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

New Substances Notification No. 18810: Amines, (2-ethylhexyl)(hydrogenated tallow alkyl)methyl

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, (2-ethylhexyl)(hydrogenated tallow alkyl)methyl (Chemical Abstracts Service Registry No. 1078712-76-1), is of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as an aliphatic amine.

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 lubricating oil additive. 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 not expected to be persistent in soil and sediment based on the moderate biodegradability of the structurally related chemicals (30-60%). The substance is not expected to bioaccumulate based on its moderate predicted bioconcentration and bioaccumulation factors (250-1000 L/kg).

Ecological Assessment

Based on the available surrogate data on structurally related chemicals, the substance has high acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration (EC_{50}) <1 mg/L). 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 1-10 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 very low. Release from notified transportation or formulation activities is expected to be negligible due to the notifier's specialized waste removal system. During use, it is expected that the releases will be widely dispersed. A predicted environmental concentration (PEC) was not estimated for notified activities given that environmental release is expected to be very low. A worst-case scenario of environmental exposure from transportation and other activities is through release of the substance to water at low rates. The PEC for these scenarios is estimated to be 0.1-1 µg/L.

Based on the expected low environmental release from notified activities, and by comparing the PEC with the PNEC resulting in a ratio of less than 1 for the other worst-case scenarios, 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 and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a high potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-effect level (NOEL) <10 mg/kg-bw/d). It is not expected to be a dermal sensitizer (0-8% response (guinea pig maximization test)). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 10-100 µg/kg-bw/d based on the 90-day NOEL from the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used as a lubricating oil additive in diesel engine oil, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. The substance will be present in end-use products at low concentrations (<2% by weight), and the use of products containing the substance for do-it-yourself diesel engine oil applications are expected to be infrequent and short in duration. The moderate to high octanol-water partition coefficient (log K_{ow} 3-8), low water solubility (0.01-10 mg/L) and charged nature of the substance will limit the ability of the substance to cross biological membranes and mitigate dermal absorption. Indirect exposure of the general population from environmental media such as drinking water is expected to be low, and the worst case scenario was estimated to be 0.01-0.1 µg/kg-bw/d. No other potential uses have been identified.

Based on a comparison of the PTDI to the estimated human exposure, and considering other available lines of evidence, 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 potential activities, 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.