

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

New Substances Notification 19587: Formaldehyde, polymer with 1,3-benzenediol and ethenylbenzene
(Chemical Abstracts Service registry number 135020-80-3)

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 formaldehyde, polymer with 1,3-benzenediol and ethenylbenzene (Chemical Abstracts Service registry number¹ 135020-80-3). 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 uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in tire rubber. 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 water and sediment. The substance is expected to be persistent in these compartments based on its low ready biodegradability (10-30% over 28 days) and its stability at all tested pH ranges. The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient (log K_{ow} 0-3).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration 1-100 mg/L) and moderate to high chronic toxicity in algae (10% effective concentration 0.1-10 mg/L; lowest-observed-effect-concentration (LOEC) <0.1 mg/L). Using the LOEC from the most sensitive organism (algae) and by

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applying an assessment factor of 5 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/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 not expected to any significant degree based on the low concentration of the substance in rubber goods and the specialized conditions on the transportation, processing and disposal of the substance. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Based on the low potential for environmental exposure when used as notified, and comparing the PEC with the PNEC for potential activities resulting in a ratio less than 1, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (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 in rubber tires, 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. 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 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 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.