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

New Substances Notification No. EAU-854: Butanedioic acid, 2-hydroxy-, sodium salt (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

Butanedioic acid, 2-hydroxy-, sodium salt (1:?) (Chemical Abstracts Service Registry No. 3105-51-9) is a chemical that can be classified as dicarboxylic acid.

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 food additive (stabilizing agent) in beverage bases, chewing gum, gelatins, and hard and soft candy. Potential uses may include as an ingredient in 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 in water based on its very high biodegradation potential. The substance is not expected to bioaccumulate based on the expected low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and low predicted bioconcentration factor (<250 L/kg).

Ecological Assessment

Based on the available hazard information and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration (EC_{50}) >100 mg/L) and low to moderate acute toxicity in algae (EC_{50} >1 mg/L). Using the EC_{50} from the most sensitive organism (algae), the predicted no-effect concentration (PNEC) was calculated to be 0.1 to 1.0 mg/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 and potential activities is expected to be mainly from processing or manufacturing by release of the substance to water at levels up to 1-10 kg/day at a single site. The predicted environmental concentration (PEC) for notified activities is estimated to be 0.001 to 0.01 mg/L, and the PEC for potential activities is estimated to be 0.01 to 0.1 mg/L.

Comparing the PEC for notified and potential activities with the PNEC, the ratio is less than 1. This along with other lines of evidence including hazard, exposure and environmental fate indicates that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information and surrogate data on structurally related chemicals, the substance is expected to have 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. It has a low potential for reproductive toxicity by the oral route of exposure (no-observed-adverse-effect level >1000 mg/kg bw/d) and a low potential for teratogenicity based on *in vitro* tests. 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 food additive (stabilizing agent), direct exposure of the general population is expected to be mainly by ingestion. 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 food additive. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of $1x10^{-6}$ to $1x10^{-5}$ mg/kg bw/d, which is very low. When the notified substance is used in its potential use as an ingredient in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin through the use of products containing the notified substance up to a 1% concentration at levels of 1 to 10 mg/kg bw-d. Indirect exposure of the general population is expected to be very low, similar to that of the notified use.

Based on the low potential for acute and subchronic 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.