

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

New Substances Notification 19986: Alcohols, C₁₂₋₁₃-branched and linear, dimerized (Chemical Abstracts Service Registry Number 2041102-78-5)

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 alcohols, C₁₂₋₁₃-branched and linear, dimerized (Chemical Abstracts Service Registry Number¹ 2041102-78-5), and is a substance referred to as unknown or variable composition, complex reaction products and 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 uses as an additive in lubricants and metalworking fluids, and as a chemical intermediate in industrial manufacturing. Potential uses may include cosmetics and coatings.

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 water and soil. The substance is not expected to be persistent in these compartments based on ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on its anticipated rapid biotransformation and low bioavailability which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median lethal loading rate >100 mg/L) and low chronic toxicity in algae (10% effective concentration >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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For potential activities, such as use in cosmetics and coatings, environmental exposure is expected to be at levels that do not pose a concern. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

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, 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 (90-day no-observed-adverse-effect level >100 mg/kg-bw/day). It is not a dermal sensitizer (0% response (guinea pig maximization test)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in lubricants and metalworking fluids, and as a chemical intermediate in industrial manufacturing, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial and commercial uses of the substance, which result in little or no release to the environment. Potential uses of the substance include use in cosmetics and coatings, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern.

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.