethanediyl), α-undecyl-ω-hydroxybranched and linear, ethers with 1,2-decanediol (1:1)

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 that 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

Poly(oxy-1,2-ethanediyl), α -undecyl- ω -hydroxy-branched and linear, ethers with 1,2-decanediol (1:1) (Chemical Abstracts Service Registry No. 501019-90-5) is a polymer that can be classified as an alkylated polyether. The substance does not meet the Reduced Regulatory Requirement criteria according to the New Substances Notification Regulations because it substantially degrades.

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 an ingredient for automatic dishwashing detergents and hard surface cleaners. 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. The substance is not expected to be persistent in water, sediment or soil because it is highly biodegradable under both aerobic and anaerobic conditions. The substance is not expected to bioaccumulate based on its large molecular weight making it unable to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance, it has moderate (EC₅₀ 1-100 mg/L) acute toxicity in aquatic organisms. The predicted no-effect concentration was calculated to be 100-1000 μ g/L using the EC₅₀ from the most sensitive organism (algae), which was used to estimate the 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 activities is expected to be mainly from the release of the substance to water through formulation, transportation, and end use. The predicted environmental concentration (PEC) for notified activities is estimated to be within the range of 0.1-10 μ g/L. Environmental exposure from other potential activities is expected to be mainly from the release of the substance to water through manufacturing. The PEC for other potential activities is estimated to be within the range of 0.1-1 μ g/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information for a similar substance, the notified substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight). It is a slight skin irritant (primary irritation index = 0.6-1.5) and mild to moderate eye irritant (maximum mean score = 15-25). Based on a report in the public literature for a similar but slightly smaller category of substance which indicated low oral toxicity for repeated exposure and the low potential for skin and eye irritation, the notified substance is considered to be of low overall health concern.

When used as an ingredient in dishwashing detergents and hard surface cleaners, direct exposure of the general population is expected to be moderate to high and mainly by contact with the skin; however uptake of the notified substance is expected to be negligible due to its large molecular size and the limited presence of low molecular weight species. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible given the substance readily biodegrades in the environment.

Based on the negligible dermal uptake of the substance through its notified and potential uses in conjunction with its low toxicity, the substance is not likely to pose a significant health risk to the general population through direct or indirect exposure, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When used as notified or for other identified potential uses, the substance 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.