

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

New Substances Notification 21291: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, acetate (Chemical Abstracts Service Registry Number 67757-47-5)

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 2-propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, acetate (Chemical Abstracts Service Registry Number¹ 67757-47-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic amine groups.

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 binder in coatings. 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 based on very low hydrolysis potential. 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

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Based on the available hazard information, the substance has moderate chronic toxicity to algae (10% effective concentration (EC₁₀) 1-10 mg/L) and is expected to have low to moderate acute toxicity to fish (median lethal concentration > 1 mg/L) and aquatic invertebrates (median effective concentration > 1 mg/L) under environmental conditions where toxicity is mitigated by adsorption to suspended solids. Using the EC₁₀ from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L, which was used to estimate the risk to the environment.

The notified 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 expected to be due to formulation and cleaning of transportation vessels resulting in potential release of the substance to water and a predicted environmental concentration (PEC) in the range of 10-100 µg/L. No potential activities that could significantly increase environmental risks compared to those notified were identified.

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 a low to moderate acute toxicity by the oral route (median lethal dose > 300 mg/kg body weight when corrected for purity). The notified substance does not contain any structural features known to be associated with adverse human health effects.

When the notified substance is used as a binder in coatings, direct exposure of the general population is expected to be mainly by contact with the skin; however, absorption through the skin is not anticipated due to the high molecular weight and cationic charge of the substance which will limit its ability to cross biological membranes. Once the product is cured, the substance will be encapsulated within a stable matrix and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water and air is not expected given the low potential for environmental release. 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 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 Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.