

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

New Substances Notification No. 18401: 9-Dodecanoic 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-Dodecanoic acid, methyl ester (Chemical Abstracts Service Registry No. 39202-17-0) 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 as a solvent ingredient in cleaning/degreasing formulations. Potential uses may include consumer cleaning products, cosmetics 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 air, soil and sediment. The substance is not expected to be persistent in air based on its very short half-life (≤ 2 hours in this compartment), or in soil and sediment based on its high biodegradation potential ($>60\%$). 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 hazard information and surrogate data on structurally related chemicals, the substance is expected to have high acute toxicity in fish and algae (median lethal concentration and median effective concentration (EC_{50}) <1 mg/L), and moderate to high acute toxicity in aquatic invertebrates ($EC_{50} <100$ mg/L). The substance is expected to have low to moderate chronic toxicity (no-observed-effect concentration (NOEC) >0.1 mg/L) in fish, high to moderate chronic toxicity (NOEC <10 mg/L) in aquatic invertebrates and algae, and low chronic toxicity (NOEC >10 mg/kg dry soil) in soil organisms. Using the NOEC from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect

concentration (PNEC) was calculated to be 1-10µg/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 to water from formulation and use in cleaners by release of the substance at low levels. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10µg/L. Other potential activities such as manufacturing were determined to have a similar PEC to the notified use.

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 and surrogate data on structurally related chemicals, 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 is expected to have a low potential for subchronic toxicity (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg bw/d) and a low potential for reproductive-developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg bw/day). It is expected to be a non-sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a solvent ingredient in industrial/commercial cleaning/degreasing formulations, direct exposure of the general population is not expected. For its potential use in consumer cleaning products, cosmetics and personal care products, direct exposure of the general population is expected to be moderate to high and mainly by contact with the skin. However, due to the extensive mammalian toxicity tests indicating that its acute and chronic toxicities are low, this is not expected to present a health risk. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible.

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.