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

New Substances Notification No. 18191: Amines, tallow alkyl, reaction products with cyclohexylamine and 1,1'-methylenebis[isocyanatobenzene]

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, amines, tallow alkyl, reaction products with cyclohexylamine and 1,1'-methylenebis[isocyanatobenzene] (Chemical Abstracts Service Registry No. 1078712-83-0), is of unknown or variable composition, complex reaction products or biological materials, can be classified as an isomeric mixture of alkyl-cycloalkyl-diphenyl substituted urea.

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 thickening agent in general purpose grease. 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 soil and sediment. The substance is expected to be persistent in soil and sediment based on its very low predicted biodegradability (≤10%). The substance is expected to bioaccumulate based on its moderate to high octanol-water partition coefficient ($\log K_{ow}$ 3-8).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in aquatic invertebrates and fish (median effective concentration and median lethal concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for 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 manufacturing and blending processes by release of the substance to water at low levels. The predicted environmental concentration for notified activities is estimated to be <0.0001 µg/L. No other potential activities have been identified.

Based on the low potential for ecotoxicity and low potential for environmental exposure, 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 is expected to have a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg). It is a non-sensitizer (0% response (Buehler scale)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a thickening agent in general purpose grease, the substance is intended for industrial use only and direct exposure of the general population is not expected. No other potential uses are expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low potential for exposure of the general population in conjunction with the low acute 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 used as notified or for other identified potential uses, 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 the *Hazardous Products Regulations* for products intended for workplace use.