

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

New Substance Notification 19513: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, *N*-oxides, acetates (Chemical Abstracts Service Registry Number 1440528-04-0)

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-, 2-(dimethylamino)ethyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, *N*-oxides, acetates (Chemical Abstracts Service Registry Number¹ 1440528-04-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic amines.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a grease and water repellent for paper packaging. Potential uses may include use as a grease and water repellent on other substrates.

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 soil and sediment. The substance is expected to be persistent in these compartments because the functional groups susceptible to degradation are embedded within the large polymer matrix; however, there is potential for some degradation over time. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

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Based on the low water extractability of the substance (<2%), the substance is not expected to be bioavailable to aquatic life and would be expected to have low toxicity in aquatic organisms. 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 activity is expected to be negligible given the low water extractability of the substance. 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 ecotoxicity.

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

Human health assessment

No mammalian toxicity data are available for the substance. The substance contains perfluorinated alkyl (PFA) components which were concluded not likely to pose a significant risk to human health based on the subchronic inhalation toxicity of the perfluorohexanoic acid breakdown product.

When the notified substance is used as a grease and water repellent for paper packaging, consumers may come into contact with end-use products containing the substance; however, direct exposure is expected to be at low levels as the substance is not expected to be released from end-use products, and the large molecular weight of the substance will limit its ability to cross biological membranes in the event of release. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible given the low potential for environmental release. Potential uses of the substance include as a grease and water repellent on other substrates, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

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