

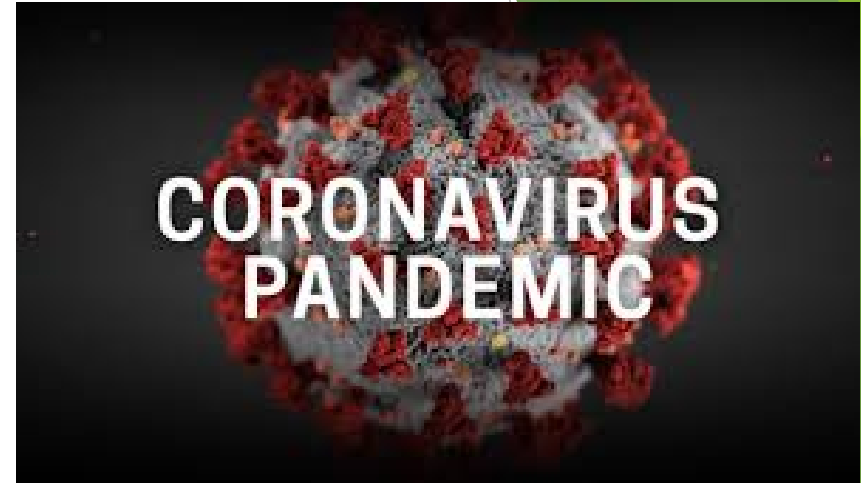


Regulations



# Hand Sanitizers, Hard Surface Sanitizers and related Health Canada Regulations

# COVID- 19



- ▶ The COVID-19 pandemic, also known as the coronavirus pandemic, is an ongoing pandemic of coronavirus disease 2019 (COVID-19) caused by the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- ▶ The outbreak was declared a Public Health Emergency of International Concern in January 2020, and a pandemic in March 2020

# Corona Virus safety

- . Wash your hands with soap at least 20 seconds
- . Alternatively, use an Alcohol-based **Hand Sanitizer**
- . Cover your nose and mouth
- . Disinfect surface around your home and work with **Hard surface sanitizer**
- . If you're sick, stay home.



# Hand Sanitizers, Alcohol base



## Licensing requirements

- ▶ **Alcohol-based hand sanitizers** are natural health products (NHPs) in **Canada** and are **regulated under** the Natural Health Products **Regulations** (NHPR).
  
- ▶ They contain these medicinal ingredients in USP grades:
  1. ethanol, also known as anhydrous alcohol, ethyl alcohol or grain alcohol
  2. isopropanol, also known as isopropyl alcohol or 2-propanol

# Hand Sanitizers, Alcohol base

## General

- ▶ All approved alcohol-based hand sanitizers must meet the necessary requirements under the NHPR.
- ▶ A site license (SL) is required to manufacture, package, label or import an NHP hand sanitizer in Canada. An SL is required to produce finished NHPs, but not to produce raw materials.
- ▶ A product license (PL) is represented by a **Natural Product Number (NPN)**. This number is required to legally distribute (for instance, donate or sell) the product.



Natural  
Product  
Number



# Hand Sanitizers, Alcohol base

## Ethanol



Ethanol used in the production of hand sanitizers should meet quality and purity standards

Health Canada has temporarily authorized the use of technical-grade ethanol in **hard-surface disinfectants** and **hand sanitizers**. This authorization is on a short-term, case-by-case basis and granted under specific conditions.

Ethanol that doesn't conform to USP standards (or to comparable standards and the acceptable deviations outlined in the interim guide Health Canada) or that isn't on the list of **approved suppliers of technical-grade** ethanol can't be used in the manufacturing of hand sanitizers products, to increase the supply of ethanol.

# Hand Sanitizers, Alcohol base



## Site Licensing and product licensing

- ▶ To facilitate the safe and efficient production of NHP hand sanitizers during the COVID-19 pandemic, Health Canada is simplifying and expediting the application and review processes for both Site Licenses and Product Licenses.
- ▶ Antiseptic Skin Cleansers (Personal Domestic Use) monograph, provides pre-cleared information on an ingredient or product, including permissible uses, and supports the licensing of certain NHPs. The monograph supports the safety and efficacy of alcohol-based hand sanitizers with a final concentration of 60-80% ethanol or 60-75% isopropanol.



