

The Graphene Council

Research, Development and Application

STATEMENT FROM THE GRAPHENE COUNCIL

DATED 9 APRIL 2021

On Friday, 2 April 2021 Health Canada, the department of the Government of Canada responsible for national health policy, issued a statement titled **“Face masks that contain graphene may pose health risks”**. The full statement may be viewed [HERE](#).

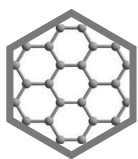
The statement reflected Health Canada’s preliminary assessment of available research and their interest to exercise caution as a result of a consumer complaint about a specific product. Further, they stated:

- Until the Department completes a thorough scientific assessment and has established the safety and effectiveness of graphene-containing face masks, it is taking a precautionary approach.
- Health Canada is seeking further assistance from suppliers.
- Health Canada has directed all known distributors, importers and manufacturers to stop selling and to recall the affected products until it has completed its scientific assessment.

The Graphene Council respects the role of Health Canada in protecting its population from the sale and distribution of potentially harmful products. It is however the opinion of The Graphene Council that Health Canada’s decision for a blanket halt to all sales and distribution of any and all graphene enabled face masks risks potential harm to legitimate, trustworthy producers and suppliers. It is our understanding that a product recall typically relates to a specific manufacturer, products and serial or lot numbers.

A blanket ban also potentially denies the public access to graphene enabled products that have been properly designed, tested and registered to be effective against pathogens.

The graphene industry at large has been extremely pro-active in the area of classification of materials and regulatory approval for the broad range of graphene products available. The Graphene Council applauds Health Canada’s intent to complete a thorough scientific assessment to establish the safety and effectiveness of graphene-containing face masks and are eager to help and collaborate as needed.



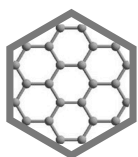
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Important Graphene Industry Efforts

1. Graphene materials and how to measure or characterize them are well defined under a set of approved international standards that are also endorsed and supported by The Graphene Council and include:
 - ISO/TR 19733:2019(E), Nanotechnologies — Matrix of properties and measurement techniques for graphene and related two-dimensional (2D) materials
 - ISO/TS 80004-13:2017(E) Nanotechnologies — Vocabulary — Part 13: Graphene and related two-dimensional (2D) materials
 - ISO/TS 21356-1:2021(E) Nanotechnologies — Structural characterization of graphene — Part 1: Graphene from powders and dispersions
2. Graphene materials have been registered under the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) under Article 20(2) Annex VII. Under the REACH Graphene Consortium, graphene substances that are registered through the consortium and that fall within the SIP (Substance Identity Profile) are approved for use in textiles, gloves or masks, within the European Union. This applies to graphene materials that are bound into the articles. REACH is one of the most stringent regulatory regimes in the world. Graphene materials have also been evaluated and approved for sale in both Australia and Canada.
3. The amount of graphene used in properly prepared face masks is typically a low percentage of the total materials used which even in a worst-case scenario, leaves an extremely small amount of material available per mask should graphene particles be able to be liberated. Embedding the graphene in a host material (either as a coating that is applied to the textile or as embedded directly as part of a mask fabric) is a method that is commonly deployed.
4. Numerous toxicological tests have demonstrated that graphene, a pure form of carbon, can be well tolerated and in many cases is bio-compatible, to cite two examples.

In 2018 the paper **“Safety Assessment of Graphene-Based Materials: Focus on Human Health and the Environment”** was published in ACS Nano. (<https://pubs.acs.org/doi/pdf/10.1021/acsnano.8b04758>) with the goal of evaluating the synthesis and characterization of Graphene Based Materials (GBMs) and the human and environmental hazard assessment of GBMs using *in vitro* and *in vivo* model systems to understand the biological effects of these materials.



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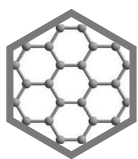
Bengt Fadeel, Karolinska Institutet, Sweden and lead author of the paper stated: "One cannot draw conclusions from previous work on other carbon-based materials such as carbon nanotubes and extrapolate to graphene. Graphene-based materials are less cytotoxic when compared to carbon nanotubes and graphene oxide is readily degradable by cells of the immune system,"

In another example, a paper published on 19 August 2020 titled **The Future of Carbon: An Update on Graphene's Dermal, Inhalation, and Gene Toxicity** (<https://www.mdpi.com/2073-4352/10/9/718/htm>) found that few-layer graphene had a low risk to health, following completion of specific regulatory testing at government approved laboratories.

Table 1. List of toxicity tests on graphene cited in this article.

