



[Canada.ca](#) > [Departments and agencies](#) > [Health Canada](#)

> [Drugs and health products](#) > [Natural health products](#)

> [Natural health products legislation and guidelines](#)

> [Guidance Documents – Legislation and guidelines – Natural health products](#)

Interim guide on the production of ethanol for use in alcohol-based hand sanitizers

On this page

- [Acceptable quality grades](#)
- [Recommended formulation](#)
- [Records](#)
- [Non-medicinal ingredients \(NMIs\)](#)
- [Formula substitutions](#)
- [Use of non-USP grade alcohol](#)
- [Excise tax implications](#)
- [Obtaining a licence, registration and/or approved formulation under the Excise Act, 2001](#)
- [End of interim measure](#)
- [Contact us](#)

This document provides information on the use of ethanol as an ingredient in alcohol-based hand sanitizers sold in Canada. Numerous Canadian entities and industries not currently regulated by Health Canada have expressed interest in providing additional and/or alternate sources of

ethanol (also known as anhydrous alcohol, ethyl alcohol, or grain alcohol) for use in the production of hand sanitizers to support the national response to the supply shortage during the COVID-19 pandemic.

To help reduce the risk of infection or spreading infection to others, Health Canada recommends that individuals wash their hands often with soap and water, or use an alcohol-based hand sanitizer if soap and water are not available. Similarly, the World Health Organization (WHO) recommends that individuals regularly and thoroughly clean their hands with soap and water, or an alcohol-based hand rub, as part of proper hand hygiene.

On March 27, 2020, Health Canada released the Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers. The purpose of that Guide is to support companies that intend to manufacture, package, label and/or distribute alcohol-based hand sanitizers in response to the current shortage by providing a simplified pathway to obtaining the required authorizations.

This document provides further guidance on the quality requirements for ethanol to be used in the production of hand sanitizers. It also highlights key formulation aspects and points to additional flexibilities that can be leveraged during this emergency situation.

To protect the health and safety of Canadians, Health Canada remains committed to its mandate while balancing the need for exceptional measures during the COVID-19 pandemic. As such, the quality of ethanol used in manufacturing hand sanitizers must be fit for purpose and meet safety, efficacy and quality requirements.

This interim measure takes into account the current policies and best practices of foreign regulatory partners, including the United States (US) Food and Drug Administration (FDA), as well as the recommendations of

the WHO and the US Pharmacopeia (USP).

Acceptable quality grades

Ethanol used for the production of hand sanitizers should conform to one of the identity and purity criteria published in any of the following quality standards, with any noted deviations provided in this interim guidance. For details on these quality standards, please refer to the weblinks provided below. Please note that some of these references may be accessed for free, while others require payment for full access:

- [USP monograph](#)
- [European Pharmacopeia \(Ph. Eur.\)](#)
- [Food Chemical Codex \(FCC\)](#)
- [British Pharmacopoeia \(BP\)](#)
- [Pharmacopée française \(Ph.f.\)](#) (refer to monographs in subfolder “13-Formulaire national”)
- [Pharmacopoeia Internationalis \(Ph.I.\)](#)
- [Japanese Pharmacopoeia \(JP\)](#) (refer to page 896)
- [National Formulary \(NF\)](#)

The [USP monograph](#) specifies that ethanol must be 94.9% to 96.0% pure by volume, and provides the following concentration limits for impurities commonly found in ethanol:

- Methanol: No more than 200 µL/L
- Acetaldehyde and acetal: No more than 10 µL/L, expressed as acetaldehyde
- Benzene: No more than 2 µL/L
- Sum of all other impurities: No more than 300 µL/L

Recommended formulation

All formulations must meet the safety and efficacy requirements established in Health Canada's [Antiseptic Skin Cleansers \(Personal Domestic Use\) monograph](#).

Health Canada recommends the manufacturing of ethanol-based hand sanitizer as per the WHO formulation. Specifically, the [WHO-recommended handrub formulations \(2010\)](#), provides a recipe for the preparation of a hand sanitizer with a final concentration of 80% v/v ethanol. While Health Canada's monograph stipulates a range of 60%-80 v/v ethanol, an 80% v/v concentration is recommended for increased efficacy.

