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

New Substances Notification 21259: 1,3-Butanediol, (3*R*)- (Chemical Abstracts Service Registry Number 6290-03-5)

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 biochemical is 1,3-butanediol, (3*R*)- (Chemical Abstracts Service Registry Number[1] 6290-03-5).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in cosmetics, air care products, food, pharmaceuticals, and other industrial, commercial, and consumer product applications. No other uses are anticipated in Canada.

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. The substance is not expected to be persistent in this compartment based on high ready biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (< 250 L/kg) and very high water solubility (> 10 g/L).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (median lethal concentration (LC_{50}) > 100 mg/L), aquatic invertebrates (median effective concentration (EC_{50}) > 100 mg/L), and algae (EC_{50} > 100 mg/L), and low chronic toxicity to aquatic invertebrates (no-observed-effect-concentration > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified 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 processing, use, and disposal by release of the substance to water at low rates. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral and inhalation routes (median lethal dose > 2000 mg/kg body weight; LC_{50} > 5 mg/L/4hr) and low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) > 100 mg/kg-bw/day; 2-year NOAEL > 100 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (negative in a human repeat insult patch test). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in commercial products or consumer products including cosmetics and air care products, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation. When the notified substance is used in pharmaceuticals or food, direct exposure of the general population is assessed by the Pharmaceutical Drugs Directorate or the Food Directorate of Health Canada, respectively, and therefore, the risk from these uses are not addressed in this assessment. When the notified substance is used in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified, 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 the *Hazardous Products Regulations* for products intended for the workplace.