

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

Significant New Activity No. 18010: Silicic acid, sodium salt, hydrolysis products with 1-[(substitutedmethoxy)alkyl] silanetriol

### 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 that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance. The Ministers have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that:

- (a) have or may have an immediate or long term harmful effect on the environment or its biological diversity, or
- (b) constitute or may constitute a danger to the environment on which life depends, or
- (c) constitute or may constitute a danger in Canada to human life or health.

However, a significant new activity (SNAc) notice was adopted based on uncertainties regarding potential environmental and human health impacts of the substance in relation to certain new activities. [SNAc Notice No. 18010](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 149, No. 40 - October 3, 2015. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

### Substance Identity

The notified substance can be classified as a surface-functionalized silica nanoparticle. The substance was notified as a polymer that meets the [Reduced Regulatory Requirements](#) criteria.

Depending on the reaction conditions, the notified substance may contain unreacted epoxy groups, which have been associated with adverse human health effects. Under this notification, however, the epoxide groups have been hydrolysed completely during the synthesis of the notified substance, as confirmed by carbon-13 nuclear magnetic resonance.

### Notified Activities

The substance is a nanomaterial and is proposed to be used as a component in industrial and consumer coatings and pigment or ink formulations.

### Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to be in water, sediment, and soil. Since the silica is not expected to degrade in the

environment and the susceptibility to biodegradation of the surface modification is unknown, the substance is expected to be persistent in these environmental compartments. The bioaccumulation potential of this substance is unknown.

### **Ecological Assessment**

No hazard information was available on the notified substance. Therefore, based on this lack of substance-specific hazard data, information on structurally related substances was used to predict hazard. As such, the notified substance is likely to have a moderate acute toxicity in aquatic invertebrates (e.g. *Daphnia magna* (a median effective concentration, EC<sub>50</sub>, of 29.7 mg/L)) and the chronic toxicity is unknown. The predicted no effect concentration was calculated to be 297 µg/L using the EC<sub>50</sub> endpoint from the most sensitive organism (*Daphnia magna*), which was used to estimate the ecological risk.

The notified activities in Canada were assessed to estimate the potential for environmental exposure to the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from formulations and industrial uses. The predicted environmental concentration for notified activities is estimated to be 2.0-10.5 µg/L in water. However, changes in its use pattern may result in increased exposure and altered fate and effects.

Based on the notified uses, conservative exposure scenarios were compared to a moderate aquatic toxicity concentration, EC<sub>50</sub>, which determined that the substance is unlikely to cause ecological harm in Canada based on current uses.

While the substance was not found to meet the criteria under section 64 of CEPA under this notification, other activities may significantly change the fate and effects of this substance. Therefore, additional information is being requested to account for this different behavior and evaluate potential environmental risks.

### **Human Health Assessment**

Based on the available hazard information on the substance contained in the products, the substance has a low potential for acute toxicity by the oral and inhalation routes of exposure (oral LD<sub>50</sub>> 5000 mg/kg bw; inhalation LC<sub>50</sub>>5 mg/L/4h; both in rats). It is not a dermal irritant or skin sensitizer but is an eye irritant. It is not an *in vitro* mutagen. Therefore the substance is considered unlikely to cause genetic damage.

No information was available on the repeated dose toxicity of the notified substance. However, based on the particulate nature of the substance and the potential presence of an epoxide moiety, there are concerns for potential reproductive toxicity, respiratory toxicity, cancer and hepatotoxicity. It is currently not possible to conclude on the repeated dose toxicity of the notified substance due to the lack of data to conduct a complete assessment.

When used in consumer coatings, direct exposure of the general population is expected to be mainly by inhalation or dermal contact, with a combined total dose of 3.93 mg/kg bw/day. Indirect exposure (mainly by ingestion) of the general population from environmental media

such as drinking water is conservatively expected to be  $2.64 \times 10^{-4}$  mg/kg bw/day for adults and  $5.65 \times 10^{-4}$  mg/kg bw/day for toddlers.

Based on the low potential for direct and indirect exposure of the general population under this notification, 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, since the substance is eligible for addition to the confidential portion of the Domestic Substances List and will likely be used widely in industrial, commercial, and consumer applications, a potential for increased direct or indirect exposure may exist. The risk arising from the use of the substance in consumer products such as cleaners and detergents is unknown at this time. Concerns exist for moderate to high inhalation exposure from its use in hard surface cleaners, and to a lesser extent oral and dermal exposure, in potential consumer uses. The substance may find applications in beverage and water treatment as well as food contact plastics, paper and board materials, where oral exposure to the substance may occur. The use of the substance in these applications may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks of new activities.

### **Assessment Conclusion**

When used as notified, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA. However, it is suspected that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the identified use at the nanometer scale, the potential risk to the general population, and the uncertainty predicting environmental fate, hazard and exposure in those uses above and beyond the notified uses, a SNAc Notice was published to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment. [SNAc Notice No. 18010](#) was published in the *Canada Gazette* Part I, Vol. 149, No. 40 on October 3, 2015.

A conclusion under CEPA on this substance, does not concern, 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