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

New Substances Notification No. 18679: 1-Octadecanol, 2-tetradecyl-

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-Octadecanol, 2-tetradecyl- (Chemical Abstracts Service Registry No. 32582-32-4), can be classified as a branched alcohol.

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 a component of various industrial, commercial and consumer products. The notified substance could have other potential uses in a variety of applications, none of which are expected to result in significantly higher exposure than those notified.

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 high biodegradability (>60%). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish (median lethal concentration >100 mg/L). Based on computer modelled terrestrial ecotoxicity data, the substance has low chronic toxicity in earthworms (chronic value >10 mg/kg dry soil). A predicted no-effect concentration was not calculated based on 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 activities is expected to be very low, mainly from consumer use through disposal down

the drain or to landfills or following industrial formulating activities by release of the substance to water. A predicted environmental concentration for notified activities was not estimated based on the expected low potential for ecological risk. The notified substance could have other potential uses in a variety of applications; however, environmental release from potential uses are not expected to significantly differ from the notified use.

Based on the low potential for significant environmental release and the low ecotoxicity suggested by surrogate data, the substance is unlikely to cause ecological harm in Canada.

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 route of exposure (median lethal dose >2000 mg/kg) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level >100 mg/kg-bw/d). Based on predictive modelling, it is not expected to be a dermal sensitizer. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in consumer products, direct exposure of the general population is expected to be mainly from contact with the skin at low levels. Direct exposure from industrial and commercial applications is not expected. The notified substance could have other potential uses in a variety of applications; however, these uses are not expected to result in higher direct exposure than the notified uses. Indirect exposure of the general population from environmental media such as drinking water is expected to be very low due to the high biodegradability (>60%) of the substance and expected removal via waste water treatment processes.

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 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.