

NOTICE TO MANUFACTURERS OF NATURAL HEALTH PRODUCT (NHP) HAND SANITIZER PRODUCTS DURING THE PANDEMIC COVID-19

Health Canada is issuing this notice in response to a number of questions coming from companies that are not currently manufacturers of health products, but have expressed interest in manufacturing hand sanitizers for public distribution during the COVID-19 pandemic. Health Canada is establishing an interim approach to support those companies in acquiring the needed licences during this public health emergency. Following this, Health Canada intends to discontinue this approach and returns to its regular licensing approach for hand sanitizers.

Companies interested in manufacturing, packaging, or labelling alcohol-based hand sanitizers need to apply for and receive a product authorization (resulting in the issuance of a Natural Product Number (NPN)) and a site licence. The process outlined in this document specifically applies to Canadian manufacturers of hand sanitizers during the COVID-19 response.

This directive applies to three separate scenarios. They are:

1. An applicant would require a **Product Licence only** if they already have a site licenced for manufacturing, packaging, labelling and/or importation of Natural Health Products and they are adding a hand sanitizer to their product line, which they intend to sell to the public.
2. An applicant would require a **Site Licence only** if they are currently manufacturing, packaging, labelling or importing alcohol-based hand sanitizers, and not distributing them to another party or selling them to the public but intends to do so.
3. Companies that do not manufacture or import Natural Health Products (e.g. a distillery) and would like to manufacture and sell alcohol-based hand sanitizers to the public would need to get a **Product and Site Licence**.

To proceed as described below, companies are asked to provide a cover letter indicating whether they are applying for a Product Licence, a Site Licence, or both.

This directive only applies to alcohol-based hand sanitizers containing the following medicinal ingredients:

- Ethanol (60-80% v/v), also known as anhydrous alcohol, ethyl alcohol, grain alcohol
- Isopropanol (60-75% v/v), also known as isopropanol, 2-propanol

Companies must hold a natural product number (NPN) and a site licence (SL) before manufacturing and selling a hand sanitizer as described above to the public. Please note that a licence is required for the production of finished natural health products, and is not required if you are only producing raw materials.

1. ONLY PRODUCT LICENCE REQUIRED:

To obtain a Natural Product Number (NPN), the following steps must be completed:

- Email the Natural and Non-prescription Health Products Directorate (NNHPD) at

hc.nnhpd-dpsnso.sc@canada.ca, with the subject line “**COVID-19 Request for Company Code**” and provide the following information to obtain a company code:

- Company name;
 - Company address;
 - Name of senior official;
 - Contact information for the senior official (telephone and email)
- Register with Canada Post to open an epost Connect™ account which is the encrypted digital platform currently used for the exchange of confidential messages relating to NHP and (SL) applications. Health Canada will send the company code and create an epost account for the applicant.
 - Submit a completed web-based Product Licence Application form [<https://nnhpd-pla-dlmm-dpsnso.hc-sc.gc.ca/pla-dlmm/>]. Select “compendial” on the form and make sure that the information provided for the product meets all safety requirements and is exactly as worded as per Health Canada’s monograph, which is consistent with the World Health Organization recommendations.

Applications made against Health Canada’s monograph and provided electronically through ePost will be reviewed in an expedited manner (within 24 hours dependent on application volume). If all requirements have been met, a product licence including a Natural Product Number (NPN) for your product will be issued.

2. ONLY SITE LICENCE REQUIRED:

To obtain a site licence (SL), the following steps must be completed:

- If your organization already holds a product licence, but does not hold a site licence and wishes to manufacture, package, and/or label alcohol-based sanitizers to help against COVID-19, you need to **apply for Site Licence**.
- Email the NNHPD at hc.nnhpd-dpsnso.sc@canada.ca, with the subject line “**COVID-19 – Application for Site Licence**”.
- If you do not already have an epost Connect™ account, register with Canada Post to open an account, as this is the encrypted digital platform currently used for the exchange of confidential messages relating to NHP and SL applications. Health Canada will initiate an ePost conversation with the applicant.
- Submit a SL 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>] to the ePost conversation created by Health Canada. The application includes an attestation to the good manufacturing practices (GMP) standards of Part 3 of the *Natural Health Products Regulations*; however, for the purposes of the response to the COVID-19, the following GMP standards are all considered acceptable for alcohol-based hand sanitizers:
 - 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];

- 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>]
- Submit a **cover letter template (attached) if you intend to manufacture, package or label** hand sanitizers. Through this cover letter, the applicant must:
 - Indicate the relevant industry
 - Indicate the intent of the application (i.e. Site Licence);
 - Select, among the acceptable GMP standards listed above, the applicable standards to which you attest your site to meet; and
 - Include the activities that will be conducted: manufacture, package and/or label;
 - Provide a signature from the senior official for the site

Once the SL application has been provided electronically through the ePost conversation, it will be reviewed in an expedited manner (within 24 hours), and a SL will be issued. The applicant will be allowed to manufacture hand sanitizers under this site licence during the COVID-19 health emergency.

3. BOTH PRODUCT AND SITE LICENCE REQUIRED:

To obtain both a Natural Product Number (NPN) and a site licence (SL), flexibility is provided in these circumstances to avoid duplicate forms.

If your organization does not hold a site licence and wishes to manufacture, package, and/or label alcohol-based sanitizers to help against COVID-19, you need to **apply for both a Product Licence and a Site Licence. To expedite the process, only the Product Licence form needs to be completed but it must be accompanied by the attached cover letter.** (See above for how to complete and submit the PLA form).

The cover letter needs to:

- Indicate the relevant industry
- Indicate the intent of the application (i.e. product and site licence);
- Select, among the acceptable GMP standards mentioned above, the applicable standards to which you attest your site to meet; and
- Include the activities that will be conducted: manufacture, package and/or label;
- Provide a signature from the senior official

NOTE: Health Canada is developing a guide with more comprehensive information on requirements that companies must follow to manufacture NHP alcohol-based hand sanitizers during the COVID-19 pandemic. This guidance document will be available on Health Canada's website by March 27. In the meantime, companies can contact Health Canada directly at hc.nnhpd-dpsnso.sc@canada.ca.