# Hand Sanitizers, Alcohol base



**Table 1: NHP medicinal ingredients**

Proper Name <sup>1</sup>	Common Name <sup>1</sup>	Source Material <sup>1</sup>	Quantity <sup>2</sup>
		Common name(s)	
Ethyl alcohol	<ul style="list-style-type: none"> <li>• Alcohol</li> <li>• Anhydrous alcohol</li> <li>• Ethanol</li> <li>• Ethyl alcohol</li> <li>• Grain alcohol</li> </ul>	Ethanol	60-80%
2-propanol	<ul style="list-style-type: none"> <li>• Isopropanol</li> <li>• Isopropyl alcohol</li> </ul>	Isopropanol	60-75%

<sup>1</sup> At least one of the following references was consulted per proper name, common name, and source material: O'Neil et al. 2018; Nikitakis 2016; USP 41.

<sup>2</sup> At least one of the following references was consulted per dosage: Sweetman 2017; WHO 2010; WHO 2009; Zimmerman 1993.



# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Recommended formulations

- ▶ Formulation for a 10-litre preparation of 80% ethanol:
- ▶ Ethanol 96%: 8,333 l
- ▶ Hydrogen peroxide 3%: 417 ml
- ▶ Glycerol 98%: 145 ml
- ▶ Water: amount to make up the remainder of the 10 L

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

=

volume of starting  
ingredient  
required

# Hand Sanitizers, Alcohol base

## Record-keeping



Natural  
Product  
Number



- ▶ Records must be maintained on how the hand sanitizer is prepared, including how the final ethanol dilution in the finished product was obtained. The amount of ethanol needed in the formulation should be calculated using the following equation (set out in the USP guidance):
- ▶ The final percentage of alcohol times the final volume of preparation divided by the starting volume of alcohol equals the volume of starting ingredient required.

# Hand Sanitizers, Alcohol base

## Record-Keeping



- ▶ Licence holders are also responsible for ensuring the quality of their licensed natural health products (NHPs) before marketing these products. They must also declare that each lot of batch of finished product meets those specifications.
- ▶ All products must be manufactured, packaged, labelled and imported according to the requirements GMP practices of the regulations. This includes maintaining records that show compliance for a period of 1 year after the product's expiry date.
- ▶ If the product licence holder relies on another party to produce the NHP, the roles and responsibilities for the development, maintenance and storage of these records must be clearly defined.

# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Site Licensing and product licensing (Interim period)

This interim approach is in effect and will be in place until **March 31, 2021** or until a notice is issued by Health Canada to licence holders (whichever is earlier). During this period, the interim approach is also available to those companies currently holding valid Site and/or Product Licences that wish to contribute to the public health response to the COVID-19 pandemic

Applications that go beyond the parameters of the monograph (such as making additional claims) are not eligible for the expedited licencing process described herein. In these cases, the applicant will need to provide supporting evidence on safety, efficacy and quality in order to receive a Product Licencing.

# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## How to Know Which Application Form is Required

- ▶ If you do not currently manufacture, package and/or label alcohol-based hand sanitizers and you intend to manufacture and distribute such products, you must apply for both a Site Licence and a Product Licence.
- ▶ If you intend to only manufacture, package and/or label alcohol-based hand sanitizers on behalf of another company, you need to apply for a Site Licence only.
- ▶ If you intend to only distribute alcohol-based hand sanitizers made by another company, you need to apply for a Product Licence only.

# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## How to Know Which Application Form is Required

- ▶ If you already hold a Site Licence for manufacturing, packaging, and/or labelling NHPs and you intend to add an alcohol-based hand sanitizer to your product line, which you intend to distribute, you need to apply for a Product Licence only.

For all above scenarios, a cover letter indicating whether you are applying for a Product Licence, a Site Licence, or both is recommended. The cover letter will help Health Canada expedite the processing of applications



# Hand Sanitizers, Alcohol base

## Before applying for a Site Licence:

- ▶ 1. A Company Code is a number assigned to each applicant or company by Health Canada. If you do not have a Company Code issued by Health Canada, send an email [tohc.nnhpd-dpsnso.sc@canada.ca](mailto:tohc.nnhpd-dpsnso.sc@canada.ca), with the subject line “COVID-19 –Request for a Company Code”. In the body of the email, include the company information that you will be using to complete your Site Licence Application Form including company name, contact information, and Senior Official(e.g., Chief Executive Officer or Director).