Test	Category	OECD Number	Animal	Results Summary	Ref.
Combined in vivo Mammalian Erythrocyte Micronucleus Test and Alkaline Comet Assay	Genotoxicity	474 & 489	Rat	No DNA damage at max respirable dose	[16]
in vitro Mammalian Chromosome Aberration Test in Human Peripheral Blood Lymphocytes	Genotoxicity	473	-	No evidence of genotoxic activity or chromosome damage; no cytotoxicity at max dose (2 mg/mL)	[17]
Dermal Sensitization Study	Dermal	406	Guinea Pig	No skin sensitization (score 0) after repeated dosing	[18]
Primary Skin Irritation Study	Dermal	404	Rabbit	No skin irritation (score 0); no signs of erythema or edema were observed	[19]
Acute Inhalation Toxicity Study of a Dry Powder with 14-Day Observation Period	Inhalation	436	Albino Rat	No adverse effect observed in lung at max achievable aerosol concentration	[20]

5. Buyers of graphene and graphene enabled materials should carefully evaluate the producer and supplier of these materials. The current issue demonstrates the need for traceability and verified supply chains, as well as identifying the type and content of graphene.
6. The Graphene Council offers a verification service to graphene producing companies as well as companies that produce graphene enabled products. The Verified Graphene Producer™ and the Verified Graphene Product™ programs administered by The Graphene Council are an independent, third party, in-person inspection and validation services that can provide trust and transparency for buyers of these products.



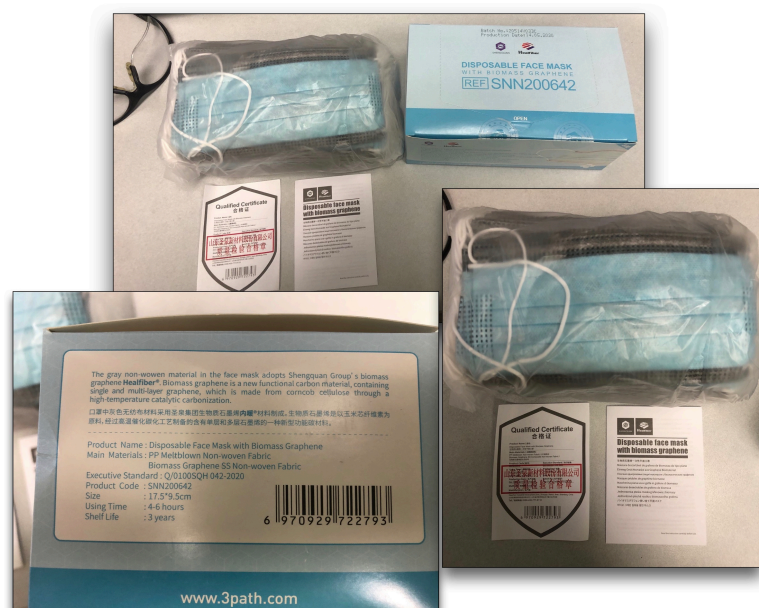
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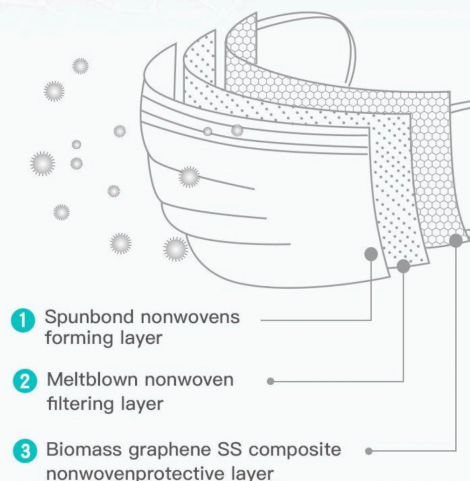
The Product In Question

The Graphene Council would welcome the opportunity to co-ordinate and work with Health Canada to understand more fully the specific product at the center of this issue.

Based on public reporting, the face mask in question is product number #SNN200642 produced by the Shengquan or SQ Group (<http://e.shengquan.com>) based in Zhangqiu City, China and refers to its material as “Biomass Graphene”.



Biomass graphene is derived from natural straws as raw material, which use the pyrolysis method based on group coordination assembly carbon deposition (China patent NO: ZL 2015 1 0819312.X), and is an important member of graphene family.



According to a description of the product which can be found online [HERE](#), the mask appears to be constructed placing the “graphene” layer directly on the wearer’s face through the incorporation into a non-woven fabric layer. Users in the complaints filed in Canada described “a feeling of having inhaled hairs or fibers”. Graphene is not a fibrous material.

The Graphene Council would be happy to engage and work with Health Canada, and any other regulators, to ensure graphene producers as well as graphene materials and products containing graphene comply with all applicable regulations.

This Statement solely reflects the views of The Graphene Council and does not necessarily reflect the views or positions of any individuals or companies. The Graphene Council was founded in 2013 as the leading independent, global trade and professional body representing graphene producers, researchers and users.

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