

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

New Substances Notification 21389: 2-Propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-propenoate and methyl 2-methyl-2-propenoate, salts with carbomonocyclodiol-epichlorohydrin-4,4'-methylenebis[2,6-dimethylphenol] polymer-2-(dimethylamino)ethanol reaction products (Confidential Accession Number 19655-3)

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 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-propenoate and methyl 2-methyl-2-propenoate, salts with carbomonocyclodiol-epichlorohydrin-4,4'-methylenebis[2,6-dimethylphenol] polymer-2-(dimethylamino)ethanol reaction products (Confidential Accession Number 19655-3). 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 in industrial coating applications. 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, soil and sediment. The substance is not expected to be persistent in these compartments based on the moderate biodegradability (30-60% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight and ionic characteristics, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance has low to moderate acute toxicity to fish (median lethal loading rate > 1 mg/L) and aquatic invertebrates (median effective loading rate (EL₅₀) > 1 mg/L) and has low chronic toxicity to algae (10% effective loading rate > 10 mg/L). Using the EL₅₀ from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 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 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 cleaning of transportation vessels, resulting in a predicted environmental concentration (PEC) in the range of 100-1000 µg/L, with the exact value being below the PNEC value. 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 low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight,) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level > 300 mg/kg-bw/day). It is not a dermal sensitizer (stimulation index < 3 in a local lymph node assay). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used for industrial coating applications, consumers may come into contact with end-use products produced using the substance; however, direct exposure is not expected because the substance will be chemically reacted and not present in the cured coating. Indirect exposure of the general population from environmental media such as drinking water or air is not expected given the low potential for environmental release. No potential uses that could significantly increase human exposure to the notified substance 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.