

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

New Substances Notification 20318: Octadecanoic acid, 12-(acetyloxy)-, 2-ethylhexyl ester (Chemical Abstracts Service registry number 61800-40-6)

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 octadecanoic acid, 12-(acetyloxy)-, 2-ethylhexyl ester (Chemical Abstracts Service registry number¹ 61800-40-6).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as lubricant for industrial and consumer applications. Potential uses may include cosmetics.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediments. The substance is not expected to be persistent in these compartments based on high biodegradation (>60% over 28 days). The substance is not expected to bioaccumulate based on high octanol-water partition coefficient ($\log K_{ow} > 6$) and expected low bioaccumulation factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is not expected to have adverse effects in saturated solutions in fish, aquatic invertebrates, and algae. A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activities is expected to be mainly by release of the substance to water at low rates. For potential activities such as manufacturing and use in cosmetics, environmental exposure is expected to be

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quantitatively similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

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

Human health risk assessment

Based on the available hazard information, 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 repeated oral doses in mammalian test animals (42-day no-observed-effect level (NOEL) >300 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOEL >300 mg/kg-bw/day). It is not expected to be a dermal sensitizer. It is not expected to be mutagenic *in vitro* and is not clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a lubricant for industrial and do-it-yourself consumer applications, direct dermal or inhalation exposure of the general population is expected to be low. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be at low levels given the low potential for environmental release and the expected biodegradation of the substance. Potential uses of the substance include use in cosmetics, where direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at levels that do not pose a concern, similar to that of the notified use.

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 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.