

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

New Substances Notification No. 19025: Isocyanic acid, polymethylenepolyphenylene ester, polymer with α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 2-methyloxirane polymer with oxirane ether with 1,1',1'',1'''-[(methylimino)bis(3,1-propanediyl)nitri]l]tetrakis[2-propanol] (4:1)

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 isocyanic acid, polymethylenepolyphenylene ester, polymer with α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 2-methyloxirane polymer with oxirane ether with 1,1',1'',1'''-[(methylimino)bis(3,1-propanediyl)nitri]l]tetrakis[2-propanol] (4:1) (Chemical Abstracts Service No. 1826089-67-1). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because of the presence of aromatic isocyanates and amine groups.

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 the notified use in industrial coatings. Potential uses may include use in other types of coatings, as well as in sealants and adhesives.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will react with moisture to form insoluble, high molecular weight species that will partition to soil and sediment. The substance is not expected to be persistent based on its ability to hydrolyze rapidly in the presence of moisture. However, the hydrolysis products are expected to be persistent in soil and sediment because these high molecular weight, insoluble species are expected to be highly resistant to biodegradation resulting in half-lives of >182 days in water and >365 days in sediment. The substance and its hydrolysis products are not expected to bioaccumulate based on their high molecular weights and complex structure which will limit the ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration >100 mg/L) and low chronic toxicity in aquatic invertebrates and algae (no-observed-effect-concentration and no-observed-effect level >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 as the substance will react with moisture to form insoluble, high molecular weight compounds and precautions are taken throughout its lifecycle to prevent contact with moisture. Once cured, the substance will be chemically reacted into a stable matrix and unavailable for release. For potential activities such as manufacturing, environmental exposure is expected to be negligible, similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and low ecotoxicity.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight).

When the notified substance is used as an industrial binder, direct exposure of the general population is not expected due to the industrial nature of the use. If the substance is used in consumer sealants and adhesives, direct exposure of the general population is expected to be mainly by contact with the skin at low levels due to the limited ability of the uncured substance to cross biological membranes given its high molecular weight, and infrequent use of products containing the substance by consumers. Once cured, the substance will be chemically reacted into the stable polymer matrix of the sealant or adhesive and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible given that the substance will react rapidly with water to form insoluble, high molecular weight compounds, resulting in little to no distribution in the aquatic environment.

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 used as notified or for other identified potential uses, 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 *Hazardous Products Regulations* for products intended for the workplace.