

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

New Substances Notification No. 19224: Butanedioic acid, 2-methylene-, telomer with sodium phosphinate (1:1), sodium zinc salt (Chemical Abstracts Service No. 1662663-05-9)

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 polymer is butanedioic acid, 2-methylene-, telomer with sodium phosphinate (1:1), sodium zinc salt (Chemical Abstracts Service No. 1662663-05-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains phosphorus and zinc above 0.2% by weight.

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 an odour neutralizer in various products such as surface cleaners, detergents, air fresheners, pet products and in waste treatment facilities. Potential uses may include a variety of applications such as use as a water softener, chelating agent, builder, stabilizer, dispersant, anti-deposition agent and sequestrant.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The organic components of the substance are not expected to be persistent in water based on high ready biodegradation (60-85% over 28 days). However, the zinc component is expected to be persistent in water. The organic components of the substance are not expected to bioaccumulate based on their high molecular weight which will limit the ability to cross biological membranes.

Ecological assessment

Given that the zinc ion of the notified substance is expected to be persistent and is an environmental concern once dissociated from the substance, potential for ecological harm was assessed based on the zinc ion. The 2016 Canadian Water Quality Guidelines long term exposure value for zinc was considered to be the predicted no-effect concentration (PNEC), 0.07 mg/L, which was used to estimate the ecological risk.

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 activities is expected to be mainly from formulation and cleaning of transportation vessels by release of zinc to water at rates of 1 to 10 kg/day. For potential activities such as consumer product use, environmental exposure is expected to be similar to or lower than that of the notified use. The predicted environmental concentration (PEC) of zinc is estimated to be between 0.001 and 0.01 mg/L for notified activities.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the hazard information on the substance and surrogate data 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 >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals. It is not expected to be a skin sensitizer (guinea pig maximization test). It is not expected to be mutagenic or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

The notified substance contains zinc and phosphorus. Zinc is an essential metal with significant biological roles in the human body and is only toxic in high concentrations. Phosphorus is also an essential mineral which is abundant in the human body. As such, zinc and phosphorus within the notified substance are not expected to be associated with significant health hazards in humans.

When the notified substance is used as an odour neutralizer, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation at low to moderate levels. Dermal exposure will be mitigated by the limited ability of the substance to cross biological membranes due to its high molecular weight, low octanol-water partition coefficient ($\log K_{ow} \leq 0$) and low concentration in consumer products. Inhalation exposure will be mitigated by the low concentration of the substance in consumer products. If the substance is used in personal care products, direct exposure of the general population is expected to be similar to that of the notified use. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low toxicity, 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.