COSMETICS ALLIANCE CANADA

L'ALLIANCE DE L'INDUSTRIE COSMÉTIQUE DU CANADA

Hand Sanitizer Interim Measures – Questions and Answers

Cosmetics Alliance has prepared this Q&A document from various sources, including questions posed during our webinars on March 24th and 27th, from questions received from our membership and from follow-up Cosmetics Alliance has had with Health Canada directly.

We are presenting this document as an evergreen document and will be updating with new information as information becomes available. The document is dated in the footer, when new information becomes available, the document will be updated with the 

flash to flag the new information.

The document is organized into the following sections:

IMPORTANT INFORMATION

1. Health Canada has indicated to CA that incomplete notification forms are being received at their end. Not all the necessary information has been included, or simply did not meet the criteria for exceptional release under this interim measure. Therefore, Health Canada has been issuing messages asking companies to wait to receive confirmation from them as it has become necessary for them to do a quick review of a submission to ensure completeness and that products qualify.

2. Notification forms which are submitted accurately and completely are being processed within 24-48 hours of receipt.

3. We have also been informed that some stakeholders are indicating on their forms that they do not intend to bring supply to the market immediately, but rather are using this interim process as a 'back-up' measure. Although we are not sure of the intent of such 'back-up measures", we encourage stakeholders who do not have DINs or NPNs for their sanitizers to apply for these licences when you are not sure you will be importing Level 1 and Level 2 products. One should only be submitting Level 1 and 2 notifications when you have sorted out and confirmed your logistics processes. Submitting incomplete forms serves to only confound the established processes.

Follow-Up Attestations Received from Health Canada:

1. Should you receive further attestations from Health Canada, after submitting your notifications, which includes terms such as "importation of unauthorized" and "safe use of these unauthorized products" when you have indicated your products will be used for internal purposes (something not specifically required to be indicated on the form).

   CAC recommends you push back on these authorizations as Health Canada has enabled the sale of these products by way of their DEL Bulletin No. 74. In this regard, these products have been determined to be duly registered with Health Canada and should be considered 'authorized' for the purposes of the emergency circumstances outlined therein.

LABELLING

1. Does a foreign-marketed product that meets the designated product provisions under DEL Bulletin No. 74 need to meet Canadian labelling regulations before importing?
   In the case of a Level 2 product, Canadian labelling regulations do not need to be met before import. The foreign markets are limited to the United States, an MRA country or a PIC/S country. Health Canada is requesting the notification include a copy of the product label that will be distributed in Canada for Level 2 products.

2. oes a label need to be submitted for Level 1 & 2? Can the existing label be submitted, accompanied by a revised label for the Canadian market?

   Yes, labels are required to be included in the notification for Level 1 & 2 products.

   Health Canada is not requesting a revised label for the Canadian market.

3. Can stakeholders follow the interim rule on hand sanitizers published by FDA in the US and import the product?

   If the product is registered or authorized in the USA, an MRA country or a PIC/S country, you can import as a Level 2 product. The antiseptic skin cleansers monograph was updated on March 20th to accommodate up to 75% isopropanol as indicated in the USFDA's Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry.

DRUG ESTABLISHMENT AND SITE LICENCES

4. Does one still need to apply for a DEL and SL specific to disinfectants/hand sanitizer importation?

   There is no relinquishment of the requirement to have a Site Licence or a Drug Establishment Licence for disinfectants or hand sanitizers. Under the interim process, there are expedited review processes for SL and DEL applications and amendments included in the March 20, 2020 "Health Canada is taking action to increase domestic capacity of hand sanitizers" document.

   For disinfectants, there are certain types of disinfectants which require a Drug Establishment Licence and certain types which do not.

5. We have a Site License and currently manufacture a hand sanitizer for other customers who own the NPN. Does a Product License Application need to be submitted or can we submit an Attestation if we are following the monograph?

   This question is related to you wishing to sell a hand sanitizer with your name on the product, versus you manufacturing a hand sanitizer whereby someone else's name appears on the label of the product. All NHP hand sanitizers require a product licence and the name of the licence holder is required to appear on the label of the product and on the product licence itself.

6. If you have a new US site that can produce a US registered OTC Hand Sanitizer that is not registered on the DEL, is there a waiver to allow importing into Canada? If a company already has a DEL as an importer in Canada, can you confirm that the new site

(outside of US) does or does not have to be added to the importers DEL as a foreign site?

There are no changes in the requirement for foreign sites to be listed on either a DEL or a SL. Health Canada does have an accelerated pathway for adding foreign site to DELs and SLs. Indicate in your cover letters or ePost connect message that the foreign site amendment is related to Hand Sanitizers and COVID-19 to access this expedited pathway.

7. Do Level 1 reviews require only attestation to monograph even though it is not applicable for healthcare?

   Level 1 speaks to products already authorized in Canada; therefore, you will have already submitted a product licence application and would have been authorized (i.e. reviewed by Health Canada and an NPN issued).

