

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

New Substances Notification No. 18150: 1,3-Isobenzofurandione, polymer with alkanediol and α -hydro- ω -hydroxypoly (oxy-1,2-ethanediyl) ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2-propenoate

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 that 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

1,3-Isobenzofurandione, polymer with alkanediol and α -hydro- ω -hydroxypoly (oxy-1,2-ethanediyl) ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2-propenoate (Confidential Accession No. 18870-6) is a polymer that can be classified as a poly (aryl-ester[ether]). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because of presence of terminal acrylate groups and a high percentage of low molecular weight components.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use in industrial wood coatings. Potential uses are expected to be similar to those notified.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, soil and sediment. The substance is not expected to be persistent in these compartments because the substance is expected to undergo hydrolysis somewhat quickly under typical environmental conditions. The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate acute toxicity in algae (median effective level (EL₅₀) 1-100 mg/L). Toxicity of acrylic acid was also considered because the notified substance

may undergo hydrolysis to release acrylic acid. Acrylic acid has moderate to low acute toxicity in daphnia and fish (median lethal concentration >1 mg/L). Using the EL₅₀ from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 100-1000 µg/L, which was used to estimate the ecological risk.

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 mainly from release from transport vessels, reconditioning facilities and industrial uses by release of the substance to waste water treatment systems at levels of 10-100 kg/day/site. The predicted environmental concentration (PEC) for the notified activity is estimated to be 10-100 µg/L.

Comparing PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral route of exposure in mammalian test animals (median lethal dose >2000 mg/kg-bw). It may be a sensitizer due to the presence of acrylate groups.

When used in industrial wood coatings specifically for cabinets and flooring, direct exposure of the general population is not expected as the substance will be chemically reacted into a stable polymer matrix after curing. Indirect exposure of the general population from environmental media is not expected. In the event of an unforeseen environmental release, indirect exposure to environmental media such as drinking water is considered unlikely.

Based on the lack of exposure in conjunction with the low acute oral toxicity in mammalian test animals, 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 used as notified, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 workplace use.