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

New Substances Notification 20689: Poly(oxy-alkanediyl), α-(substituteddocosyl)-ω-[(substituteddocosyl)oxy]- (Confidential Accession No. 19550-8)

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 poly(oxy-alkanediyl), α-(substituteddocosyl)-ω-[(substituteddocosyl)oxy]- (Confidential Accession No. 19550-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains a high percentage of low molecular weight components.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in diesel fuel. Potential uses may include personal care products, inks and coatings, and toner formulations.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water and sediments. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not anticipated to be persistent in water and sediments based on the ready/inherent biodegradation of structurally similar alcohol ethoxylates. The substance is not expected to bioaccumulate based on expected low to moderate bioconcentration factors (< 1000 L/kg) for alcohol ethoxylates.

Environmental risk assessment

Based on the available hazard information for alcohol ethoxylates, the substance is expected to have high acute and chronic toxicity to fish, aquatic invertebrates, and algae. Based on

Environment and Climate Change Canada's Federal Water Quality Guidelines, the predicted no-effect concentration (PNEC) was determined to be 70 µg/L, which was used to estimate the risk to the environment.

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 not expected, as the substance will be combusted through its use in diesel fuel formulation. For potential activities such as industrial formulation and use in personal care products, environmental exposure is expected to be mainly from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L, with the exact value being below the PNEC.

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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose range > 2000 mg/kg body weight) and is expected to have a low acute toxicity by the inhalation route (median lethal concentration > 5.0 mg/L). It is expected to have low subchronic toxicity following repeated oral doses in mammalian test animals (28-day and 90-day no-observed-adverse-effect level > 300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0% response (guinea pig maximization test)). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a fuel additive, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water or air is not expected, given the low potential for environmental release, very low water extractability, and predicted low vapour pressure.

Potential uses of the substance include personal care products, ink and coatings, and toner formulations, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use. If the substance is used in personal care products, direct exposure is expected to be mainly by contact with the skin or by inhalation, where exposure is expected to be limited by the high molecular weight and low vapour pressure of the notified substance, and the low concentration in products.

Based on the expected 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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 the workplace.