8. For submission of a DIN application for hard surface disinfectant drugs, will the expedited timelines still be applied and is the efficiency test still required?

   Domestic companies that do no currently have a DIN for a disinfectant may apply for expedited review to Health Canada.

   For disinfectant product requirements, please consult Health Canada's disinfectant website.

   https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants.html

9. What are the steps to manufacture a DIN product that is already registered but in a location that does not have a DEL?

   If a location does not have a DEL to fabricate, package or label a DIN product, they will need to apply for a Drug Establishment Licence, if the product is not exempt from a DEL (such as some types of disinfectants).

   Indicate in your cover letter that the application is related to Hand Sanitizers and COVID-19 to access the expedited pathway for issuance of a DEL.

10. Can the listing of the foreign site on our SL be expedited?

    Yes. Indicate in your ePost connect message that the foreign site amendment is related to Hand Sanitizers and COVID-19 to access this expedited pathway.

11. We are working on completing Product and Site Licence application for our non-GMP facility which has huge capacity to manufacture hand sanitizers to help support COVID-

19 efforts. Do we wait until we receive ePost reply and COVID-19 account from HC to submit the PLA?

If you already have an ePost connect account, you only need to indicate in your cover letters and/or New Message thread that your application is for a HAND SANITIZER and COVID-19.

If you do not have an ePost connect account, you open one with Canada Post. Then inform Health Canada you have one via the email supplied in the guidance documents. They will then send to you the COVID-19 thread in your ePost account.

12. We are a distributor and need to add benzalkonium chloride to our DEL-Table A. Can we start importing as soon as we have submitted our updated Table A? Do we need a quality agreement, or can we send the signed attestation to ISO for the foreign manufacturer of the BAK?

    The intent of Table A for products falling under the Consumer Health Product API Pilot was for Health Canada to know the sources of the APIs being used in these products.

    There is no attestation associated with the CHP API Pilot. Column L is used to exempt from Part C, Division 2 of the Food and Drug Regulations. When you are importing ingredients not part of the CHP API Pilot, the attestation form is required.

REGULATORY REQUIREMENTS

13. How many months of Stability data is required? Is equipment validation data required? Shelf-life?

    Health Canada has released their document: Notice of Manufacturers of Natural Health Product (NHP) Hand Sanitizer Products During the Pandemic COVID-19. There are details regarding stability and shelf-life requirements in this document. There is no equipment validation (in the DIN or drug-sense) required for NHPs.

14. How soon after the notification form is submitted can you import sanitizers manufactured in an MRA country?

    Health Canada will approve your notification within 24-48 hours. See IMPORTANT INFORMATION, Point #1 for further details.

15. How will HC handle the US FDA's temporary Hand Sanitizer guidelines and WHO formula 1 and formula 2?

    Health Canada has released their document: Notice of Manufacturers of Natural Health Product (NHP) Hand Sanitizer Products During the Pandemic COVID-19 which covers the WHO recommendations.

    The antiseptic skin cleansers monograph was updated on March 20th to accommodate up to 75% isopropanol as indicated in the USFDA's Temporary

    Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry.

16. Do you have guidance for an existing NPN that can be manufactured in a new packaging format, for example: currently in bottles in various sizes but we are looking to manufacture in a BOV delivery system with no formula change. Is a notification or amendment required to be submitted for this existing NPN.

    Please consult the Post-Licensing Guidance Document for post-approval changes to NHPs which addresses this question and details whether this type of change is an amendment, notification or a circumstance which is not required to be submitted.

17. What happens after the pandemic is over - how long do we have to clear the product off the market which has been allowed as an interim measure?

    Health Canada has released their document: Interim Guide on the Production of Ethanol for Use in Alcohol-Based Hand Sanitizers which includes the end of the 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.

    Cosmetics Alliance Canada is working with Health Canada to ensure early communications of the transition considerations to enable an orderly and predictable transition process that will look to "return to normal" in a manner that is least disruptive to the marketplace.

18. For API importers, how fast would HC approve a Table A revision for a hand sanitizer API?

If your ingredient falls under the CHP API Pilot, Table A submissions are and have always been notifications. If your ingredient does not fall under the CHP API Pilot, and you mention that your submission is for a hand sanitizer your submission will be expedited.

19. On the notification form, for Level 2, they are asking for the foreign registration number. If the sanitizer is made in the US, should we include the submission ID for submissions filed on CDER direct?

    If you employ the NDC option, use your NDC associated with your DRLS registration. If you do not, use your submission ID.

20. Is there a go-to place to find out who has raw materials, packaging components, active ingredients available for sale?

    Cosmetics Alliance, along with the Canadian Consumer Specialty Products Association (CCPSA) and the Canadian Distillers Association (Spirits Canada), have launched the Hand-Sanitizer Manufacturing Exchange.

    At the urging of Health Canada and Canadian Manufacturing & Exporters, we have been encouraged to assist in matching manufacturers with suppliers of ingredients, components and supportive services to maximize the domestic production of all-important hand-sanitizers during the COVID-19 pandemic.

