

CLARIFICATION // PRECISION DEL Bulletin LEPP No. 74 COVID-19 Disinfectants and Hand Sanitizers // COVID-19 Désinfectants et désinfectants pour les mains

Release Date: March 20th, 2020

Clarification to March 17 DEL bulletin #74

Clarification: Health Canada is taking action to increase supplies of disinfectants and hand sanitizers

Further to the March 17 information on an interim measure for disinfectants and hand sanitizers, the following elements of our initial communication are further clarified.

Licensing requirements for companies interested in accessing this pathway

- Importers who currently have a Drug Establishment Licence (DEL) or Site Licence (SL) to conduct activities related to disinfectants and 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 disinfectants and 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 disinfectant or hand sanitizer product may submit an application for expedited review to Health Canada.

In addition, Health Canada is clarifying that importers of hard-surface disinfectants that are [antimicrobial agents](#) continue to be exempt from requirements under Part C Divisions 1A (Drug Establishment Licensing) and 2 (Good Manufacturing Practices) of the Food and Drug Regulations. There is a voluntary Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices (GUI-0049).

Disinfectants and hand sanitizers may also be subject to other requirements under the Food and Drugs Act and its Regulations.

Clarifications related to the form

The following are clarifications related to the form that you must complete, in order to access this pathway:

- You should provide a copy of the product label that will be distributed in Canada for both Level 1 and Level 2 requests.
- The form must be completed and submitted to hc.covid19healthproducts-produitsdesante.sc@canada.ca prior to importation.
- To facilitate our processing of your notification, companies seeking to use this pathway are asked to provide the following information along with your request:
 - Valid DEL or SL number
 - Name of the logistics company to be used

The form is not required for Level 3 and 4 requests. For Levels 3 and 4, please submit a Product Licence Application or a Drug Identification Number Application. These will be subject to expedited review timelines. For more information, contact the Natural and Non-Prescription Health Products Directorate (NNHPD) at hc.nnnpd-dpsnso.sc@canada.ca.

Clarification related to Products in Level 2 categories:

Approved products in a [PIC/s](#) country will also be included in this interim measure. Please indicate which PIC/s country in your application.