

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

New Substances Notification 20091: Butanedioic acid, polyisobutenyl derivs., magnesium salts (Chemical Abstracts Service Registry Number 160498-44-2)

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 butanedioic acid, polyisobutenyl derivs., magnesium salts (Chemical Abstracts Service Registry Number¹ No. 160498-44-2). 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.

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 detergent additive in crankcase lubricant and transmission fluids.

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 very low biodegradability ($\leq 10\%$ over 28 days). The substance is not expected to bioaccumulate based on its low water extractability which will limit its bioavailability.

Ecological assessment

Based on the low water extractability ($< 2\%$), the substance is expected have low bioavailability. Therefore, a predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. No release to the aquatic environment is expected based on the low

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water extractability. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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

Human health assessment

Based on the available hazard information, the substance has low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and low to moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level 300-1000 mg/kg bw/day). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used industrially or commercially as a detergent additive in crankcase lubricants and transmission fluids, direct exposure of the general population is not expected. Do-it-yourself consumers may come into direct contact with the notified substance mainly by dermal or inhalation exposure. However, concerns for dermal and inhalation exposure to the substance are mitigated by the low vapour pressure and low dermal uptake of the substance. Further, exposure is expected to be low due to its infrequent use, short duration of exposure, and low concentration in end-use products. Indirect exposure of the general population from environmental media such as drinking water and air 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 the substance, 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.