



Natural and non-prescription health products directorate Notification on the use of technical-grade ethanol form

Please read:

1. Complete this form to notify Health Canada of the use of technical-grade ethanol in your hand sanitizer or hard-surface disinfectant. Please send the completed form to hc.rmd.coordination-dgr.sc@canada.ca with the subject line: "Technical-grade ethanol notification - <NPN/DIN> <Brand name>".
2. Companies must receive Health Canada's approval before manufacturing or selling hand sanitizer or hard-surface disinfectant containing technical-grade ethanol. A no objection letter will be issued once the requested information in this form has been assessed and accepted.
3. Companies that have received a no objection letter for using technical-grade ethanol in hand sanitizer or hard-surface disinfectant will be listed on Health Canada's website to provide transparency to the general public. See [Manufacturers of hand sanitizers and hard-surface disinfectants using technical-grade ethanol](#).
4. Please note that incomplete notifications will not be processed. It is the applicant's responsibility to ensure all required and relevant fields of the form are completed, and all supplemental information is included in the submission package. Incomplete submissions will not be reviewed.

Section A - Complete the following fields for the impacted product	
Company name of product licence / Market authorization holder:	Company code:
Product name (as per product licence):	NPN or DIN:
Contact information of Senior official / Executive officer / Sponsor of authorized product (e.g., Chief executive officer or director)	
Name:	
Telephone:	
Email:	
Manufacturer's information	
Manufacturer name:	
Manufacturer address:	
Site licence or drug establishment number:	

Section B - Complete the following fields for the source of technical-grade ethanol**Note:**

Technical-grade ethanol must be sourced from a supplier that has been approved by Health Canada. Please see list of [authorized suppliers](#). If your technical-grade ethanol supplier or ethanol product does not appear on this list, it cannot be used for the manufacturing of hand sanitizer or hard-surface disinfectants for distribution in Canada. Contact hc.rmd.coordination-dgr.sc@canada.ca for more information

Technical-grade ethanol supplier name:

Technical-grade ethanol supplier address:

Product name or product code of technical-grade ethanol: (**Note:** This information is identified on the certification of analysis)

Acetaldehyde level of Technical-Grade Ethanol: (**Note:** This information is identified on the Certification of Analysis)

Above 75ppm: **(Proceed to Section C)**

Equal to or below 75ppm: **(Proceed to Section D)**

Important: You must provide proof of contractual agreement between the Health Canada approved supplier of technical-grade ethanol and the product licence/market authorization holder to confirm the existing working relationship with respect to the procurement of technical-grade ethanol for the purpose of manufacturing hand sanitizer or hard-surface disinfectant.

Have you included proof of a contractual agreement with your notification? Yes No

Section C – Product label requirements if using technical-grade ethanol with acetaldehyde level above 75ppm**Notes:**

- Additional risk statements are required on the product label when using technical-grade ethanol with acetaldehyde level above 75ppm. Refer to table below.
- Additional risk statements must appear on the primary container label. If the product has an external package (e.g. box), the additional risk statements must appear on BOTH the primary container and the external package.
- Due to the high volume of demand for hand sanitizers and hard-surface disinfectants during the course of the COVID-19 pandemic, Health Canada is permitting companies to implement the necessary revisions to their product labels by using an over sticker on the product container and on the external package (e.g., box).
- Label information must appear in English and French for products distributed in Canada, regardless of the region of distribution.

English:

- Under Medicinal Ingredients: "Ethanol XX% (technical-grade)"
- Under Directions: "Adults only"
- Under Warnings: "Do not use on broken or damaged skin"; "Not recommended for use by women who are pregnant or breastfeeding"; "Do not inhale".
- Include a statement for consumers to "Report any incident to Canada.ca/drug-device-reporting."
- Include "Questions? Call 1-866-234-2345 to report any adverse reaction"

French :

- Sous « Ingrédients médicinaux », spécifiez « Éthanol XX% (qualité technique) »
- Sous « Mode d'emploi », spécifiez « Adultes seulement »
- Sous « Mises en garde », spécifiez « Ne pas utiliser sur peau endommagée ou présentant des lésions »; « Utilisation non recommandée pour les femmes enceintes ou qui allaitent »; « Ne pas inhaler ».
- Inclure une déclaration demandant aux consommateurs de signaler tout incident à Canada.ca/medicament-instrument-declaration
- Inclure « Questions? Appelez le 1-866-234- 2345 pour signaler tout effet indésirable »

Does your product have:		Primary container only	Primary container and external package
Important: You must provide a copy of the primary container label, and external packaging label if applicable, for assessment. The label must reflect the additional risk statements in English and French.			
Have you included a copy of the bilingual product label with your notification?		Yes	No
Section D – Product label requirements if using technical-grade ethanol with acetaldehyde level below 75ppm			
Note: Additional risk statements are not required on the product label when using technical-grade ethanol with acetaldehyde level below or equal to 75ppm. Please complete all fields in this section.			
Lot or batch number of technical-grade ethanol: (Note: This information is identified on the Certification of Analysis)		Acetaldehyde level (in parts per million): (Note: This information is identified on the Certification of Analysis)	
Important: If you are completing Section D, you must provide a copy of the Certificate of Analysis for the lot or batch of technical-grade ethanol identified.			
Have you included the Certificate of Analysis with your notification?		Yes	No
Does your product have:		Primary container only	Primary container and external package
Important: You must provide a copy of the primary container label, and outer packaging label if applicable, for assessment.			
Have you included a copy of the bilingual product label with your notification?		Yes	No
Section E – Complete the following field for product distribution information			
Specify the region and/or location to which the product supply is intended: Nationally Provincially / Territorially Regionally		Specify what distribution sector the product supply is intended for: Hospitals and/or clinics Commercial Retail Domestic or personal use	
Section F – Attestation and Signature			
I attest that the information provided on this form is true and that all requirements will be met prior to the product being made available to the Canadian market.			
Name (please print):		Title (e.g. Senior official):	
Signature:		Date:	