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

New Substances Notification No. 18686: 1-Propanaminium, 2-hydroxy-*N*-(2-hydroxypropyl)-*N*,*N*-dimethyl-, diesters with C_{18}-unsaturated fatty acids, Me sulfates

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 chemical, 1-Propanaminium, 2-hydroxy-*N*-(2-hydroxypropyl)-*N*,*N*-dimethyl-, diesters with C_{18}-unsaturated fatty acids, Me sulfates (Chemical Abstracts Service Registry No. 1810046-45-7), can be classified as a quaternary ammonium, diester, unsaturated fatty acids.

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 conditioner in hair conditioners, conditioning shampoos, hair and body shampoos and detangling sprays. Potential uses may include as a conditioner or surfactant in other products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in soil and sediment based on its moderate to high biodegradability (30-85%) and high rate of hydrolysis. The substance is not expected to bioaccumulate based on its low water solubility (0.01-10 mg/L) and moderate to high biodegradability.

Ecological Assessment

In the presence of humic acid, the substance has moderate acute toxicity in algae (median effective concentration (EC_{50}) 1-100 mg/L) and low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solution). Humic acid in test solution is considered a surrogate for organic matter expected to be present in the environment. The substance is expected to bind to negatively charged particles if released to the environment and similarly has a tendency to bind to humic acid present in test solution. Toxicity data in the presence of humic acid therefore provides a more realistic assessment of the toxicity of the

substance in the aquatic environment. Using the EC_{50} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/L, 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 activity is expected to be mainly from rinsing of the products containing the substance down the drain during use and industrial formulation activities resulting in release of the substance to water. The predicted environmental concentration (PEC) for notified and potential activities (other applications as a conditioner/surfactant) is estimated to be 0.1-1 µg/L for the consumer release scenario and 10-100 µg/L for the industrial release scenario.

Comparing the PEC for consumer and industrial releases with the PNEC, the ratios are 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 low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d). It is not a dermal sensitizer (0% response (guinea pig maximization test)). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a conditioner in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media such as drinking water is expected to be very low. Potential uses of the substance in applications other than in personal care products are expected to result in significantly lower exposure than the notified use.

Based on the low acute and subchronic 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 expected 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.