

Update: Graphene face masks by Shandong Shengquan New Materials Co. Ltd. can resume sale in Canada; Health Canada found no health risks of concern with these products

Report a Concern
(<http://www.healthycanadians.gc.ca/report-signalez/index-eng.php>)

Starting date:	April 2, 2021
Posting date:	July 13, 2021
Type of communication:	Advisory
Subcategory:	Medical Device
Source of recall:	Health Canada
Issue:	Product Safety
Audience:	General Public, Healthcare Professionals, Hospitals
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Last updated: 2021-07-13

Summary

- **Product:** Face masks manufactured by Shandong Shengquan New Materials Co. Ltd. labelled to contain biomass graphene.
- **Issue:** Health Canada assessed four models produced by the company and found no health risks of concern. As a result, sale of these masks can resume in Canada. No other graphene face masks are currently permitted for sale in Canada. If additional graphene masks are permitted for sale, Health Canada will update Canadians.
- **What to do:** Do not use face masks labelled to contain graphene unless they are listed in the table below. Report any health product [adverse events \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html), or [complaints \(http://healthycanadians.gc.ca/apps/radar/MD-IM-0005.08.html\)](http://healthycanadians.gc.ca/apps/radar/MD-IM-0005.08.html) to Health Canada.

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Issue

UPDATE (July 13, 2021): Health Canada previously advised Canadians not to use face masks that contain graphene after a preliminary assessment identified some potential for inhaled graphene particles to cause early lung effects in animals (e.g., early signs of inflammation). As a precaution while a risk assessment was ongoing, Health Canada directed all known importers and distributors of these masks to [remove \(https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75391r-eng.php\)](https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75391r-eng.php) four mask models from one manufacturer, Shandong Shengquan New Materials Co. Ltd., from the market.

Health Canada has reviewed the available scientific literature along with data provided by Shandong Shengquan New Materials Co. Ltd., related to the biomass graphene contained within its four models. The review found that biomass graphene particles are not shed from these masks in quantities that are likely to cause adverse lung effects.

Health Canada also determined that the filtration performance of these masks meets the performance standard listed on the label. The Department did not find evidence that biomass graphene provides any added antimicrobial, or antiviral protection.

As a result, given the evidence supporting the safety and effectiveness of these products, Health Canada is permitting the sale of the four Shandong Shengquan New Materials Co. Ltd. mask models to resume in Canada (see models listed below).

No other graphene face masks are currently permitted for sale in Canada. Consumers should notify Health Canada by [submitting an online complaint form \(https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-device-consumer.html\)](https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-device-consumer.html) should they become aware of other graphene masks being sold in Canada.

Companies wishing to sell graphene masks must first provide evidence to Health Canada demonstrating the safety and effectiveness of their models, as the risks with using graphene masks may vary depending on mask design.

Graphene masks permitted for sale

Manufacturer	Model Number
Shandong Shengquan New Materials Co. Ltd.	SMDP20605
	SNN200642
	SNN70369B (C-Shaped)
	SNN70370B (Willow Leaf-Shaped)

Health Canada will continue to update Canadians if additional graphene masks are permitted for sale in Canada.

Original Advisory (April 2, 2021): Face masks that contain graphene may pose health risks

Issue

Health Canada is advising Canadians not to use face masks that contain graphene because there is a potential that they could inhale graphene particles, which may pose health risks.

Graphene is a novel nanomaterial (materials made of tiny particles) reported to have antiviral and antibacterial properties. Health Canada conducted a preliminary scientific assessment after being made aware that masks containing graphene have been sold with COVID-19 claims and used by adults and children in schools and daycares. Health Canada believes they may also have been distributed for use in health care settings.

Health Canada's preliminary assessment of available research identified that inhaled graphene particles had some potential to cause early lung toxicity in animals. However, the potential for people to inhale graphene particles from face masks and the related health risks are not yet known, and may vary based on mask design. The health risk to people of any age is not clear. Variables, such as the amount and duration of exposure, and the type and characteristics of the graphene material used, all affect the potential to inhale particles and the associated health risks. Health Canada has requested data from mask manufacturers to assess the potential health risks related to their masks that contain graphene.

Until the Department completes a thorough scientific assessment and has established the safety and effectiveness of graphene-containing face masks, it is taking the precautionary approach of removing them from the market while continuing to gather and assess information. Health Canada has directed all known distributors, importers and manufacturers to stop selling and to recall the affected products. Additionally, Health Canada has written to provinces and territories advising them to stop distribution and use of masks containing graphene. The Department will continue to take appropriate action to stop the import and sale of graphene face masks.

Products affected

Face masks labelled as containing graphene or biomass graphene.

What you should do

- Do not use face masks labelled to contain graphene or biomass graphene.
- Consult your health care provider if you have used graphene face masks and have health concerns, such as new or unexplained shortness of breath, discomfort or difficulty breathing.
- Report any health product [adverse events \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) or [complaints \(https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/health-product-complaint-form-0317.html\)](https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/health-product-complaint-form-0317.html), regarding graphene face masks to Health Canada.

Media enquiries

Health Canada

613-957-2983

hc.media.sc@canada.ca (<mailto:hc.media.sc@canada.ca>)

Public enquiries

613-957-2991

1-866-225-0709

hcinfo.infosc@canada.ca (<mailto:hcinfo.infosc@canada.ca>)

For more information

- [COVID-19 medical masks and respirators \(https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators.html)
- [Canada.ca/coronavirus](http://www.canada.ca/coronavirus) (<http://www.canada.ca/coronavirus>)

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