

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

New Substances Notification 19471: Benzenesulfonic acid, mono-C₂₀₋₂₄-sec-alkyl derivatives, calcium salts, overbased (Chemical Abstracts Service Registry Number 1078715-97-5)

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 chemical is benzenesulfonic acid, mono-C₂₀₋₂₄-sec-alkyl derivatives, calcium salts, overbased (Chemical Abstracts Service Registry Number¹ 1078715-97-5), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a lubricant additive. Potential uses may include as a lubricant additive in other applications.

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 soil and sediment. The substance is expected to be persistent in these compartments based on its low biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (<250 L/kg).

Ecological assessment

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

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The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its lifecycle. Environmental exposure from the notified activities is not expected during the life cycle of the substance. For potential activities such as manufacturing or processing, environmental exposure is not expected, similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for 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 for the substance and surrogate data on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low to moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day for males, >30 mg/kg-bw/day for females). The substance is expected to have moderate subchronic toxicity following repeat dermal doses in mammalian test animals (28-day-NOAEL 60-600 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >250 mg/kg-bw/day with no adverse effects). It is not expected to be a skin sensitizer (0% response (Buehler scale); negative result in human repeat insult patch test). 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 lubricant additive by do-it-yourself consumers, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Exposure will be limited by the low concentration of the substance in end-use products (<0.1%) and the infrequent use of products containing the substance. As well, its high molecular weight will limit its ability to cross biological membranes and its high octanol-water partition coefficient ($\log K_{ow} > 8$) will limit systemic uptake. 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 which could significantly increase human health risks compared to the notified uses were identified.

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 or for other identified potential activities, 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 *Hazardous Products Regulations* for products intended for the workplace.