Natural  
Product  
Number





# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Quality: Good Manufacturing Practices

For the purposes of this interim approach, any of the following GMP standards are considered acceptable. The standard to which you are attesting the site to comply will need to be selected in the cover letter

- ▶ Part 3 of the NHPR( the regulation sets up the GMP)
- ▶ Division 2 of the Food and Drug Regulations( follow up requirements of the division in fabricating, packaging and labeling)
- ▶ Guide to Food Safety(HASIB Reg), or
- ▶ Good Manufacturing Practices for Cosmetic Products

*\*\*Note: Health Canada encourages all cosmetic manufacturers to follow GMP, and endorses the use of the International Standards Organization(ISO) Guidelines on Good Manufacturing Practices for Cosmetics, ISO Standard 22716.*

# Hand Sanitizers, Alcohol base

## Good Manufacturing Practices

Given the *interim nature of the Site Licences* issued under the approach outlined here in, certain GMP requirements that are usually required for NHPs are *waived* during this period, specifically:

- ▶ Stability testing is not required
- ▶ A Quality Assurance Report or other forms of evidence required as part of the standard process is not required
- ▶ For products containing more than 50% alcohol, finished product testing for microbiological contaminants is not required.
- ▶ **Regardless of the GMP standard selected, appropriate controls must be in place to avoid contamination throughout the entire manufacturing and packaging process.**



Natural  
Product  
Number



# Hand Sanitizers, Alcohol base

## Site Licence

The completed cover letter template and Site Licence Application Form are to be submitted via the ePost conversation within the ePost Connect™ site

The Site Licence Application for alcohol-based hand sanitizers will be reviewed in an expedited manner, and Site Licences will be issued within 24 hours (depending on volume of submissions). A Site Licence issued as described herein will remain valid only while the interim approach is in effect.

**Following this period, if you wish to maintain a valid Site Licence to produce NHPs, the supporting evidence mentioned above (i.e. Quality Assurance Report, stability testing, finished product testing) will be required as per the NHPR, and the site will be required to meet the GMP standards outlined in Part 3 of the NHPR**



# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Applying for a Product Licence

Before applying for a Product Licence:

3. Complete the cover letter template and the Product Licence Application Form, and submit both via the ePost conversation within the ePost Connect™ site.

To complete the Product Licence Application Form, please follow the instructions:

(<https://nnhpd-pla-dlmm-dpsnso.hc-sc.gc.ca/pla-dlmm/en/landing>)

# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Applying for both Product Licence and site Licence

Companies Applying for BOTH a Product Licence and a Site Licence To facilitate timely access to safe NHP hand sanitizers during the period within which this **interim approach** is in effect, Health Canada is further simplifying the application process in cases where both a Site Licence and a Product Licence are required.

**If your company is seeking both a Product Licence and a Site Licence, you may apply by only completing the Product Licence Application Form accompanied by a cover letter.**

# Hand Sanitizers, Alcohol base



Natural  
Product  
Number



## Applying for both Product Licence and site Licence

The information contained in the cover letter will provide sufficient information to support the Site Licence Application, including:

- ▶ The relevant industry(i.e., the line of business the applicant is currently in, such as distillery, or cosmetics).
- ▶ The intent of the application (i.e., sanitizer product + COVID-19 Site Licence);
- ▶ The GMP standard that is being met.
- ▶ The activities to be performed (e.g. manufacturing, labelling, and/or packaging).
- ▶ The signature from a Senior Official.



