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

New Substances Notification No. 18228: Butanedioic acid, mono (mixed alken-1-yl and polyisobutylene) derivatives, ethylene esters, Confidential Accession No. 18908-8

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 chemical, butanedioic acid, mono (mixed alken-1-yl and polyisobutylene) derivatives, ethylene esters (Confidential Accession No. 18908-8), of unknown or variable composition, complex reaction products or biological materials (UVCB), can be classified as an 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 surfactant in industrial applications. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in soil and sediment based on a moderate biodegradation rate (30-60%) measured for an analogue substance. However, the resulting degradation products are expected to be persistent in sediment and soil due to their structures that would be resistant to biodegradation. The substance and its degradation products are not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information, the notified 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 potential for ecological risk.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. The potential for environmental exposure from the notified activity is expected to be negligible. The substance will be applied in an industrial setting and will be incinerated upon disposal. Consequently, a predicted environmental concentration for notified activities has not been estimated given the low potential for environmental exposure. No other potential activities have been identified.

Given the low potential for ecotoxicity and environmental release, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information and 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 moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level 30-300 mg/kg-bw/d). It does not cause skin sensitization is a (0% response (Buehler scale)). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a surfactant in industrial applications, the potential for direct exposure of the general population is expected to be negligible. Releases of the substance during formulation or use are not expected. The potential for significant environmental release resulting in indirect exposure of the general population is considered low due to the use of the substance in a closed system. Other potential applications in consumer products are considered unlikely.

Based on the low potential for exposure, 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, 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.