Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers

This document provides information on the interim expedited licensing approach implemented by Health Canada to support companies that intend to use their facilities to manufacture, package, and/or label alcohol-based hand sanitizers in response to the COVID-19 pandemic.

Alcohol-based hand sanitizers containing the following medicinal ingredients are natural health products (NHPs) in Canada and are regulated under the *Natural Health Products Regulations* (NHPR):

- Ethanol, also known as "anhydrous alcohol", "ethyl alcohol", or "grain alcohol".
- Isopropanol, also known as "isopropyl alcohol" or "2-propanol".

All approved hand sanitizer products must meet the necessary requirements under the NHPR. A **Site Licence** is required to manufacture, package, and/or label an NHP hand sanitizer in Canada. Please note that a Site Licence is required for the production of finished NHPs, and is not required for the production of raw materials.

A **Product Licence**, represented by a Natural Product Number (or NPN), is required to legally distribute (i.e., donate or sell) the product. A Product Licence is required even if donating these products.

To facilitate the safe and efficient production of NHP hand sanitizers during the COVID-19 pandemic, Health Canada is simplifying and expediting the application and review processes for both Site Licences and Product Licences.

This interim approach applies to products that strictly comply with Health Canada's Antiseptic Skin Cleansers (Personal Domestic Use) monograph. A monograph provides pre-cleared information on an ingredient or product, including permissible uses, and supports the licensing of certain NHPs. The monograph supports the safety and efficacy of alcohol-based hand sanitizers with a final concentration of 60-80% ethanol or 60-75% isopropanol.

Products licensed through a monograph are generally for personal use only. Given the COVID-19 pandemic, and as part of this interim measure, alcohol-based hand sanitizers can be distributed for use in hospitals, clinics, commercial settings, and other acceptable facilities. The licence holder must notify Health Canada of this intent. Further details are provided herein, including labelling rules.

Applications that go beyond the parameters of the monograph (such as making additional claims) are not eligible for the expedited licensing process described herein. In these cases, the applicant will need to provide supporting evidence on safety, efficacy and quality in order to receive a Product Licence. For more information on these types of applications, please refer to Health Canada's NHP Management of Applications Policy.

This interim approach is in effect immediately, and will be in place until March 31, 2021 or until a notice is issued by Health Canada to licence holders (whichever is earlier).

During this period, the interim approach is also available to those companies currently holding valid Site and/or Product Licences that wish to contribute to the public health response to the COVID-19 pandemic.

How to Know Which Application Form is Required

- If you do not currently manufacture, package and/or label alcohol-based hand sanitizers and you intend to manufacture and distribute such products, you must apply for both a Site Licence and a Product Licence.

- If you intend to only manufacture, package and/or label alcohol-based hand sanitizers on behalf of another company, you need to apply for a Site Licence only.

- If you intend to only distribute alcohol-based hand sanitizers made by another company, you need to apply for a Product Licence only.

- If you already hold a Site Licence for manufacturing, packaging, and/or labelling NHPs and you intend to add an alcohol-based hand sanitizer to your product line, which you intend to distribute, you need to apply for a Product Licence only.

For all above scenarios, a cover letter indicating whether you are applying for a Product Licence, a Site Licence, or both is recommended. The cover letter will help Health Canada expedite the processing of applications.

The following is a step-by-step guide on how to apply for Site and/or Product Licences:

Companies Only Applying for a Site Licence

Before applying for a Site Licence:

1. A Company Code is a number assigned to each applicant or company by Health Canada. If you do not have a Company Code issued by Health Canada, send an email to hc.nnhpd-dpsnso.sc@canada.ca, with the subject line "**COVID-19 – Request for a Company Code**". In the body of the email, include the company information that you will be using to complete your Site Licence Application Form including company name, contact information, and Senior Official (e.g., Chief Executive Officer or Director).

2. Health Canada will provide the Company Code via email and initiate an ePost conversation with the applicant through ePost Connect™. If you do not have an ePost Connect™ account, register with Canada Post to open an account by following the instructions in the conversation notification email. EPost is the

encrypted digital platform currently used for the exchange of confidential messages relating to NHP licensing applications.

3. Complete the cover letter template and the Site Licence Application Form and submit both via the ePost conversation within the ePost Connect™ site.

To complete the Site Licence Application Form, please follow the instructions below:

Part 1 – Applicant and Contact Information

- Block A, Applicant or Licensee Information: Provide the full legal name of the applicant or company applying for a Site Licence. **Do not abbreviate the applicant or company name.**

- Block B, Senior Official: Provide the name of the Senior Official who represents the company at the address given.