# Hand Sanitizers, Alcohol base

## Labelling Requirements

As per the Food and Drugs Act, it is illegal to label, sell or advertise a product, including hand sanitizers, in a false, misleading or deceptive manner. Labelling must be compliant with the product licence; in this case, the claims made must be consistent (verbatim) with what is provided in the Antiseptic Skin Cleansers monograph. **Authorization under this monograph does not permit any specific references to “COVID-19”, “SARS-CoV-2” or “coronavirus”.**

**Product Licence holders are responsible for ensuring that the label complies with the labelling requirements set out in NHPR, if applicable.**

**You are not allowed to sell an NHP unless it is packaged and labelled in accordance with the NHPR**



Natural  
Product  
Number





# Hand Sanitizers, Alcohol base

## Labelling Requirements

A checklist is provided that itemizes the elements required on the label and their location(if specified)

**Label information must be presented in both official languages (i.e., French and English) under the NHPR. However, given the urgent need for these products, Health Canada is allowing certain flexibilities for imported products, including waiving the requirement for bilingual labelling. Similarly, as part of this interim approach, this flexibility has been provided to domestic products, though the use of bilingual labels remains strongly encouraged, particularly for distribution in bilingual regions.**



Natural  
Product  
Number



# Hand Sanitizers, Alcohol base

## Labelling checklist



Natural  
Product  
Number



<b>Elements that must appear on the Principal Display Panel:</b>	
• Primary Brand Name	
• Product Number (NPN, issued upon approval of your product)	
• Dosage Form	
• Net amount in the container in terms of weight or measure	
<b>Elements that must appear on any panel:</b>	
• Name and address of the product licence holder	
• Name of each Medicinal Ingredient	
• Quantity of the Medicinal Ingredient per Dosage Unit (i.e. %)	
• Recommended Use or Purpose	
• Recommended Route of Administration – topical (if not self-evident)	
• Recommended Dose (including subpopulation amount, frequency, and directions of use, if any)	
• Risk Information	
• List of all Non-Medicinal Ingredients	
• Recommended Storage Conditions (if any)	
• Lot number	
• Expiry date	
• Storage Conditions (if outside normal conditions)	
<b>Other</b>	
• Cautionary statements (e.g., flammability, poison warning, etc.)	
• All information must be clearly and predominantly displayed and readily discernible to the consumer	

# Hand Sanitizers, Alcohol base

## Adverse Reaction Reporting



Natural  
Product  
Number



As with any health product, an adverse reaction may occur with the use of alcohol-based hand sanitizers. **Product Licence holders are required to report serious adverse reactions that occur in Canada as well as serious adverse reactions that occur internationally.** You must report any adverse reactions to Health Canada within 15 days of receiving the information or risk potential compliance and enforcement actions.

This mandatory reporting is done through Health Canada's ***Canada Vigilance Program***

# Hand Sanitizers , Alcohol base



Natural  
Product  
Number



## Hand-Sanitizers Manufacturing Exchange(Interim)

- ▶ To help expand production, Health Canada has facilitated a dialogue between the hand sanitizer industry and other industries that are able to provide ingredients and materials. As a result, Cosmetics Alliance Canada (CAC), Spirits Canada/Association of Canadian Distillers (ACS) and the Canadian Consumer Specialty Products Association (CCSPA) have created the [Hand-Sanitizers Manufacturing Exchange](#). Through this exchange, manufacturing capacity will be matched with suppliers of raw materials.

# Hand Sanitizers , Alcohol base



Natural  
Product  
Number



## Compounding information for pharmacists( Interim)

- ▶ During the COVID-19 pandemic, licensed pharmacists are allowed to compound and sell hand sanitizers in their province or territory of practice. It has been recommend pharmacists follow a reputable formula, such as the one published by the **World Health Organization**.
- ▶ Should a pharmacist wish to distribute their product for resale by a third party, they would be required to obtain a valid site and product licence through the process **we discussed**.
- ▶ For more information, please contact by email:  
**[hc.nnhpddpsnso.sc@canada.ca](mailto:hc.nnhpddpsnso.sc@canada.ca)**.

# Hand Sanitizers , Alcohol base



Natural  
Product  
Number



## Packaging of hand sanitizers(Interim)

- ▶ Any food or pharmaceutical grade packaging can be used to package hand sanitizers (for instance, bottles or bags/pouches for use in dispensers), provided that it is chemically resistant to the hand sanitizer.
- ▶ Although hand sanitizers are generally packed in clear (see-through) containers, appropriately graded packaging that is opaque (for example, white, colored) can also be used.