Formulation for a 10-Litre Preparation

- Ethanol 96%: 8,333 ml
- Hydrogen peroxide 3%: 417 ml
- Glycerol 98%: 145 ml

Other acceptable formulations include:

- The [USP guidance, as updated on March 25, 2020](#)
- The [US FDA guidance, released on March 27, 2020](#)

Records

Records must be maintained on how the hand sanitizer is prepared, including details on how the final ethanol dilution in the finished product was derived. The amount of ethanol needed in the formulation should be calculated using the following equation (as set out in the [USP guidance](#)):

$$\frac{(\text{final \% alcohol}) \times (\text{final volume of preparation})}{(\text{starting \% alcohol})} = \text{volume of starting ingredient required}$$

► Image - Long description

Non-medicinal ingredients (NMIs)

All NMIs added to a hand sanitizer product must be listed in Health Canada's Natural Health Products Ingredient Database (NHPID), indicated with an acceptable purpose and comply with all listed restrictions (as per the NHPID). Additional information is outlined below on quality requirements for specific NMIs used in ethanol-based hand sanitizers, based on the WHO guidance:

NMI	Quality Requirements
Hydrogen peroxide	The low concentration of Hydrogen peroxide in the finished product (0.125%) is intended to help eliminate contaminating spores in the bulk solutions and recipients and is not an active substance for hand antiseptics.

NMI	Quality Requirements
Glycerol and other humectants or emollients	<p>Glycerol (also known as glycerine or 1,2,3-Propanetriol) is added as a humectant at a final concentration of 1.45%, to increase the acceptability of the product and not to enhance viscosity.</p> <p>Other humectants or emollients at a similar concentration may be used for skin care, provided that they are affordable, available locally, miscible (mixable) in water and alcohol, non-toxic, and not likely to cause an allergic reaction. Glycerol has been chosen because it is safe and relatively inexpensive. Lowering the percentage of glycerol may be considered to further reduce the stickiness of the handrub.</p>
Use of proper water	While sterile distilled water is preferred, boiled and cooled tap water may also be used as long as it is free of visible particles.

NMI	Quality Requirements
Addition of other additives	<p>It is strongly recommended that no ingredients other than those specified in this document be added to the formulations. All NMIs (including denaturants) must be listed in the Product Licence application.</p> <p>If additions or substitutions of an NMI are made after the product licence is issued, documentation must be maintained on the safety of the additive and its compatibility with the other ingredients. These documents must be available upon request by Health Canada.</p> <p>Any substitutions should come from approved ingredients in the NHPID. If the NMI that you intend to use is not found in NHPID, you can complete a Natural Health Products Ingredients Database Issue Form and submit to this email to add the ingredient</p> <p>The full list of ingredients must be provided on the product label.</p>
Denaturants	<p>The use of denaturants is recommended to avoid the unintentional ingestion of hand sanitizers (particularly by children), but is not required under this interim measure. The NHPID includes a listing of acceptable denaturants that should be used if applicable in your formulation.</p> <p>Once this interim measure ceases to be in effect, to continue with the manufacture of hand sanitizer products, companies will be required to confirm with Health Canada that denaturants will be used from that point on.</p>

NMI	Quality Requirements
Gelling agents	No data are available to assess the suitability of adding gelling agents to WHO-recommended liquid formulations; any additives selected for this purpose must be listed in Health Canada's <u>NHPID</u> and comply with listed restrictions. The addition of a gelling agent must be included in the list of ingredients on the product label.
Fragrances	Adding fragrances, while not prohibited, is not recommended because of the risk of potential allergic reactions. As with other ingredients, a fragrance would be considered an NMI and must be included in the Product Licence application and be listed on the product label.

Formula substitutions

Ingredients adhering to USP (or other acceptable standards, as listed above) should be used as the source of ingredients. However, given that there may currently be shortages of ingredients used to manufacture formulations of alcohol-based hand sanitizers, the following substitutions are acceptable:

- When components meeting compendial quality standards are not obtainable, components of similar quality – such as those that are chemically pure, analytical reagent grade, or American Chemical Society-certified – may be used.
- No ingredients should be added to enhance viscosity as they may decrease the effectiveness of the final preparation.

Disinfectant product ingredients, whether registered with the US Environmental Protection Agency or Health Canada, are not suitable as components for manufacturing hand sanitizers as they may not be safe for use on skin (i.e., may cause burns).

Use of non-USP grade alcohol

As per the *Natural Health Products Regulations* (NHPR), a Product Licence will not be issued if a product is likely to result in injury to the health of the consumer. Non-USP grade ethanol should be of a level of quality that is fit for human use in the finished hand sanitizer formulation.

