

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

New Substances Notification No. 18537: Isooctadecanoic acid, 1,1'-(2,2-dimethyl-1,3-propanediyl) 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, isooctadecanoic acid, 1,1'-(2,2-dimethyl-1,3-propanediyl) ester (Chemical Abstracts Service Registry No. 109884-54-0), can be classified as a glycol diester.

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 for military marine applications. Potential uses may include other industrial applications and personal care products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is not expected to be persistent in soil and sediment based on its very high ready biodegradation (>85%). The substance is not expected to bioaccumulate based on its predicted low bioconcentration and bioaccumulation factors (<250 L/kg).

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 (median loading level and effective loading level >100 mg/L) and low chronic toxicity in aquatic invertebrates and algae (no-observed-effect level >10mg/L). A predicted no-effect concentration was not calculated given 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 and other potential activities in industrial lubricants or personal care products is expected to be low. A predicted environmental concentration for notified and potential activities was not estimated given the low bioavailability and low ecotoxicity of the substance.

Based on the low ecotoxicity of the substance, and low potential for environmental exposure, persistence and bioaccumulation, 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 route of exposure (median lethal dose >2000 mg/kg body weight). It is not a skin sensitizer (effective concentration >10% (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the substance is used as notified, direct and indirect exposure of the general population is not expected due to the industrial nature of the use. Potential uses of the notified substance include other industrial applications and in personal care products. In the event of use in personal care products, there is an increased potential for direct exposure via the dermal, inhalation (aerosol applications) and ingestion routes. However, given its very low water solubility (≤ 0.01 mg/L), the substance is expected to have limited bioavailability and systemic uptake and exposure is expected to be low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low 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.