# Hand Sanitizers, Non-Alcohol base



## Antiseptic skin cleansers

are classified as non-prescription drugs necessary to receive market authorization a Drug Identification Number (DIN) and if they contain at least one ingredient from following monograph table at a quantity listed.

Applicants applying for a DIN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html>.

Manufacturing site should apply for DEL (**drug establishment licence**)



# Hand Sanitizers, Non-Alcohol base



Health  
Canada

Santé  
Canada

**Table 2: Non-prescription drug medicinal ingredients**

Proper Name	Common Name	Source Material	Quantity
		Common name(s)	
<ul style="list-style-type: none"> <li>Alkyldimethyl(phenylmethyl)ammonium chloride</li> <li>Ammonium, alkyldimethyl(phenylmethyl)-, chloride</li> </ul>	Benzalkonium chloride	Benzalkonium chloride	0.1 - 0.15%
<ul style="list-style-type: none"> <li>Benzyldimethyl[2-[2-(p-1,1,3,3-tetramethylbutylphenoxy)ethoxy]ethyl]ammonium chloride</li> <li>N,N-Dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]benzenemethanaminium chloride</li> </ul>	Benzethonium chloride	Benzethonium chloride	0.05 - 0.5%
<ul style="list-style-type: none"> <li>1,1'-Hexamethylenebis [5-(p-chlorophenyl)biguanide] di-D-gluconate</li> <li>N,N''-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide di-D-gluconate</li> </ul>	<ul style="list-style-type: none"> <li>Chlorhexidine digluconate</li> <li>Chlorhexidine gluconate</li> </ul>	<ul style="list-style-type: none"> <li>Chlorhexidine digluconate</li> <li>Chlorhexidine gluconate</li> </ul>	2 - 4%
<ul style="list-style-type: none"> <li>4-Chloro-3,5-dimethylphenol</li> <li>4-Chloro-3,5-xylenol</li> </ul>	Chloroxylenol	Chloroxylenol	0.5 - 3%
<ul style="list-style-type: none"> <li>2,4,4'-Trichloro-2'-hydroxydiphenyl ether</li> <li>5-Chloro-2-(2,4-dichlorophenoxy)phenol</li> </ul>	Triclosan	Triclosan	0.1 - 1%

**DIN REGISTERED  
DISINFECTANT**

# Hand Sanitizers, Non-Alcohol base

**DIN REGISTERED  
DISINFECTANT**

## ► Labelling

Must be met requirements described in the Regulations to the Food and Drugs Act.

<b>Drug Facts</b>	
<b>Active ingredient (v/v)</b>	<b>Purpose</b>
Benzalkonium chloride XX %.....	Antiseptic skin cleanser
<b>Uses</b> • Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Kills harmful bacteria/germs • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria	
<b>Warnings</b> For external use only When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if irritation develops. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
<b>Directions</b> Adults and children over 2 years: • For occasional and personal domestic use • Supervise children when they use this product [For hand sanitizers] • Rub thoroughly into hands for at least 30 seconds. Allow to dry. [For hand washes] • Lather in hands with water for at least 30 seconds. Rinse well.	
<b>Other information</b> [If no information here, delete this section]	
<b>Inactive ingredients</b> List all NMIs	
<b>Questions?</b> 1-XXX-XXX-XXXX (or other contact information)	

# Hand Sanitizers, Import



Natural  
Product  
Number



## Expedited access for importers(Interim)

- ▶ The expedited access measure allows importers to supply sanitizers or disinfectants that:
- ▶ do not fully meet Health Canada requirements **or**
- ▶ are authorized or registered in other jurisdictions where the regulatory frameworks and quality assurances are similar
- ▶ Under this measure, importers must:
- ▶ notify Health Canada prior to importing

# Hand Sanitizers, Import



Natural  
Product  
Number



## Expedited access for importers(Interim)

- ▶ keep records in the event of a product recall
- ▶ Contact Health Canada by email at [hc.covid19healthproducts-produitsdesante.sc@canada.ca](mailto:hc.covid19healthproducts-produitsdesante.sc@canada.ca) for an attestation form.
- ▶ This attestation form helps HC work with the Canada Border Services Agency to facilitate importation. The information provided helps authorities take necessary action if the product is considered to pose a health risk.

