Government of Canada / Gouvernement du Canada

Notice: Technical requirements for anti-microbial claims for medical masks

Date published: April 21, 2021
Date updated: May 5, 2021

This notice outlines the safety and effectiveness requirements for Class I medical masks and face coverings with anti-microbial claims. This notice is for manufacturers using either an interim order (IO) authorization or medical device establishment licence (MDEL) to manufacture, import or sell these devices in Canada.

This notice does not cover anti-microbial agents sold separately and applied to face coverings or medical masks prior to use.

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About masks with anti-microbial substances

The COVID-19 pandemic has created a public health requirement to wear face coverings and medical masks. Face coverings are not classified as medical devices unless there are medical claims or representations. Some mask and face covering medical devices may incorporate or be coated with materials that claim to be anti-microbial. Anti-microbial substances may kill or inhibit the growth of microorganisms. Some examples of anti-microbial substances include, but are not limited to:

- silver
- copper
- Nanoform Graphene fabric coatings
- salt

To date, Health Canada has not received any data that support the safety and effectiveness of these substances when used with masks or face coverings. It is also not known whether these substances improve the performance of medical masks in a measurable way.

Regulatory considerations and claims

In Canada, face coverings that are used only to reduce droplets or aerosols passing between individuals are not regulated as medical devices. However, if the product label includes anti-microbial claims, these face coverings become Class I medical devices.

Section 25 of the *Medical Device Regulations* allows for the request of supporting safety, effectiveness and quality information from Class I manufacturers.

Limitations to the claims

Bacterial Filtration Efficiency (BFE) is a measurement of a medical mask material's resistance to penetration of aerosolized droplets of a culture suspension of Staphylococcus aureus (3.0 um or 3000 nm in size). Results

are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. Higher BFE percentages in this test indicate better barrier efficiency. In general, a BFE rating could be interpreted as material filtration efficiency.

This measurement is not to be taken in isolation and without a reference to a test method or international standard. To achieve a high level of filtration, anti-microbial non-medical masks should be manufactured from a non-woven polypropylene material. All claims must be supported by evidence and available for review upon request.

Safety and effectiveness requirements

Medical masks or other personal protective equipment claiming microbial protection should meet the safety and effectiveness requirements described below. This information must be available for review upon request in the case of MDEL holders. It should be submitted by manufacturers filing an interim order (IO) application or responding to regulatory requests for information.

1. A clear intended use/indications statement for the product along with complete labelling. Labelling includes user manuals, instructions for use (IFU), directions for use (DFU), outer package labelling, promotional material and website links.
2. A detailed description of the list of materials (for example, chemical and popular/trade names) and their technical specifications (for example, physical/chemical properties), used in the manufacture of the mask. This includes all material constituents added to the mask to impart anti-microbial or anti-viral properties.
3. A full description of how the anti-microbial or anti-viral technology (for example, coatings) is produced and incorporated into, or bonded with, the mask materials, as well as a mechanistic description of the expected anti-microbial action.

4. If the anti-microbial substances are present in nanoform(s), a characterization of those substances (for example, derivitization, layers, platelets, thickness, lateral dimensions, charged sites), including a certificate of analysis showing impurities.
5. Information describing potential inhalation exposure to anti-microbial substance particulates that includes at least:
    a. intended use pattern (such as frequency, number of uses)
    b. summarized test data that fully characterize the amount (mass) and sizes (particle size distribution and mass median aerodynamic diameter - MMAD) of particulates that are shed during the intended use pattern and
    c. human inhalation exposure range estimates in terms of mg/L/hr, and mg/kg-bw/day, based on the information in a) and b)
6. Evidence in the form of test reports that support all anti-viral (anti-COVID-19) and/or antimicrobial claims made on the product label. This may include the use of one or more scientifically justified surrogate virus(es). The test reports should describe the testing procedure and include a detailed description of the specific component/materials that were tested.
7. The test samples should be identical to the product. If there are differences between the test samples and the final product (e.g. different materials, concentrations, or other properties) these should be clearly described along with providing a justification for how the samples are representative of the final product in spite of these differences.
8. Evidence of biocompatibility demonstrating that the patient-contacting materials in the final product are non-cytotoxic (ISO 10993-5), non-irritating, and non-sensitizing (ISO 10993-10).
9. Performance data/reports demonstrating that the respirators/masks meet ASTM F2100, EN 14683, EN 149 and GB2626

(or any other standards claimed).

10. If it is claimed that the mask can be washed, then instructions for washing should be provided. In addition, evidence must be provided that the performance claims made (for example, in 6 and 9 above) are maintained after a proposed maximum number of wash cycles as indicated in the device labelling.

International activity

The U.S. Food and Drug Administration regulates face coverings with anti-microbial claims as medical devices.

Self-sanitizing claims are detergent claims that are overseen by the Pest Management Regulatory Agency in Canada and the Environmental Protection Agency in the United States.

Related links

- Interim order no. 2 respecting the importation and sale of medical devices for use in relation to COVID-19 guidance document
- Applications for medical devices under the interim order for use in relation to COVID-19 - Guidance document
- Medical Device Establishment Licence (MDEL) application
- Notice: Expedited review of health product submissions and applications to address COVID-19

Glossary of terms

Face coverings (also known as non-medical masks):
Source control masks (to help control an infected wearer from transmitting the virus to others) that are made from a variety of woven fabrics. Face coverings may be made of different combinations of fabrics, layering sequences and available in diverse shapes. They are a sewn mask secured with ties or straps around the head or behind the ears.

They are factory-made or made from household items such as scarves or t-shirts. The fabrics and/or materials used in face coverings are not the same as the ones used in medical masks or respirators.

Medical device:

A device within the meaning of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals.

Medical masks:

Includes surgical, procedural, isolation and other infection control devices intended to offer protection to the wearer. They are designed with 3-4 layers of non-woven materials and meet labelled filtration levels (≥ 95%) using recognized standards.

Personal protective equipment (PPE):

Personal protective equipment consists of gowns, gloves, masks, facial protection (masks and eye protection, face shields or masks with visor attachment) or respirators. They can be used by health care workers to provide a barrier that will prevent potential exposure to infectious microorganisms.

Respirator:

A device that is tested and certified by procedures established by testing and certification agencies recognized by the authority having jurisdiction and is used to protect the user from inhaling a hazardous atmosphere. The most common respirator used in health care is a N95 half-face piece filtering respirator. It's a personal protective device that fits tightly around the nose and mouth of the wearer. It's used to reduce the risk of inhaling hazardous airborne particles and aerosols, including dust particles and infectious agents.

Date modified:

2021-05-06