- Block C, Contact for this Application: Provide the name of the primary contact person to whom Health Canada will direct application-specific questions. This may be an employee of the company or a consultant.

- Block D, Quality Assurance Person: Provide the name of the individual who is responsible for assuring the quality of the alcohol-based hand sanitizer before it is distributed. This person should be qualified to perform quality assurance activities through education, training and/or experience.

Part 2 – Application Information

- Select the “New Site Licence Application” box.

Part 3 – Canadian Site Information

- Provide the requested details on the building(s) where each of the authorized activities will be performed.

Part 4 – Foreign Site Information

- This section is only applicable to importers and is not required for a domestic manufacturer.

Part 5 – Attestation

- The attestation must be signed by both the Quality Assurance Person[1] identified in Block D and the Senior Official named in Block B. If the Senior Official is currently in quarantine or teleworking, an electronic signature is acceptable.

- As part of the cover letter template, complete the attestation certifying that the site complies with the applicable Good Manufacturing Practices (GMP), and have it signed by the Senior Official.

Good Manufacturing Practices

- For the purposes of this interim approach, any of the following GMP standards are considered acceptable. The standard to which you are attesting the site to comply will need to be selected in the cover letter:
    - Part 3 of the NHPR
    - Division 2 of the *Food and Drug Regulations*
    - Guide to Food Safety, or
    - Good Manufacturing Practices for Cosmetic Products*

  *Note: Health Canada encourages all cosmetic manufacturers to follow GMP, and endorses the use of the International Standards Organization (ISO) Guidelines on Good Manufacturing Practices for Cosmetics, ISO Standard 22716.

- Given the interim nature of the Site Licences issued under the approach outlined herein, certain GMP requirements that are usually required for NHPs are waived during this period, specifically:
    - Stability testing is not required
    - A Quality Assurance Report or other forms of evidence required as part of the standard process is not required
    - For products containing more than 50% alcohol, finished product testing for microbiological contaminants is not required

- Regardless of the GMP standard selected, appropriate controls must be in place to avoid contamination throughout the entire manufacturing and packaging process.

For additional guidance on how to complete the Site Licence Application Form, please refer to the Guide for Completing the Site Licence Application.

The completed cover letter template and Site Licence Application Form are to be submitted via the ePost conversation within the ePost Connect™ site.

[1] For the purpose of this interim approach, the Quality Assurance Person is the person responsible for the area of GMP concerned with sampling, specifications, testing including documentation, and product release to market procedures. The Quality Assurance Person bears the responsibility of assuring that each product is suitable for sale. This ensures that the necessary and relevant tests are carried out and that products are not released for sale until their quality has been determined to be satisfactory by confirming that all product specifications are met.

The Site Licence Application for alcohol-based hand sanitizers will be reviewed in an expedited manner, and Site Licences will be issued within 24 hours (depending on volume of submissions). A Site Licence issued as described herein will remain valid only while the interim approach is in effect.

Following this period, if you wish to maintain a valid Site Licence to produce NHPs, the supporting evidence mentioned above (i.e. Quality Assurance Report, stability testing, finished product testing) will be required as per the NHPR, and the site will be required to meet the GMP standards outlined in Part 3 of the NHPR.

Companies Only Applying for a Product Licence

Before applying for a Product Licence:

1. If you do not have a Company Code issued by Health Canada, send an email to hc.nnhpd-dpsnso.sc@canada.ca, with the subject line "**COVID-19 – Request for a Company Code**". In the body of the email, include the company information to be included in your web Product Licence Application Form, including the company name, contact information, and Senior Official.

2. Health Canada will send the Company Code via email and initiate an ePost conversation with the applicant through ePost Connect™. If you do not have an ePost Connect™ account, register with Canada Post to open an account by following the instructions in the conversation notification e-mail.

3. Complete the cover letter template and the Product Licence Application Form, and submit both via the ePost conversation within the ePost Connect™ site.