# Hand Sanitizers

# RECALL



## Recall of Hand Sanitizer

Health Canada can recall hand sanitizers that may pose health risks or do not meet Health Canada requirements. Recently certain lots of hand sanitizers are being recalled from the market . Some of the issues were:

- ▶ containing (or possibly containing) ingredients that are not permitted by Health Canada;
- ▶ improper labelling;
- ▶ missing risk statements;
- ▶ being unauthorized for sale in Canada;
- ▶ being sold without proper product testing;
- ▶ being counterfeit; or
- ▶ having defective or faulty packaging.

# Hard surface Sanitizers



## Introduction

Most chemical products represented for use in Canada as disinfectants on environmental surfaces and inanimate objects, or represented for use to reprocess non-critical medical devices are regulated as drugs under the *Food and Drugs Act*, due to either

- ▶ their uses in mitigating, or
- ▶ preventing the transmission of human or animal disease, or
- ▶ due to their uses in premises where food is manufactured, prepared or kept.



# Hard surface Sanitizers



## Introduction

The Natural and Non-prescription Health Products Directorate is the regulatory body within Health Canada that assesses applications for products that are represented for use as:

- ▶ disinfectants for use on non-critical medical devices and hard non-porous environmental
- ▶ surfaces and inanimate objects in domestic, industrial/institutional, hospital, food
- ▶ processing and/or barn premises, referred to as “hard surface disinfectants”, and that
- ▶ additionally may indicate hard non-porous food and non-food contact surface sanitizer
- ▶ claims on their labelling, in which case they are referred to as “disinfectant-sanitizers

# Hard surface Sanitizers



## Hard Surface Disinfectants Monograph

- ▶ This monograph identifies the permitted active ingredients, minimum in-use concentrations, target microorganism classes, contact times, and associated use areas for these products to be licensed without the submission of additional evidence to Health Canada.
- ▶ Products which do not meet the criteria outlined in this monograph should apply for market authorization outside of the monograph stream.

# Hard surface Sanitizers



## Hard Surface Disinfectants Monograph

- ▶ Applicants are not required to submit efficacy data through the monograph process.
- ▶ **Active Ingredient(s)**
- ▶ A list of permitted active ingredients with minimum in-use concentrations, expressed as parts-per-million (ppm), is provided in Table 1. This list is applicable for all hard surface disinfectants, including toilet bowl disinfectants and disinfectant-sanitizers.

# Hard surface Sanitizers



## Permitted Active Ingredients, Minimum In-Use Concentrations, Target Classes of Microorganisms, Contact Times and Use Areas for All Hard Surface Disinfectants

Category	Preferred name	Synonym	Minimum In-Use Concentration	Target Microorganism Classes	Contact Time for Disinfection and Sanitization	Use Areas <sup>1</sup>
<b>Quaternary ammonium compound</b>	Alkyl dimethyl ethyl benzyl ammonium chloride		≥450 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	<ul style="list-style-type: none"> <li>• Domestic</li> <li>• Commercial</li> </ul>
	Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride				
	Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride				
	Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride				
	Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium				
	Dioctyl dimethyl	Chloride dioctyl dimethylammonium				

	ammonium chloride					
	Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethyl benzyl ammonium				
	Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium				
	Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium				
	Octyl decyl dimethyl ammonium chloride	Chloride octyl decyl dimethyl ammonium				
	Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium				
<b>Phenolic</b>	Chloro-ortho-phenylphenol	Chloro-2-phenylphenol	≥700 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	<ul style="list-style-type: none"> <li>• Domestic</li> <li>• Commercial</li> </ul>
	Chlorophenol					
	Clorophene	o-benzyl-p-chlorophenol				
	o-phenylphenol	orthoxenol				
	p-phenylphenol	paraxenol				
	p-tert-pentylphenol	p-tert-amylphenol				
<b>Iodophor</b>	Nonylphenoxy polyethoxyethanol iodine complex	Nonoxynol iodophor	≥ 30 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	<ul style="list-style-type: none"> <li>• Domestic</li> <li>• Commercial</li> </ul>
	Polyethoxy polypropoxy polyethoxy ethanol iodine complex	a-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) iodine complex Iodine polyethoxy polypropoxy polyethoxy ethanol				
<b>Chlorine releasing compound</b>	Calcium hypochlorite		≥100 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	<ul style="list-style-type: none"> <li>• Domestic</li> <li>• Commercial</li> </ul>
	Sodium hypochlorite					
<b>Organic acid</b>	Citric acid	2-Hydroxy-1,2,3-Propanetricarboxylic Acid	≥ 25,000 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	5 minutes	• Domestic
			≥ 45,000 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	• Commercial
<b>Peroxygen</b>	Hydrogen peroxide	Hydrogen dioxide	≥ 5,000 ppm	<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	5 minutes	• Domestic
				<ul style="list-style-type: none"> <li>• BACTERIA</li> <li>• VIRUS</li> <li>• FUNGI</li> </ul>	10 minutes	• Commercial

