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

New Substances Notification No. 18555: Butanedioic acid, 2-[[(alkylalkyl)amino]methyl]-, 1,4-bis(polyalkylalkyl) ester

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, butanedioic acid, 2-[[(alkylalkyl)amino]methyl]-, 1,4-bis(polyalkylalkyl) ester (Confidential Accession No. 19008-0), can be classified as an aliphatic amine-ester.

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 lubricant 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 air, sediment and soil. The substance is not expected to be persistent in these compartments based on its short predicted half-life (<2 days in air, <182 days in soil and <365 days in sediment). The substance is not expected to bioaccumulate based on its low modelled bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solution), high acute toxicity in algae (median effective concentration (EC_{50}) <1 mg/L) and is predicted to have high chronic toxicity in aquatic organisms. Predictions based on the potential hydrolysis products show low to moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and EC_{50} >1mg/L). Using the chronic value 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 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 the cleaning of railcars and drums used in the transportation of the substance and cleaning of blending vessels at users' sites, resulting in the release of the substance to the aquatic environment via wastewater. Environmental exposure from other potential activities is expected to be at similar levels. The predicted environmental concentration (PEC) for both notified and potential activities is estimated to be 0.1-10 µg/L.

Comparing the PEC for notified and potential activities with the PNEC, the ratio is 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, the substance has a low acute toxicity by oral and dermal routes (median lethal dose >2000 mg/kg body weight) and a low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/d). It is a weak skin sensitizer (effective concentration (EC_3) >10% (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 0.1-1 mg/kg-bw/d based on the NOAEL of the oral repeat dose study in mammalian test animals. An acceptable exposure level (AEL) was calculated to be 0.1-1mg/cm^2 based on the sensitization EC_3 of the local lymph node assay.

When the notified substance is used as an industrial lubricant additive, direct exposure of the general population is not expected. If the substance becomes available to consumers for do-it-yourself lubricant applications, direct exposure via dermal contact is conservatively estimated to be 0.1-1mg/cm^2. However, the lubricant is expected to be wiped off immediately, resulting in significantly lower dermal exposure. Indirect exposure of the general population from environmental media such as drinking water is expected to be mainly by ingestion at levels of 0.0001-0.001 mg/kg-bw/d. No other potential uses have been identified.

Based on a comparison of the anticipated direct exposure levels with the AEL, and a comparison of the anticipated indirect exposure levels with the PTDI, 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.