To complete the Product Licence Application Form, please follow the instructions below:

Access the web Product Licence Application Form. You may begin to fill the application form while you are waiting for your Company Code to be provided, by selecting the "Table of Contents" button at the bottom of the page, which will open the other sections to be completed. The form must be completed in its entirety before submitting, but you may complete it by going back and entering the Company Code once received.

a. Under "Application Type", select "**Compendial**" and select "**Antiseptic Hand Cleansers**" from the drop-down list of monographs.
b. For "Is this formulation hypothetical", indicate "**no**". No Reference submission or Master File is required.
c. For the "Primary Brand Name", please indicate a **generic descriptor of the product and alcohol content**, e.g. "Company name-Ethanol sanitizer 80%". Do not include any references to viruses including "COVID-19", "SARS-CoV-2" or "coronavirus", diseases, or infectious conditions as these are outside of the Antiseptic Skin Cleansers monograph.

d. Under “Dosage Form”, select the appropriate dosage form for your product, such as “**Gel**”, “**Solution**”, “**Liquid**” **or** “**Aerosol (spray)**”.
e. For “Sterile?” select “**no**”.
f. In the “Medicinal Ingredient” page, select the applicable type of alcohol to be incorporated in your product, by proceeding as per **one** of the following instructions:
    - Search for “**Ethanol**” or “**Ethyl Alcohol**” and add it as a “Medicinal Ingredient”. Once added, click on “**Modify**”, and indicate a concentration between 60-80% in the “Quantity per Dosage Unit” field. OR
    - Search for “**Isopropanol**” or “**Isopropyl Alcohol**”, and add it as a “Medicinal Ingredient”. Once added, click on “**Modify**”, and indicate a concentration between 60-75% in the “Quantity per Dosage Unit” field.
g. Add any acceptable “Non-Medicinal Ingredients” (e.g. hydrogen peroxide) to the list, as applicable.
    - The Natural Health Products Ingredient Database (NHPID) includes a listing of acceptable ingredients, which can be used in the product formulation. This includes denaturants, which reduce the risk of accidental or deliberate ingestion.
    - The use of denaturants, including Denatonium benzoate, Sucrose octaacetate and t-Butyl alcohol, is recommended but is not required under this interim approach. However, once this interim approach ceases to be in effect, you may receive a request from Health Canada to confirm that denaturants will be used in the manufacture of all hand sanitizer products from that point on.
    - If you are following the World Health Organization-recommended handrub formulations and use a final concentration of 0.125% (v/v) hydrogen peroxide and 1.45% (v/v) glycerol, and water please indicate so in the “Non-Medicinal Ingredients” section.
h. Select the desired “Recommended uses” or “Purposes” from the drop-down list by checking the applicable boxes.
i. Add any desired “Subpopulation(s)” from the drop-down list.
j. Add the following “Directions for Use” statements:
    - For all products:
        1. “Supervise children when they use this product”
        2. “For occasional and personal domestic use”
    - For products intended as handrubs or wipes, also add:
        1. “Rub thoroughly into hands for at least 30 seconds. Allow to dry”
    - For products intended as handwashes, also add:
        1. “Lather in hands with water for at least 30 seconds. Rinse well”
k. No “Duration of Use” statement (e.g., “For use beyond X days, see a health care practitioner”) is required.
l. All “Cautions and Warnings” statements listed in the monograph are required.
m. Once the form is completed, a label text will be generated for the product:
    - Provide the “Net Quantity” in the packaged final product (numerical value and units such as mL, L).

- “Security features” (e.g., plastic bottle seal cap) are not required for these products under this interim approach.

Before completing the form, carefully review the “Summary” and the “Attestation” at the bottom of the page. To sign the attestation, select the "I agree" checkbox. This will generate an Attestation Code confirming that you accept the terms of the attestation. After agreeing with the attestation, the “Finalize” button will appear. Click on "Finalize" to lock the form, generate a unique Tracking Number and go to the “Finalized Form”.

The “Finalized Form” includes the Tracking Number, a summary of the application and a signed attestation. Once completed, the cover letter and application form (in .html format) must be submitted via the ePost conversation. If the application meets all requirements of the monograph, Health Canada will issue a Product Licence under the expedited timeline of 24 hours (dependent on volume of applications).

Use of Domestic Hand Sanitizer Product in Other Settings

A Product Licence issued under this interim approach allows for the use of the product for antibacterial hand sanitizing in a personal (domestic) setting. However, Health Canada recognizes that healthcare institutions, such as hospitals or clinics, or other commercial settings may be experiencing shortages and, in this context, may wish to access these products. **Given the COVID-19 pandemic, and as part of this interim approach, a product authorized for personal use can be distributed to hospitals and clinics.** To do so, companies must notify Health Canada by email at hc.nnhpd-dpsnso.sc@canada.ca, including:

- A subject line of “**COVID-19 product notification**”
- In the body of the email, information on the product (referencing the NPN) and its intended distribution

Companies must submit the e-mail notification prior to distribution but do not require a response from Health Canada.

As these products have not met the evidence requirements for higher risk uses in a general healthcare setting or as pre-surgical scrubs, these products must be labelled for personal use only.

