

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

New Substances Notification 20405: Graphene (Chemical Abstracts Service registry number 1034343-98-0)

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 2021-87-08-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 156, No. 1 on January 5, 2022. The SNAC was amended under [Order 2022-87-07-01 Amending the Domestic Substances List](#), published in the *Canada Gazette* Part II, Vol. 156, No. 19 on September 14, 2022. 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 chemical is graphene (Chemical Abstracts Service registry number¹ 1034343-98-0). It is a Few-Layer Graphene (FLG) nanoplatelet with 3 to 10 layers of stacked graphene sheets, ranging in thickness from 1 to 3.35 nm with a predominant lateral dimension of 1-2 µm and very low degree of oxidation.

Notified and potential uses

The substance is proposed to be manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use as a multifunctional additive in paints and coatings, plastics, thermosetting composites and a component of battery electrodes.

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Potential sectors of use include composites and coatings, electronics, data communications, membranes (for example, for water purification and desalination, control of water or gas flow in geomembranes, gas barriers in food packaging), biomedical technologies, sensors and imaging, energy harvest, conversion and storage. Potential uses also include many possible products and manufactured articles available to consumers, including but not limited to car seats, clothing and footwear, cutlery, diapers, dishes, electronics, toys, food packaging materials, feminine hygiene products, cosmetics and personal care products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, sediment and soil. The substance is expected to be persistent in these compartments based on low biodegradability (0% over 28 days). The substance is expected to bioaccumulate based on direct uptake from the environment.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to aquatic invertebrates (no-observed-effect-concentration (NOEC) > 100 mg/L, median lethal concentration (LC₅₀) > 16 mg/L) and algae (median effective concentration 62.2 mg/L) and low to high chronic toxicity to fish (NOEC > 100 mg/L and 0.02 mg/L, 96-h LC₅₀ < 0.03 mg/L). Using the NOEC from the most sensitive organism (fish) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be 2 µg/L, which was used to estimate the risk to the environment.

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 is expected to be mainly from manufacturing and processing by release of the substance to water resulting in predicted environmental concentration (PEC) in the range of 0.086 to 0.767 µg/L. For potential activities such as manufacturing and processing in higher quantities, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.175 to 1.535 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Should the substance be manufactured as a different nanoform of graphene than the notified substance, it may have different properties and behaviours, so additional information will be required to further evaluate potential environmental risks.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and inhalation routes (oral median lethal dose >300 mg/kg body weight; inhalation $LC_{50} >1.99$ mg/L/4hr; with no toxicity observed with highest dose tested by either route) and is expected to have moderate to high subchronic toxicity following repeated inhalation doses in mammalian test animals (28-day no-observed-adverse-effect level 0.003 86 mg/L/6 hour or 0.71 mg/kg-bw/day; minimal toxicity observed at highest dose). It is not a dermal sensitizer (0% response (Buehler test)). It is not mutagenic or clastogenic *in vitro* or genotoxic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a component of plastics, polymer epoxies, domestic paints (interior or exterior), rubber and other product materials/matrices, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance is expected to be embedded in a stable matrix once cured and will not be readily released. Migration or leaching from the cured matrix or surfaces is expected to be minimal under normal use conditions; however, the notified substance may be released from cutting and sanding of materials during Do-It-Yourself projects. Direct exposure to dust from sanding of flooring with a coating containing the notified substance is conservatively estimated to be at levels in the range of 0.04 mg/kg bw/day (assuming full personal protective equipment (PPE) including sander dust bag and N95 mask) to 1.77 mg/kg bw/day (assuming no PPE).

Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 1.3×10^{-5} to 2.5×10^{-5} mg/kg bw/day and mainly by ingestion. Indirect exposure of the general population from air downstream of manufacturing facilities is expected to be negligible given the low potential for release to the environment and dispersion/dilution potential in the atmosphere. Inhalation exposure via ambient air might be expected in proximity to food packaging or other waste recycling and incineration facilities based on one study reporting “large amounts” of single isolated graphene nanoplatelets released from incineration of food packaging films.

Potential uses of the substance include its inclusion in manufactured articles/goods such as car seats, clothing and footwear, cutlery, diapers, dishes, electronics, toys, etc. where direct contact with the product by the general population (including children and infants) is expected to be mainly by mouth and skin and in feminine hygiene products by the female urogenital region. Direct exposure of the general population to the notified substance from food packaging materials by ingestion is conservatively estimated (assuming 100% oral absorption) to be 3.02×10^{-4} mg/kg bw/day based on empirical release from plastic food packaging films. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 2.6×10^{-5} to 5×10^{-5} mg/kg bw/day and mainly by ingestion.

However, if the substance is used as a spray, mist or aerosol such as in spray paints and hair dye sprays, an increased level of direct exposure may exist, and is expected to be infrequent/intermittent and by inhalation at levels in the range of 0.000 32 to 0.013 mg/kg-body weight per event.

Based on the exposure and the characteristics 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 the potential for increased inhalation exposure combined with indications that the substance has suspected inhalation toxicity, the potential use of the substance in consumer or cosmetic sprays, such as spray paints or hair dye sprays, or the potential use of the substance manufactured as an alternative nanoform could significantly alter the exposure and conditions of use as well as hazard characteristics, resulting in the substance becoming harmful to human health. Consequently, additional information is necessary to better characterize potential health risks associated with these activities.

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

Nanomaterial considerations

There is evidence that the notified substance may be produced as different nanoforms under the same CAS registry number. These nanoforms may exhibit significantly different physical chemical properties (e.g. thickness, lateral size, degree of oxidation, surface chemistry, and impurity), environmental fate, toxicity, and exposure potential. Therefore, additional information is necessary to better characterize potential environmental and health risks of these different nanoforms.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment according to 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 suspected inhalation toxicity if the substance were to be used in consumer or cosmetic sprays, as well as the identified potential for engineering or use of the substance as different nanoforms and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, the SNAC provisions under CEPA were applied to the substance in order to obtain additional information to ensure that the substance undergoes further assessment before these potential activities are undertaken.

Order 2021-87-08-01 was published in the *Canada Gazette* Part II, Vol. 156, No. 1 on January 5, 2022.

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.