

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

New Substances Notification No. 19086: Silsesquioxanes, 3-[[[3,5-dimethyl-heteromonocycle-1-yl)carbonyl]amino]propyl Pr, polymers with silicic acid (H_4SiO_4) tetra-Et ester, alkoxy- and hydroxy-terminated, reaction products with 4-alkyl-1,3-dioxolan-2-one-3-(trialkoxysilyl)-1-propanamine polymer

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 silsesquioxanes, 3-[[[3,5-dimethyl-heteromonocycle-1-yl)carbonyl]amino]propyl Pr, polymers with silicic acid (H_4SiO_4) tetra-Et ester, alkoxy- and hydroxy-terminated, reaction products with 4-alkyl-1,3-dioxolan-2-one-3-(trialkoxysilyl)-1-propanamine polymer (Confidential Accession No. 19372-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains silanol and alkoxy silane 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. No potential activities have been identified.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will react with moisture to hydrolyze and further react to form insoluble, high molecular weight compounds that will tend to partition to soil and sediment. The substance is not expected to be persistent based on its rapid hydrolysis. However, the reaction products are expected to be persistent in soil and sediment as the high molecular weight, insoluble species are expected to be highly resistant to biodegradation. The substance and its hydrolysis products are not expected to bioaccumulate based on their high molecular weight which will limit their ability to cross biological membranes.

Ecological assessment

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

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 activities such as formulation and use in industrial coatings is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for release. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and low ecotoxicity. No potential activities have been identified.

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 (median lethal dose >2000 mg/kg body weight).

When the notified substance is used in industrial coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses have been 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.

Assessment conclusion

When the substance is used as notified, it 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.