

March 17, 2020

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

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 permitting the importation of some supplies that may not fully meet Canadian regulatory requirements under the Food and Drugs Act and its Regulations.

In Canada, disinfectant products are classified as non-prescription drugs and hand sanitizers are classified as natural health products (NHPs) or non-prescription drugs, depending on the ingredients. Typically, these products require authorization from Health Canada before they are sold in Canada and importers require a Drug Establishment Licence or Site Licence for NHPs.

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

- 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).
- Products that are not authorized for sale in Canada but are authorized or registered in the United States or an MRA country.

Importers of products that fall under these categories are required to notify and submit information to Health Canada prior to importation (form attached) at hc.covid19healthproducts-produitsdesante.sc@canada.ca. This will enable the Department to work with the Canada Border Services Agency to facilitate importation and take action if a risk to health is identified. 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. As an added measure, Health Canada is also expediting the review of applications for market authorization related to disinfectants or hand sanitizers. Any COVID-19 related product licence applications will be reviewed using adjusted service standards which will be provided on our website. Other product applications should follow the established pre-market application process for NHPs and OTCs, and as such, will be subject to a review by the NNHPD for safety, efficacy and quality.

Additional information will be posted on the Health Canada website in the coming days.