For any products containing ethanol with specifications that deviate from the recommended standards, such as higher than permitted level of impurities in the above referenced standards, a risk assessment must be conducted and submitted to Health Canada for review. Each risk assessment will be evaluated on a case-by-case basis to determine if the ethanol is safe for use in hand sanitizer production.

In the risk assessment, particular attention should be given to identify and quantify impurities, which are expected to be present (or likely to be present) as a result of manufacturing processes, starting materials, etc. An example of some impurities that would be expected in a non-USP or food grade ethanol product include acetaldehyde, benzene and methanol, though there may be others as well.

Documentation including certificates of analysis (CoA) must be kept on record and made available at the request of Health Canada.

Excise tax implications

The Canada Revenue Agency (CRA) administers the *Excise Act, 2001* which governs the federal taxation of several commodities, including spirits¹, and regulates activities involving the manufacture, possession and distribution of these products. For example, persons who produce and package spirits, persons who use non-duty-paid spirits in the manufacture of non-beverage spirit-based products such as cosmetics or hand sanitizers, and persons who operate warehouses to store non-duty-paid alcohol must possess an excise duty licence issued under the *Excise Act, 2001*.

Depending on the circumstances, a person may require a spirits licence, a user's licence and/or a specially denatured alcohol registration in order to legally produce hand sanitizer using non-duty-paid alcohol in Canada.

There are a number of ways hand sanitizer can be produced by licensees or registrants without incurring an excise duty liability, for example:

- A user licensee can produce hand sanitizer in accordance with an approved formulation without the payment of excise duty on the final product.
- There are also provisions that would allow a specially denatured alcohol registrant to possess and use certain grades of specially denatured alcohol to produce hand sanitizer without the payment of duty.
- A spirits licensee is authorized under the *Excise Act, 2001* to denature spirits according to specified criteria², which are not subject to excise duty.
- Although it could be cost prohibitive, there is also the option to use duty-paid alcohol to produce hand sanitizer.

The requirements under the Act will vary depending on the circumstances of each case and the proposed activities to be undertaken.

Obtaining a licence, registration and/or approved formulation under the Excise Act, 2001

A number of spirits licensees, licenced users and brewer licensees (excise licensees) have expressed an interest in using non-duty-paid alcohol to make hand sanitizer. These are existing excise licensees who are seeking to temporarily expand their operations in response to the shortage in supply as a result of the COVID-19 pandemic. In some cases, excise licensees are requesting specially denatured alcohol registrations to allow them to possess and use specially denatured alcohol for this purpose. In other cases, spirits or brewer licensees are requesting users' licences and approved formulations. The CRA is also receiving enquiries from non-licensees who would like to apply for a specially denatured alcohol registration or user's licence and approved formulation for the purpose of producing hand sanitizer.

In response to the current circumstances, the CRA has implemented a streamlined process to expedite the review and approval of these applications.

Applications for users' licences and specially denatured alcohol registrations should be submitted to your regional excise duty office using Form L63 Licence and Registration Application Excise Act, 2001. Applications for formulation approval should be submitted using Form Y15D - Request for Formula Approval. Note that a sample is not currently required for excise licensees applying for an approved formulation for the production of hand sanitizer.

For questions or further information, please visit this website [Excise Duties, Excise Taxes, Fuel Charge and Air Travellers Security Charge](#), which also includes the contact information for your regional excise duty office. These regional offices are your best source for information on excise taxes.

End of interim measure

Health Canada will lift the interim measure when the regular supply stabilizes.

Contact us

If you have questions in relation to this Guide or the licensing of alcohol-based hand sanitizers, please contact Health Canada's Natural and Non-prescription Health Products Directorate at hc.nnhpd-dpsnso.sc@canada.ca.

Footnotes

- 1 *Spirits* is included among the defined terms in section 2 of the *Excise Act, 2001*. For purposes of the *Excise Act, 2001*, *spirits* means any material or substance containing more than 0.5% absolute ethyl alcohol by volume other than (a) *wine*; (b) *beer*; (c) vinegar; (d) *denatured alcohol*; (e) *specially denatured alcohol*; (f) fusel oil or other refuse produced as a result of the distillation process; (g) an *approved formulation*; or (h) any product containing or manufactured from a material or substance referred to in paragraphs (b) to (g) that is not consumable as a beverage.

 - 2 Prescribed grades of denatured alcohol and specially denatured alcohol, for purposes of the *Excise Act, 2001*, are set out in the *Denatured and Specially Denatured Alcohol Regulations*.
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Date modified:

2020-05-09