

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

New Substances Notification 20915: Benzene, 1,1'-(1,1,2,2-tetramethyl-1,2-ethanediyl)bis- (Chemical Abstracts Service Registry Number 1889-67-4)

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 benzene, 1,1'-(1,1,2,2-tetramethyl-1,2-ethanediyl)bis- (Chemical Abstracts Service Registry Number¹ 1889-67-4).

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 additive for preparation of industrial and commercial polymer formulations. Potential uses may include use as a polymerization initiator and as a component of polymer/plastic products for industrial, commercial and consumer applications.

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 very low ready biodegradation ($\leq 10\%$ over 28 days). The substance is expected to bioaccumulate based on a high octanol-water partition coefficient ($\log K_{ow}$ 6-8) and a moderate to high bioconcentration factors (250-5000 L/kg).

Environmental risk assessment

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.

Based on the available hazard information, the substance is expected to have low acute toxicity to fish and aquatic invertebrates (no adverse effects observed in saturated solutions) and high chronic toxicity to algae (no-observed-effect concentration (NOEC) < 100 µg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 2 to account for acute to chronic extrapolation, species sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 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 activity is not expected from the production of polymer formulations. For potential activities such as the cleaning of transportation vessels, manufacturing of the substance, polymer manufacturing and handling of raw materials, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 0.01-10 µg/L, with the exact values being below the PNEC value.

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 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 and dermal route (median lethal dose > 2000 mg/kg body weight). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive for preparation of industrial and commercial polymer formulations, direct exposure of the general population is not expected. If consumers come into contact with end-use products containing the substance, direct exposure is not expected because the substance will be used at low concentrations in end-use products and will be encapsulated in the product matrix and not available for uptake. 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 manufactured articles such as electronics, textiles, carpets, furniture, building materials, paints and fillers, 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 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.