    If your company has manufacturing capacity but requires ingredients, components or supportive services; or if you have ingredients, components or supportive services available, this Manufacturing Exchange can help make the match. For more information click here.

21. When we submit the Health Canada Application and Notification Form for Exceptional Release of Disinfectant and Sanitizing Products form for level 1 or level 2, do we need to wait to get an acknowledgment from HC before we import?

    Health Canada will approve your notification within 24-48 hours. See IMPORTANT INFORMATION, Point #1 for further details.

22. For a chemical production site without DEL or SL or GMP in place, can we re-package hand sanitizer purchased from Canadian producer from drums to small containers (1-L capacity) and distribute for own employee use at sites across Canada? And possibly further distribute to hospitals, health care centers?

    If yes, what are the requirements regarding operations, container labeling, transportation, UN-packaging since hand sanitizers are TDG-regulated?

If no, do we need to apply for DEL or SL, and GMP approval? What are the requirements?

No one can package (or re-package) drug or NHP products without a DEL or SL respectively.

No one can sell (or use internally), a drug or NHP which has not been issued a DIN or NPN licence.

The Good Manufacturing Practices for packaging and re-packaging and transportation are found in the Natural Health Product Good Manufacturing Practices located here.

Regarding the question related to container labelling. The products need to be labelled according the product licence issued to the name of the company listed on the label (i.e. the product licence holder) specific for the product being packaged and labelled.

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.nnhpddpsnso.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**

Transport Canada has announced that they will issue Temporary Certificates to Enable the Facilitated Transport of Hand Sanitizers (and other essential medical supplies) During the CoVID-19 Crisis. Please see our announcement on our website located here.

23. Does Health Canada allow the use of industrial grade, fuel-grade, non-USP Ethanol and ingredients in manufacturing hand sanitizers in Canada to address COVID-19 pandemic?

    Please visit our website here for Cosmetics Alliance's statement on the use of fuel-grade ethanol in hand sanitizers.

24. Do you have a direct contact email, phone # at Health Canada for COVID-19 hand sanitizers questions?

    Health Canada has created the following e-mail address for questions:

hc.covid19healthproducts-produitsdesante.sc@canada.ca

25. What are the requirements if the product is not registered or authorized in USA/MRA country or PIC/s country?

    You need to apply for a product licence. Health Canada issued their Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers. Please see our website.

26. How are CEPA requirements being managed for example NSN requirements?

    There are no interim policy proposals related to CEPA requirements currently.

27. Do you submit the Notification Form once if the product is being imported more than one time?

    Part IV contains a "Date of Import", therefore if the product is being imported more than one time, another form will need to be submitted.

28. Does Health Canada expedite the review and approval of hand sanitizer for commercial use?

    Yes. Indicate in your NHP ePost connect message or DIN submission cover letter that the application is related to Hand Sanitizers and COVID-19 to access this expedited pathway.

29. Does Health Canada allow the use of industrial grade alcohols (ethanol) under the Antiseptic Skin Cleanser Monograph?

    Please visit our website here for Cosmetics Alliance's statement on the use of fuel-grade ethanol in hand sanitizers.

GOOD MANUFACTURING PRACTICES

30. Has Health Canada speculated on which "non-traditional' quality systems they may accept for GMP compliance for either a DEL or SL for hand sanitizers?

    The non-traditional standards for GMP during this interim measure are listed in the Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers. If you use a GMP standard not included in this list, a Quality Assurance Report may be used to demonstrate compliance with the NHP GMPs.

31. What are the four types of alternative GMPs allowed under Health Canada's action to increase domestic capacity of hand sanitizers?

    The March 20th document "Health Canada is taking action to increase domestic capacity of hand sanitizers includes:

    - 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].

    Note: We have followed-up with Health Canada on *Division 2 of the Food and Drug Regulations* as this link points to Part B (Foods) of the Food and Drug

    Regulations – Alcoholic Beverages. This link is intended to point to Division 2 (Part C) of the Food and Drug Regulations located here.

    Alternative to these standards, should you wish to use other quality systems, the Quality Assurance Report remains an option to demonstrate equivalence of your quality system to the NHP Good Manufacturing Practices Regulations.

32. If a level 2 notification is submitted does the GMP document containing CoA's, stability records need to be submitted?

    The notification details for Level 2, that labels are required to be submitted.

33. HC has removed the requirement for submission of a QAR for site licensing, does this apply to importation as well?

    No. This applies only to the activities of manufacturing, packaging or labelling alcohol-based sanitizers. The requirement for submission of a QAR has not been removed and remains an option when demonstrating GMP compliance.

34. Does HC allow the use of industrial grade alcohols (medicinal ingredients) and industrial NMIs in hand sanitizers, along with attestation statements on adherence to GMP standard, during COVID-19 pandemic?

    To be clear, there are no GMP standards for NHP raw materials.

Please visit our website here for Cosmetics Alliance's statement on the use of fuel-grade ethanol in hand sanitizers.