

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

New Substances Notification 19386: Fatty acids, alkanes, alkyl esters (Confidential Accession No. 19259-7)

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 notified chemical is fatty acids, alkanes, alkyl esters (Confidential Accession No. 19259-7), is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in metalworking. Potential uses may include applications in printing ink, solvents, adhesives, oils and cosmetics.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released into the environment, it will tend to partition to soil and sediment. The substance is not expected to be persistent in these compartments based on its expected moderate biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on its predicted low bioconcentration and bioaccumulation factors (<250 L/kg) and its expected rapid biotransformation.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal loading rate and median effective loading rate >100 mg/L; no adverse effects observed in saturated solutions) and low chronic toxicity in aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is not expected as the substance is imported in low volumes and at low concentrations in products ($\leq 10\%$), and

specialized controls are in place to minimize environmental release. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day). It is not expected to be a skin sensitizer (estimated concentration required to produce a stimulation index of 3 >10% (local lymph node assay)). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in metalworking, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment.

Potential uses of the substance include consumer products such as cosmetics, printing inks or engine oil, where direct exposure of the general population is expected to be mainly by contact with the skin. Systemic exposure will be limited by the very high octanol-water partition coefficient ($\log K_{ow} > 8$) of the notified substance, which will inhibit its systemic uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected, similar to that of the notified use.

Based on the low potential for exposure and 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 activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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 *Hazardous Products Regulations* for products intended for the workplace.