OVERVIEW

• Establishment Licence Bulletin LEPP No. 74 COVID-19 Disinfectants and Hand Sanitizers

• As an interim measure for COVID-19 pandemic, Health Canada is permitting the importation of some supplies that may not fully meet Canadian regulatory requirements under the Food and Drugs Act and its Regulations.

• 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.

WHO DOES THIS APPLY TO?

• This applies to companies that intend to use their facilities to import alcohol-based hand sanitizers in response to the COVID-19 pandemic.

• For importers of hand sanitizers that are classified as natural health products (NHPs) or non-prescription drugs, depending on the ingredients.

KEY POINTS

• As an interim measure, to help manage the spread of COVID-19 Health Canada will facilitate the importation of the following:

  o Products that are already authorized for sale in Canada but are not fully compliant with Health Canada requirements – e.g., English-only labelling; Hand sanitizers that meet the NNHPD’s Antiseptic skin cleansers monograph requirements and have a DIN or NPN for personal commercial use or for a different dosage form);

  o Products that are not authorized for sale in Canada but are authorized or registered in the United States or an MRA or PIC/s country.

• Importers of products that fall under these categories are required to notify and submit to Health Canada the Health Canada Application and
Notification Form for Exceptional Release of Disinfectant and Sanitizing Products.

- Companies are required to maintain records to facilitate product recalls if needed.
- Notified products will be added to a public communication posted on the Health Canada website - “List of products accepted under interim measure”.

**WHAT DO I NEED TO DO?**

- Importers who currently have a Drug Establishment Licence (DEL) or Site Licence (SL) to conduct activities related to hand sanitizers covered by this measure are required to notify Health Canada in advance that they will be importing products and maintain records that will facilitate product recalls, if needed.
- Domestic companies that do not currently have a DEL or SL to conduct activities (such as import) related to hand sanitizers covered by this measure may submit an application for expedited review to Health Canada.
- Domestic companies that do not currently have a DIN or NPN for a hand sanitizer product may submit an application for expedited review to Health Canada.
FAQ

1. How was the Health Canada Interim Measure communicated to stakeholders?


2. When will Health Canada start enforcing this bulletin?

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 earliest).

3. What licences do I need to bring alcohol-based Hand Sanitizers into Canada?

All approved alcohol-based hand sanitizers must meet the necessary requirements under the Natural Health Product Regulations (NHPR).

A Site Licence is required to manufacture, package, label and/or import an NHP hand sanitizer in Canada.

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.

4. How do I know which application form is required?

If you do not currently manufacture, package, label and/or import 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 (NPN).

If you intend to only manufacture, package, label and/or import 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 (NPN).

If you already hold a site licence for manufacturing, packaging, labelling and/or importing NHPs and you are adding an alcohol-based hand sanitizer to your product line, which you intend to distribute, you need to apply for a product licence only.
5. **What Health Canada standards am I required to meet for hand sanitizers?**

This interim approach applies to products that strictly comply with Health Canada’s Antiseptic Skin Cleansers (Personal Domestic Use) monograph.

6. **What if I want to make additional claims on my Hand Sanitizer outside of what is allowed in the monograph?**

Applications that go beyond the parameters of the monograph (such as making additional claims) are not eligible for the expedited licensing process described in this guide. In these cases, the applicant would need to provide supporting evidence on safety, efficacy and quality in order to receive a product licence.

7. **Do I need a Site Licence (SL) and/or Drug Establishment Licence (DEL) to sell hand sanitizers in Canada?**

Yes, importers or domestic companies require they hold a SL for hand sanitizers that have been issued an NPN (Natural Health Product Number) or a DEL for hand sanitizers that have been issued a DIN (Drug Identification Number).

8. **Are there any GMP Exemptions under this Interim Measure?**

The expectation for all importers is to maintain records that will permit recalls of products approved under this interim measure. Importers should maintain their current processes to ensure that the information is available.

9. **Are all the products compliant to Antiseptic Monograph included in the scope of this Interim Measure?**

Yes, but *Food & Drug Regulations* apply to products that are classified as non-prescription drugs (DINs) as per the Antiseptic Monograph. This includes importation under a valid Drug Establishment Licence (DEL) and compliance to GMPs under the FDR.
We wrote the book on compliance...literally. Over 150,000 Blue Books have been published and used worldwide since 2002.

Q&C is the largest full-service consultant and importer for Health Canada regulated drugs, APIs, medical devices, cannabis and natural health products. We bring over 20 years of experience to our clients, providing expert consulting on regulatory and compliance matters, including industry best practices, assistance passing inspections and audits, and expert guidance for drug importation into Canada.

We can help you. Call us today at 1-877-877-5152 ext. 232 or visit www.qualityandcompliance.com