# Hard surface Sanitizers



## Hard Surface Disinfectants Labelling

### 1. Use(s) or Purpose(s):

The intended drug use areas (i.e., premises for disinfection) for which the product is recommended.

### 2. The use or purpose for which the product is recommended, including one or more of the following:

#### ► *Required:*

Disinfectant

#### ► *Optional, as supported in Table*

Kills bacteria / Bactericide / Bactericidal

Cleaner

Sanitizer



# Hard surface Sanitizers



## Hard Surface Disinfectants Labelling

### 3. Directions for Use

The directions for use should be consistent with the labelling recommendations provided within the guidance documents *Disinfectant Drugs* and *Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs*.

► ***For all products, the following should be indicated:***

- a. The types of hard surfaces to which the product may be applied (e.g., floors, walls, countertops);
- b. For dilutable products, specific instructions for the preparation of the in-use dilution, in metric units of measurement milliliters per liter) or ratios (e.g., 1:256)
- c. The mode of application for the product (e.g., spray, wipe, apply with a cloth or sponge);
- d. A pre-cleaning statement for heavily soiled hard surfaces; a statement to the effect of one of the following is recommended: • For heavily soiled surface, a pre-cleaning step is required; or Pre-clean heavily soiled areas.
- e. A contact time is required for all disinfection uses : *Allow surface to remain wet for (X) minutes*

# Hard surface Sanitizers

## Hard Surface Disinfectants Labelling



### 3. Directions for Use

It is recommended that a statement to the effect of the following be indicated on the labelling to remove potentially toxic residues:

- a) For hard surfaces and/or objects that may come into direct contact with children at the mouthing stage of development;

*A rinse with potable water is recommended*

- b) For food processing; *Avoid contamination of food during application and storage or; Rinse surface prior to use*

- c) For products for use in animal housing areas;

*Empty all feeding and watering appliances prior to disinfection*

- d) For all products, the following directions for use should also be indicated on the labelling;

Warning statement : *Read the label before using or Keep out of reach of children*

# Hard surface Sanitizers

## Hard Surface Disinfectants Labelling



e) Precautionary statements:

Signal words and hazard statements

Personal protective equipment statements

First aid statements

f) Physical and chemical hazards statements

- ▶ Storage instructions
- ▶ Disposal instructions

# Hard surface Sanitizers



## Hard Surface Disinfectants Labelling

***For all products, the following regulatory information must be indicated on the labelling:***

- a) The name and address of the manufacturer of the product, including a toll-free phone number and website for consumers to be able to report complaints and provide feedback. If the address of the manufacturer is not in Canada, then the name and address of the importer must be indicated on the label.
- b) The identity and percent nominal concentration of each active ingredient in the product, expressed as a percentage on a weight-per-weight basis (% w/w).
- c) The net contents of the product in its marketed packaging.
- d) A placeholder for the lot number.
- e) A placeholder for the expiration date for all commercial products.
- f) A placeholder for the drug identification number (DIN).

# Hard surface Sanitizers



## Hard Surface Disinfectants Labeling

- ▶ **Non-Medicinal Ingredients**
- ▶ Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database. For additions or modifications to the NHPID, an NHPID Issue Form should be completed and submitted to Health Canada in advance of an application for a disinfectant drug.
- ▶ **Note:** The presence of non-medicinal ingredients should not adversely affect the efficacy or safety of the active ingredient(s).

