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

New Substances Notification No. 18672: Isooctadecanamide

**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, isooctadecanamide (Chemical Abstracts Service Registry No. 83052-84-0), can be classified as a fatty acid amide.

## Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as an industrial polymer additive to lower friction between surfaces. Potential uses may include personal care products, grease and lubricants, adhesives and sealants, polymers, and as a manufacturing ingredient.

## 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 biodegradability (30-60%). The substance is not expected to bioaccumulate based on its bioconcentration factor (<5000 L/kg) and low bioavailability due to its low water solubility (0.01-10 mg/L).

## Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solution) and low chronic toxicity in aquatic invertebrates (no adverse effects observed in saturated solution). A predicted no-effect concentration was not calculated due to 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 activity is not expected as release of the substance to water would not result in elevated concentrations in the aquatic environment due to its low water solubility (0.01-10 mg/L). A predicted environmental concentration for notified activities was not estimated given the low ecotoxicity and bioavailability of the substance.

The substance may be used in a variety of potential uses, including in grease and lubricants, adhesives and sealants, polymers, and as a manufacturing ingredient. These potential uses could result in increased environmental releases than from the notified use; however, given the low ecotoxicity and bioavailability of the substance no increased environmental risk is expected.

Based on the low potential for environmental exposure and the low ecotoxicity and bioavailability, the substance is unlikely to cause ecological harm in Canada.

**Human Health Assessment**

Based on the available hazard information, 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 does not cause skin sensitization (effective concentration >10% (local lymph node assay)). 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 polymer additive for industrial use, direct exposure of the general population is not expected. Consumers may come into direct dermal contact with end-use products containing the substance but the concentration of the substance in end-use products is low (≤1%) and its rate of release from end-use products is also expected to be low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Other potential industrial and commercial uses of the substance are not expected to result in an increased potential for direct or indirect exposure to the general population. Use of the substance in personal care products could increase dermal exposure. Given the low toxicity for the substance significant direct human health risks are not expected.

Based on the low toxicity and the low potential for direct or indirect exposure from notified and potential industrial uses, 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.