

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

New Substances Notification 20393: 2-Alkenoic acid, methyl-, 2-ethylhexyl ester, polymer with hexadecyl alkyl-alkenoate, α -(methyl-oxo-alkenyl)- ω -hydroxy poly(oxy-1,2-ethanediyl), octadecyl alkyl-alkenoate and polyhaloalkyl alkyl-alkenoate (Confidential Accession No. 19475-3)

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. 20393](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 154, No. 38 on August 8, 2020. 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-alkenoic acid, methyl-, 2-ethylhexyl ester, polymer with hexadecyl alkyl-alkenoate, α -(methyl-oxo-alkenyl)- ω -hydroxy poly(oxy-1,2-ethanediyl), octadecyl alkyl-alkenoate and polyhaloalkyl alkyl-alkenoate (Confidential Accession No. 19475-3). The substance meets the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)*.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use as a stain repellent finish for level 1 medical isolation gowns. Potential uses may include water and stain repellents for protective work wear or consumer use.

Environmental fate and behaviour

Based on its physical and chemical properties, the substance is expected to partition to water. The substance is not expected to bioaccumulate based on its large molecular structure, which will limit its ability to cross biological membranes. Removal efficiency at a waste water treatment facility is considered high.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to aquatic invertebrates (median effective concentration >100 mg/L).

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental risk from treatment of textiles, laundering of medical gowns, and disposal of medical gowns is expected to be negligible. For potential activities such as manufacture of the substance, incorporation into food packaging and other consumer products, and do-it-yourself stain repellency products, environmental exposure is also expected to be negligible.

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

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >300 mg/kg body weight). It is a weak dermal sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. It is noted that high molecular weight water insoluble polymers have been linked to irreversible lung damage which is believed to arise from longer term chronic exposures. Based on the available data, it is not certain if this substance causes the expected chronic damage effects.

When the notified substance is used in medical gowns, direct exposure of the general population is expected to be negligible. Potential uses of the substance include aerosol consumer stain repellents, where direct exposure of the general population is expected to be mainly by inhalation. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release.

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, the potential for the substance to be used in spray forms of consumer products such as stain repellents could significantly alter the exposure, resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these uses.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the 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 spray forms by consumers, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. SNAc Notice No. 20393 was published in the *Canada Gazette* Part I, Vol. 154, No. 38 on August 8, 2020.

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.