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

New Substances Notification No. 19443: Siloxanes and silicones, di-Me, mono[3-[(2-methyl-1-oxo-2-propenyl)oxy]propyl] group-terminated, polymers with Bu methacrylate, 2-ethylhexyl acrylate and Me methacrylate (Chemical Abstracts Service No. 756819-45-1)

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. 19443 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 152, No. 38 on September 22, 2018. 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, mono[3-[(2-methyl-1-oxo-2-propenyl)oxy]propyl] group-terminated, polymers with Bu methacrylate, 2-ethylhexyl acrylate and Me methacrylate (Chemical Abstracts Service Registry Number[1] 756819-45-1). 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 cosmetics. 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 this potential activity.

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 structural features associated with environmental toxicity.

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 activity is not expected. Rinsing of products containing the substance down the drain during consumer use is highly dispersive, and the substance is expected to be removed efficiently during wastewater treatment. No potential activities which could significantly increase environmental risks compared to those notified were 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, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features associated with human toxicity. However, high molecular weight water insoluble polymers have been linked to irreversible lung damage.

When the notified substance is used in cosmetics, direct exposure of the general population is expected to be mainly by contact with the skin and eyes 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 exposure by inhalation 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 may cause inhalation toxicity, the potential use of the substance in aerosol personal care 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 this activity.

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. 19443 was published in the *Canada Gazette* Part I, Vol. 152, No. 38 on September 22, 2018.

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.