

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

New Substances Notification No. 18958: Benzoic acid, hydroxyl, mono-alkyl derivatives, calcium salts (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

The notified polymer is benzoic acid, hydroxyl, mono-alkyl derivatives, calcium salts (2:1) (Confidential Accession No. 19165-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons and because it contains unsubstituted positions ortho or para to phenolic hydroxyl.

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 the notified use as an oil additive for industrial applications. 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 soil and sediment. The substance is expected to be persistent in soil and sediment based on its expected half-lives of >182 days in soil and >365 days in sediment. The substance is not expected to bioaccumulate based on its low bioavailability and its susceptibility to metabolism.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal loading rate and median effective loading rate >100 mg/L), and low chronic toxicity in algae (no-observed-effects level >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activity is expected to be mainly from cleaning of transportation vessels, formulation and use by release

of the substance to water at low rates. For potential uses such as use as an oil additive in other industrial applications, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity and environmental exposure.

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

Human health assessment

Based on the available hazard information 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 >300 mg/kg body weight without mortality or evidence of toxicity) and low subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/day). The substance has low reproductive and developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day). It is expected to be a moderate dermal sensitizer (28-80% response (Buehler scale)). 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 as an additive and surfactant, 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 not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If the substance is used as an oil additive in other industrial applications, direct and indirect exposure of the general population is expected to be similar to that of the notified use.

Based on the low potential for human 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 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 *Hazardous Products Regulations* for products intended for the workplace.