

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

New Substances Notification No. 18359: 1,3-Dioxolane-4-methanol, 2-methyl-2-(2-methylpropyl)-

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

1,3-Dioxolane-4-methanol, 2-methyl-2-(2-methylpropyl)- (Chemical Abstracts Service Registry No. 5660-53-7) is a chemical that can be classified as an alkyl dioxolane.

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 in consumer degreasers. Potential uses may include a wider variety of consumer 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 and water. In air, the substance has a short half-life (<2 days) and is therefore not expected to be persistent in this compartment. In water, the substance has a long half-life (>182 days), and is therefore expected to be persistent in this compartment. The substance is not expected to bioaccumulate based on its predicted low 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 low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L) and low chronic toxicity in fish, aquatic invertebrates and algae (chronic value >10 mg/L). A predicted no-effect concentration was not calculated given the low potential ecotoxicity.

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 consumer use as a solvent but no major point sources were identified. A predicted environmental concentration for notified activities was not calculated given the low hazard profile of the notified substance, and given that no significant releases are expected.

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

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight). It is not sensitizing to skin. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a solvent in consumer degreasers, direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation at low to moderate levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels. If the substance is used in a wider variety of consumer products, an increased direct exposure potential to the skin and via inhalation may exist. However, this is unlikely to present a health risk due to its low toxicity.

Based on the low potential for 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.