

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

New Substances Notification 20490: Siloxanes and silicones, di-Me, alkene Me, [(alkenedimethylsilyl)oxy]-terminated, polymers with hydrogen-terminated di-Me siloxanes (Confidential Accession No. 19494-2)

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. [Order 2021-87-02-01 amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 155, No. 14 on July 7, 2021. 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 siloxanes and silicones, di-Me, alkene Me, [(alkenedimethylsilyl)oxy]-terminated, polymers with hydrogen-terminated di-Me siloxanes (Confidential Accession No. 19494-2). 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 component of liquid and powder cosmetics. Potential activities may include spray-application cosmetic products (such as deodorant).

Environmental fate and behaviour

Based on its physical and chemical properties, the substance is expected to partition to soil and sediment. The substance is not expected to bioaccumulate based on its large molecular structure which will limit its ability to cross biological membranes.

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 blending and formulation and through the notified use in liquid or powder cosmetics is expected to be negligible. For potential activities such as manufacturing of the substance, the risk from environmental exposure is also expected to be negligible.

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

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the dermal or oral route (median lethal dose > 2000 mg/kg body weight). 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.

When the notified substance is used in cosmetics, direct exposure to the general population is expected to be mainly by contact with the skin. Potential uses of the substance include spray application of cosmetics where there is the potential for direct exposure to the general population through 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 cosmetics 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 activities.

The assumptions made in the assessment and the risk management measures applied are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

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 form 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. Order 2021-87-02-01 was published in the *Canada Gazette* Part II, Vol. 155, No. 14 on July 7, 2021.

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 the workplace.