

Health Canada is taking action to increase domestic capacity of hand sanitizers

NOTE: Health Canada is working on a document that will outline the complete set of requirements for hand sanitizers during the COVID-19 pandemic.

In light of the unprecedented demand and urgent need for disinfectants and hand sanitizers during the COVID-19 pandemic, as an interim measure, Health Canada is facilitating access to products that may not fully meet current regulatory requirements.

In Canada, hand sanitizers are classified as natural health products (NHPs) or non-prescription drugs, depending on the ingredients. These products require authorization from Health Canada before they are sold in Canada; however, the review process is being expedited at this time. Applicants may refer to the [NNHPD Antiseptic Skin Cleansers \(Personal Domestic Use\) monograph \(2018\)](#) for topical hand sanitizers that are intended for domestic personal use. For more information on obtaining market authorization, please contact the Natural and Non-prescription Health Products Directorate at hc.nnhpd-dpsnso.sc@canada.ca.

Companies that wish to manufacture, package, label or import NHPs or non-prescription drugs need to obtain a site or drug establishment licence. The below process applies only to domestic manufacturers of antiseptic skin cleansers (i.e. hand sanitizers) related to the COVID-19 response and does not change the regulatory requirements for other health products. Manufacturers must have a way to accept and submit adverse event reports for any products they manufacture.

For sanitizing products requiring a Site Licence (SL)

As an interim measure, domestic companies that do not currently have a site licence (SL), but with a capacity to produce antiseptic skin cleansers (i.e. hand sanitizers) will be issued a site licence under an interim process.

The company will need to email the Natural and Non-prescription Health Products Directorate (NNHPD) at hc.nnhpd-dpsnso.sc@canada.ca, clearly indicating that they want to avail themselves of the interim SL process. NNHPD will then initiate an ePost conversation through a special COVID-19 account and the company will need to submit an application to that account which includes:

- A duly completed site licence application form [<https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/site-licensing/forms/site-licence-application-form-site-licensing.html>];

The company will not need to submit a Quality Assurance Report or other forms of evidence. The licensing will be based on the attestation included as part of the application form. For the purposes of this interim approach, the attestation will cover the following acceptable Good Manufacturing Practices (GMP) standards:

- Part 3 of the Natural Health Products Regulations (<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-5.html#h-700670>);

- Division 2 of the Food and Drug Regulations [[https://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 870/page-29.html#h-569708](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-29.html#h-569708)];
- Good Manufacturing Practices for Cosmetic Products Guidelines for cosmetics [<https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/regulatory-information/good-manufacturing-practices.html>];
- Guide to Food Safety [<https://www.inspection.gc.ca/food-safety-for-industry/archived-food-guidance/non-federally-registered/safe-food-production/guide/eng/1352824546303/1352824822033>].

A site licence will be issued to the company in an expedited manner (24-48 hours) for the sole purpose of manufacturing antiseptic skin cleansers (i.e. hand sanitizers) as an interim measure and valid only for the duration of the COVID-19 emergency response.

For sanitizing products requiring a DEL license:

The Health Products Inspections & Licensing (HPIL) division will be focusing on critical services directed at facilitating responses to the COVID-19 pandemic to protect the safety of all Canadians. This includes increasing the supply of sanitizing products requiring DELs.

- Health Canada will accept DEL applications for hand sanitizers and disinfectants that are based on an attestation, and where possible, will process within 24-48 business hours.
- For that, applicants will have to provide an attestation signed by a company executive attesting to GMP compliance for domestic buildings or having GMP evidence for foreign building

The company will need to submit an application to HPCD at Hc.el.applications-le.sc@canada.ca,

including:

- the Drug Establishment Licence Application [<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html>] and
- a cover letter that highlights the COVID-19 related nature of the application;
- To identify these as high priority, DEL applicants will have to use “COVID-19” in the subject line of their email application and indicate the application is for hand sanitizers or disinfectants.