

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

New Substances Notification No. 19794: 2-Propenoic acid, 2-methyl-, methyl ester, polymer with isooctyl 2-propenoate and 3-[3,3,3-trimethyl-1,1-bis[(trimethylsilyl)oxy]-1-disiloxanyl]propyl 2-methyl-2-propenoate (Chemical Abstracts Service No. 175283-06-4)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Significant New Activity Notice No. 19794](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 153, No. 13 on March 30, 2019. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified polymer is 2-propenoic acid, 2-methyl-, methyl ester, polymer with isooctyl 2-propenoate and 3-[3,3,3-trimethyl-1,1-bis[(trimethylsilyl)oxy]-1-disiloxanyl]propyl 2-methyl-2-propenoate (Chemical Abstracts Service Registry Number¹ 175283-06-4). The substance meets the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)*.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use in liquid bandages and barrier films. The potential use of the substance in aerosol consumer products has also been considered and it was determined that insufficient information is available to assess the risks associated with these potential uses and activities.

Environmental fate and behaviour

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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 based on its high molecular weight and complex structure will limit biodegradation potential. The substance is not expected to bioaccumulate based on its large molecular structure which will limit its ability to cross biological membranes.

Ecological assessment

No ecological toxicity data are available for the substance. The substance does not contain functional groups associated with environmental toxicity.

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 not expected. Consumer use is highly dispersive, and the substance is expected to be removed efficiently during wastewater treatment. For potential activities such as formulation, environmental exposure is expected to be similar to that of the notified use.

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 does not contain structural features associated with adverse human health effects. However, high molecular weight water insoluble polymers have been linked to irreversible lung damage.

When the notified substance is used in liquid bandages and barrier films, direct exposure of the general population is expected to be mainly by contact with the skin at low levels due to its high molecular weight which will limit its ability to cross biological membranes. However, if the substance is used in aerosol personal care products, an increased level of direct inhalation exposure may exist. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels because environmental exposure is expected to be low.

Based on the low potential for exposure when used as notified, 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.

However, based on increased inhalation exposure combined with indications that the substance causes inhalation toxicity, the potential use of the substance in aerosol consumer products could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or environment within the meaning of the criteria under section 64 of the Act. However, it is suspected

that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to inhalation toxicity if the substance is used in aerosol consumer products, a SNAc notice was issued to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. SNAc Notice No. 19794 was published in the *Canada Gazette* Part I, Vol. 153, No. 13 on March 30, 2019.

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.