

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

New Substances Notification No. 18258: Butanoic acid, 3-hydroxy-, butyl 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 that 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

Butanoic acid, 3-hydroxy-, butyl ester (Chemical Abstracts Service Registry No. 53605-94-0) is a chemical that can be classified as an aliphatic 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 in the formulation of aqueous cleaners. Potential uses may include 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 water. The substance is not expected to be persistent based on its short half-life (<10 days in water). The substance is not expected to bioaccumulate based on the low predicted 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 to moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration (LC₅₀) and median effective concentration >1 mg/L). Using the LC₅₀ from the most sensitive organism (fish) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 1000-10000 µg/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 activities is expected to be mainly from container cleaning, blending and end-use in

industrial cleaners by release of the substance to water. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10 µg/L and 0.1-1 µg/L for container cleaning and end-use in industrial cleaners, respectively. The PEC for potential activities such as manufacturing is estimated to be 10-100 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that 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-bw) and is expected to have a low potential for subchronic and reproductive/developmental toxicity following repeat oral doses in mammalian test animals (no-observed-adverse-effect level >1000 mg/kg-bw/d). It is non-sensitizing and it is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. Testing showed no evidence of endocrine disrupting (estrogenic) potential.

When the notified substance is used as a solvent for formulating aqueous cleaners, or for potential uses in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin or inhalation at moderate to high levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be low because it is readily biodegradable in the aquatic environment.

Based on the low acute oral 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 used as notified or for other identified potential uses, the substance 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.