

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

New Substances Notification No. 18754: 2-Oxepanone, polymer with 2,4-diisocyanato-1-methylbenzene and tetrahydro-2*H*-pyran-2-one, polyalkyl ester, 1*H*-imidazole-1-alkaneamine-blocked

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 polymer, 2-oxepanone, polymer with 2,4-diisocyanato-1-methylbenzene and tetrahydro-2*H*-pyran-2-one, polyalkyl ester, 1*H*-imidazole-1-alkaneamine-blocked (Confidential Accession No. 19049-5), can be classified as a poly(ester)aryluurethane-triazine-trione. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains potentially cationic 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 use in industrial paints and coatings largely for the automotive industry. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the water-soluble portion of the substance (approximately 25%) will tend to partition to water, while the insoluble portion will tend to partition to soil and sediment. The substance is expected to be persistent in water, soil and sediment because its overall low water solubility is expected to inhibit the hydrolysis potential of the ester functional groups, and the substance is not expected to be susceptible to biodegradation. The substance is not expected to bioaccumulate based on its negligible solubility in lipid-like materials and its high molecular weight, which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in algae (median effective loading >100 mg/L). Based on predictive modelling data, the substance is expected to have low acute toxicity in aquatic invertebrates (median effective concentration >100 mg/L) and moderate acute toxicity in fish (median lethal concentration 1-100 mg/L). Toxicity will be mitigated by the presence of dissolved organic carbon, which would be present under environmental conditions. A predicted no-effect concentration was not calculated given the low ecotoxicity.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. The substance will be consumed during the manufacturing process, which is expected to occur in contained industrial environments. Environmental exposure from the notified activity is expected to be mainly from the cleaning of transportation vessels or formulation activities by release of the substance to wastewater at low rates. If released to the aquatic environment, the substance is expected to be efficiently removed by waste water treatment processes via adsorption due to its very high adsorption-desorption coefficient ($\log K_{oc} > 4.5$). A predicted environmental concentration for notified activities was not estimated given the low ecotoxicity. No other potential activities have been identified.

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

Human Health Assessment

Based on the available information, the substance has a low potential for toxicity based upon its high molecular weight, which limits its ability to cross biological membranes. Functional groups of the substance have not been associated with human toxicity.

When the notified substance is used in industrial paints and coatings largely for the automotive industry, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is not expected. No other potential uses were identified.

Based on the low potential for exposure in conjunction with the low potential for toxicity based upon its structure and functional groups, 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 uses, it is not expected 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.