

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

New Substances Notification 21440: Hexanedioic acid, polymer with oxybis[propanol] and 1,2,3-propanetriol (Chemical Abstracts Service Registry Number 1151511-68-0)

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 polymer is hexanedioic acid, polymer with oxybis[propanol] and 1,2,3-propanetriol (Chemical Abstracts Service Registry Number¹ 1151511-68-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains a high percentage of low molecular weight components.

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 a component in the manufacture of insulating foam boards. No other uses are anticipated in Canada.

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 because the functional groups susceptible to degradation are embedded within the large polymer matrix. The substance is not expected to bioaccumulate based on the high molecular weight of some components, which will limit their ability to cross biological membranes, and the low predicted bioaccumulation and bioconcentration factors (< 250 L/kg) for low molecular weight components.

¹ The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low toxicity to algae (no-observed-effect level (NOEL) > 10 mg/L) and is not expected to have adverse effects in saturated solutions to fish and aquatic invertebrates. Using the NOEL from the most sensitive organism (algae) and by applying an assessment factor of 50 to account for species sensitivity variation, the predicted no-effect loading rate (PNEL) was calculated to be in the range of 0.1-1 mg/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 cleaning of transportation vessels from the release of the substance to waste water resulting in a predicted environmental loading rate (PEL) in the range of 0.01-0.1 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be low, similar to that of the notified use.

Comparing the PEL with the PNEL, 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 harm to the environment in Canada.

Human health risk 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). The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as a component in the manufacture of insulating foam boards, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

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, 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 the Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.