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

New Substances Notification No. 19033: Glycerides, alkyl and alkynyl, esters with polyalkylene glycol ether with glycerol (3:1)

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 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 notified polymer is glycerides, alkyl and alkynyl, esters with polyalkylene glycol ether with glycerol (3:1) (Confidential Accession) No. 19207-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

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 the notified use in consumer detergents. 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 based on its predicted biodegradation (60-85%). The substance is not expected to bioaccumulate based on its high water solubility (>10 000 mg/L) and its expected bioaccumulation factor (<5000 L/kg).

Ecological Assessment

Based on the available surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) 1-100 mg/L) and moderate chronic toxicity in algae (median effective concentration 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 0.01 to 0.1 mg/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 mainly from formulation and use of end-use products containing the substance by release of the substance to water. The predicted environmental concentration (PEC) is estimated to be 0.001 to 0.01 mg/L for industrial applications and 0.001 to 0.1 mg/L for consumer applications. No other potential activities have been identified.

Comparing the PEC for notified activities with the PNEC, the ratio is less than 1 for industrial releases. This along with other lines of evidence including hazard, exposure and environmental fate indicates that the substance is unlikely to cause ecological harm in Canada as a result of industrial use.

Based on the low potential environmental exposure, predicted biodegradability and lack of bioaccumulation potential, the substance is unlikely to cause ecological harm in Canada as a result of consumer use.

Human Health Assessment

Based on the available surrogate data on 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 bw) and low subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >250 mg/kg-bw/day with no reproductive or developmental effects). It is not expected to be a skin sensitizer (0% response (Buehler scale)). It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a surfactant, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 1 to 100 mL per application. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. No other potential uses have been identified.

Based on the low toxicity and low potential for 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 used as notified, 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 *Hazardous Products Regulations* for products intended for the workplace.