

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

Significant New Activity No. 17192: Multi-wall carbon nanotubes.

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), 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, and have determined that it 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.

However, a significant new activity (SNAc) notice was recommended based on uncertainties regarding potential environmental and human health impacts of the substance in relation to certain new activities, such as use at increased volumes or in consumer products. [SNAc No. 17192](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 147, No. 34 –August 24, 2013. 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 substance is a short tangled multi-walled carbon nanotube that can be classified as a nanomaterial.

Notified Activities

The substance is proposed to be manufactured in or imported into Canada in quantities greater than 1000 kg/yr for use as an additive in plastics.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, sediment, soil, and ambient air. The substance is expected to be persistent in these compartments because it is a stable inorganic chemical that will not degrade. Based on the limited understanding of uptake by organisms, more data is required to assess the bioaccumulation potential of this substance at the current schedule notification.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related nanomaterials, the substance has low to moderate (1-100 mg/L) acute toxicity in aquatic life (fish/daphnia/algae). The predicted no effect concentration was calculated to be <1 mg/L using the $E_{rC_{50}}$ from the most sensitive organism (*P. subcapitata*), which was used to estimate the environmental risk.

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 activities was determined through a conservative generic single point-source release blending scenario. The predicted environmental concentration for notified activities is estimated to be 2.1 $\mu\text{g/L}$.

Based on the current use profile in conjunction with low to moderate ecotoxicity endpoints, the substance is unlikely to cause ecological harm in Canada.

However, based on the current understanding of carbon nanotubes and nanomaterials in general, a change in the use profile of the substance (SNAc No. 17192) may significantly alter the exposure resulting in the substance becoming harmful to the environment. Consequently, more information is necessary to better characterize potential environmental risks.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral, dermal and inhalation routes of exposure (oral and dermal $LD_{50} > 2000$ mg/kg bw; inhalation $LC_{50} > 1.3 \text{ mg/m}^3$). It is a severe eye irritant (MAS score = 68), a mild skin irritant (PII = 1.08) and at most a weak sensitizer (because the positive control was tested at a concentration 10X higher than the test substance). It is not an *in vitro* mutagen (negative in a mammalian cell gene mutation test and in a mammalian chromosome aberration test). Therefore the substance is unlikely to cause genetic damage.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

However, based on the available information on structurally related nanomaterials, the substance may cause respiratory toxicity, immunotoxicity, cardiovascular toxicity and carcinogenicity following oral and inhalation exposure.

When used as an additive in plastics, the substance is expected to be manufactured in or imported into Canada encapsulated in a solid polymer matrix. The potential site of exposure to the substance is expected to be within industrial facilities. Therefore, direct exposure of the general population is expected to be low. No significant environmental release is anticipated due to the specialized use under this notification and therefore indirect exposure of the general population from environmental media is also expected to be low. However, if the substance is

produced in different forms (e.g. liquid polymer form), applied in different formulations or used in any other potential applications, an increased direct or indirect exposure potential may exist.

Based on the low potential for direct and indirect exposure of the general population under the industrial uses identified in this submission, 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 the current understanding of carbon nanotubes and of nanomaterials in general, the risk arising from the use of the substance in consumer products is not known at this time. The use of the substance in consumer products or in products intended for use by or for children may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Similarly, the import or manufacture of the substance in quantities greater than 10 000 kg/yr may significantly increase the exposure levels of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Other Considerations

The US Environmental Protection Agency has published a Significant New Use Rule prohibiting the manufacture, processing or use of the substance for commercial or consumer products, or in consumer products (Proposed Significant New Use Rules on Certain Chemical Substances PMN Number P-09-188. Federal Register **76**(249): 81452 (2011); <http://www.gpo.gov/fdsys/pkg/FR-2011-12-28/pdf/2011-33261.pdf>).

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 1999. 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 potential risk to the environment (related to aquatic, soil, and sediment toxicity) and due to the potential risk to the general population (related to respiratory toxicity, immunotoxicity, cardiovascular toxicity and carcinogenicity following oral and inhalation exposure) if the substance is used in increased amounts or in consumer products, a SNAc notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment. SNAc notice No. 17192 was published in the *Canada Gazette* Part I, Vol. 147, No. 34 –August 24, 2013.

A conclusion under CEPA 1999, on this substance, is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.