

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

New Substances Notification No. 18438: 9-Decenoic acid, methyl 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

9-Decenoic acid, methyl ester (Chemical Abstracts Service Registry No. 25601-41-6) is a chemical that can be classified as an 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 in cleaning/degreasing formulations. Other potential uses may include consumer cleaning products 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 soil and sediment. The substance is not expected to be persistent in soil and sediment based on its high ready biodegradation (60-85%). The substance is not expected to bioaccumulate based on its low predicted 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 moderate to high acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration <100 mg/L). The substance has low to moderate chronic toxicity in fish, algae and soil organisms, and moderate to high chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) <10 mg/L). Using the chronic NOEC from the most sensitive organism (aquatic invertebrates), the predicted no-effect concentration (PNEC) was calculated to be 10-100 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 mainly from formulation and use by release of the substance to water at levels of 1-10 µg/L. Environmental exposure from potential manufacturing activities is expected to release the substance to water at levels of 1-10 µg/L. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 1-10µg/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 hazard, exposure and environmental fate indicates that 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). It has a low potential for subchronic toxicity (no-observed-adverse-effect level (NOAEL) >300 mg/kg/d) and a low potential for developmental/reproductive toxicity (NOAEL > 1000 mg/kg/d) following repeat oral doses in mammalian test animals. It is not a skin sensitizer and it is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used in industrial/commercial cleaning/degreasing formulations, direct exposure of the general population to the notified substance is not expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels. In its potential uses in consumer cleaning products and personal care products, direct exposure of the general population to the notified substance is expected to be mainly by contact with the skin or by inhalation. Dermal absorption of the substance is possible based on its moderate octanol-water partition coefficient (logK_{ow} 3-6) and molecular weight; however, systemic distribution is expected to be limited by its low water solubility (0.01 to 10 mg/L).

Based on the low potential for acute and subchronic 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.