Should a company wish to obtain approval to label their product for use by health professionals, for uses such as pre-surgical scrubs, or make explicit claims related to COVID-19, additional evidence must be submitted to support safety and efficacy, and the expedited timeline described herein (24 hours) will not apply. For more information on these types of applications, please refer to Health Canada’s NHP Management of Applications Policy.

Companies Applying for BOTH a Product Licence and a Site Licence

To facilitate timely access to safe NHP hand sanitizers during the period within which this interim approach is in effect, Health Canada is further simplifying the application process in cases where both a Site Licence and a Product Licence are required.

If your company is seeking both a Product Licence and a Site Licence, you may apply by **only completing the** Product Licence Application Form **accompanied by a cover letter.**

The information contained in the cover letter will provide sufficient information to support the Site Licence Application, including:

- The relevant industry (i.e., the line of business the applicant is currently in, such as distillery, or cosmetics).
- The intent of the application (i.e., sanitizer product + COVID-19 Site Licence);
- The GMP standard that is being met.
- The activities to be performed (e.g. manufacturing, labelling, and/or packaging).
- The signature from a Senior Official.

Labelling Requirements

This section outlines the applicable labelling requirements for a marketed product to comply with the regulatory requirements found in Part 3 of the NHPR.

As per the *Food and Drugs Act*, it is illegal to label, sell or advertise a product, including hand sanitizers, in a false, misleading or deceptive manner. Labelling must be compliant with the product licence; in this case, the claims made must be consistent **(verbatim)** with what is provided in the Antiseptic Skin Cleansers monograph. Authorization under this monograph does not permit any specific references to “COVID-19”, “SARS-CoV-2” or “coronavirus”.

Product Licence holders are responsible for ensuring that the label complies with the labelling requirements set out in Part 5 of the NHPR, specifically Sections 93, 94, 95, and 97, if applicable. As per section 86(1), you are not allowed to sell an NHP unless it is packaged and labelled in accordance with the NHPR. A checklist is provided below that itemizes the elements required on the label and their location (if specified).

Label information must be presented in both official languages (i.e., French and English) under the NHPR. However, given the urgent need for these products, Health Canada is allowing certain flexibilities for imported products, including waiving the requirement for bilingual labelling. Similarly, as part of this interim approach, we are providing this flexibility to domestic products, though the use of bilingual labels remains strongly encouraged, particularly for distribution in bilingual regions.

Labelling Checklist

Elements that must appear on the Principal Display Panel:	
• Primary Brand Name	
• Product Number (NPN, issued upon approval of your product)	
• Dosage Form	
• Net amount in the container in terms of weight or measure	
Elements that must appear on any panel:	
• Name and address of the product licence holder	
• Name of each Medicinal Ingredient	
• Quantity of the Medicinal Ingredient per Dosage Unit (i.e. %)	
• Recommended Use or Purpose	
• Recommended Route of Administration – topical (if not self-evident)	
• Recommended Dose (including subpopulation amount, frequency, and directions of use, if any)	
• Risk Information	
• List of all Non-Medicinal Ingredients	
• Recommended Storage Conditions (if any)	
• Lot number	
• Expiry date	
• Storage Conditions (if outside normal conditions)	
Other	
• Cautionary statements (e.g., flammability, poison warning, etc.)	
• All information must be clearly and predominantly displayed and readily discernible to the consumer	

Adverse Reaction Reporting

As with any health product, an adverse reaction may occur with the use of alcohol-based hand sanitizers. Product Licence holders are required to report serious adverse reactions that occur in Canada as well as serious adverse reactions that occur internationally. You must report any adverse reactions to Health Canada within 15 days of receiving the information or risk potential compliance and enforcement actions.

This mandatory reporting is done through Health Canada's Canada Vigilance Program. Once you have a licence, you must submit adverse reaction reports as noted above here and select the "Natural Health Products" box.

You can find additional information on reporting adverse reactions in the Reporting Adverse Reactions to Marketed Health Products – Guidance Document for Industry.

End of Interim Approach

This interim approach is in effect immediately, and will be in effect until March 31, 2021 or until a notice is issued by Health Canada to licence holders (whichever is earliest).

When the approach expires, production must cease, although existing product stock can be exhausted.

Questions?

If you have questions regarding the licensing of alcohol-based hand sanitizers or sites that are not addressed in this document, you can contact Health Canada's Natural and Non-prescription Health Products Directorate at hc.nnhpd-dpsnso.sc@canada.ca.

Given the expedited manner in which Health Canada is processing applications as part of the COVID-19 pandemic, we would ask that you refrain from contacting the department for status updates on your applications.