

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

New Substances Notification 21321: Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt (Chemical Abstracts Service Registry Number 2220235-78-7)

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, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt (Chemical Abstracts Service Registry Number¹ 2220235-78-7). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations (Chemicals and Polymers) because it degrades substantially and it contains zinc above 0.2% by weight.

Notified and potential uses

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. Potential uses may include use in absorbents, adhesives and binders.

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 this compartment because of its biodegradation potential (> 60% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish, aquatic invertebrates and algae (median effective concentrations (EC₅₀) > 1 mg/L). Using the EC₅₀ from the most sensitive organism (algae) and by applying an assessment factor of 25 to account for species sensitivity variation and median to low effects, the predicted no-effect concentration (PNEC)

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was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

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 industrial processing and use in cosmetics from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, with the exact value being below the PNEC value. For potential activities such as industrial manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 µg/L, with the exact value being also below the PNEC value.

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

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral and inhalation routes. It is not expected to be a dermal sensitizer. It is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in cosmetics, direct exposure of the general population is expected to be mainly by contact with the skin. Systemic exposure will be limited by the high molecular weight of the substance, which will limit its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.1-1 µg/kg bw/day for children and adults and mainly by ingestion.

Potential uses of the substance include use as a component of absorbents and binders, where consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Potential activities include manufacturing, where indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.1-1 µg/kg bw/day for children and adults.

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 the *Hazardous Products Regulations* for products intended for the workplace.