

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

New Substances Notification No. EAU-785: 1-Propanaminium, 3-carboxy-2-hydroxy-*N,N,N*-trimethyl-, (2R)-, (2R,3R)-2,3-dihydroxybutanedioate (2:1)

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-Propanaminium, 3-carboxy-2-hydroxy-*N,N,N*-trimethyl-, (2R)-, (2R,3R)-2,3-dihydroxybutanedioate (2:1) (Chemical Abstracts Service Registry No. 36687-82-8) is a chemical that can be classified as a quaternary ammonium compound.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities up to or greater than 10 000 kg/yr for use as a source of L-carnitine and L-tartaric acid in dietary supplements and foods. Other potential uses are expected to be similar to those notified.

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 in water based on its very high biodegradation potential. The substance is not expected to bioaccumulate based on the notified substance components having low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and low predicted bioconcentration factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low 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 and potential activities is expected to be mainly from industrial formulation, and consumer product usage and disposal to water at very low rates. A predicted environmental concentration for notified or potential activities was not calculated due to the low toxicity and low potential for release.

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

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level >1000 mg/kg bw/day). It is a weak sensitizer. It is not mutagenic *in vitro* and is not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used for its notified and potential use in food and as a dietary supplement, direct exposure of the general population is expected to be mainly by ingestion through the use of consumer products containing the notified substance. The Food Directorate and the Natural Health Products Directorate of Health Canada are responsible for the human health risk assessments associated with direct exposure to this substance through use as a novel food and in dietary supplements. Indirect exposure of the general population from environmental media such as drinking water is expected to be very low.

Based on its low toxicity, the substance is not likely to pose a significant health risk to the general population through indirect exposure, 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.