

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

New Substances Notification 18193: Pentanedioic acid, lithium salt (1:2) (Chemical Abstracts Service registry number 29126-51-0)

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 pentanedioic acid, lithium salt (1:2) (Chemical Abstracts Service registry number¹ 29126-51-0)

Notified and potential uses

The substance is proposed to be imported into Canada in quantities up to or greater than 10 000 kg/yr for the notified use as an additive in industrial greases. Potential uses may include an additive in commercial and consumer greases and in batteries.

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 water based on ready biodegradation (>85% in 28 days). The substance is not expected to bioaccumulate based on its very low octanol-water partitioning coefficient ($\log K_{ow} \leq 0$) and bioconcentration factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish and aquatic invertebrates (median lethal concentration and median effective concentration (EC_{50}) >100 mg/L) and low chronic toxicity to aquatic invertebrates and algae (EC_{50} >10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 20 to account for species sensitivity variation, mode of action, and endpoint standardization, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1-1 mg/L.

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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 by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. 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 ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight). It is not expected to be a dermal sensitizer (the estimated concentration required to produce a stimulation index of 3 could not be determined (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a grease additive in automobiles, Do-It-Yourself users may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance has very low dermal absorption. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses of the substance include use in lithium batteries, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity and 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.

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 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.