# Hard surface Sanitizers



## Hard Surface Disinfectants Labelling

### Specifications

Fabricators, packagers/labellers, distributors, importers and testers of disinfectants which meet the regulatory definition of an “antimicrobial agent” are not required to obtain an establishment licence or meet Good Manufacturing Practices (GMP) compliance requirements; however, they are still expected to meet the provisions of section 8 of the *Food and Drugs Act*, which denotes the prohibition on selling drugs manufactured under unsanitary conditions or that are adulterated.

To support compliance with this regulatory requirement, a voluntary standard was developed by Health Canada: *Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices*, Version 2 (Guide-0049).



# Hard surface Sanitizers



## Hard Surface Disinfectants Label sample

**Fast Effective Antibacterial Formula Disinfects, Sanitizes, Cleans, and Deodorizes in One Step. Streak-Free Hard Surface Disinfectant Cleaner with Hydrogen Peroxide.** Use to clean and disinfect non-porous hard surfaces such as concrete floors, stainless steel, glass, rubber, and chrome. Do not use on marble, unfinished wood or vinyl that is not waxed or sealed. For surfaces not listed, test on a small area before using.

**Directions:** Spray and wipe. Shake well before each use. Remove all solid waste and pre-clean heavily soiled areas before applying. Allow surface to remain wet for 10 minutes for commercial and 5 minutes for domestic areas.

**Caution:** KEEP OUT OF REACH OF CHILDREN. Trigger sprayer has many small parts that can be a choking hazard. IRRITANT. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Wear eye protection and protective gloves when handling. Wash thoroughly with soap and water after handling. Do not mix with toilet bowl cleaners, acids or products containing ammonia. For hard surfaces and/or objects that may come into direct contact with children at the mouthing stage of development, it is recommended that you rinse the area with potable water. Avoid contact with food.

**First Aid Treatment:** If swallowed, call a poison control centre or doctor immediately. Do not induce vomiting. If in eyes, remove contact lenses if present and easy to do, and rinse eyes with water for at least 15 minutes. If on skin, rinse well with water. If inhaled and breathing becomes difficult, get fresh air. Seek medical attention if symptoms persist. Take the container label or product name and Drug Identification Number (DIN) with you when seeking medical attention. For information on the disposal of unused or unwanted products, contact the manufacturer or the appropriate municipal/provincial/territorial agency or product stewardship organization.

**Active ingredient (w/w)** Hydrogen Peroxide 0.6% **Inactive ingredients** Water, Polysorbate 20, Fragrance, Coco-Betaine, Caprylyl/Capryl Glucoside, Citric acid.

Store tightly in cool dry place (15-30C)  
Rinse the empty container thoroughly prior to disposal.

**Manufactured by Trade Management**  
631 Rivermede Road Concord,  
ON, L4K 2G8 | [www.doverhunt.com](http://www.doverhunt.com)

Questions? Comments? 1-888-760-2291

Made in Canada WARNING: IRRITANT



**Formule désinfectante antibactérienne rapide et efficace, nettoye et désodorise en une étape. Nettoyant désinfectant sans trace avec peroxyde d'hydrogène pour les surfaces dures.**

Utilisez pour nettoyer et désinfecter toutes surfaces dures non poreuses e.x. les planchers en béton, l'acier inoxydable, le verre, le caoutchouc et le chrome. Ne pas utiliser sur le marbre, le bois brut ou le vinyle non-ciré ni scellés. Pour toutes surfaces non indiquées, testez sur une partie avant d'utiliser.

**Directions :** Vaporisez et essuyez. Agitez bien avant chaque utilisation. Enlevez les déchets solides et nettoyez toutes surfaces souillées avant d'utiliser. Laissez la surface mouillée pendant 10 minutes pour les lieux commerciaux et 5 minutes pour les lieux domestiques.

**Mises en garde :** TENIR HORS DE LA PORTÉE DES ENFANTS. Le vaporisateur à gâchette se consiste de plusieurs petits pièces. IRRITANT. Peut irriter les yeux/la peau. Évitez tout contact avec les yeux, la peau ou les vêtements. Portez des lunettes protectrices et des gants. Lavez-les bien avec de l'eau et du savon après avoir maniés. Ne pas mélanger avec des nettoyeurs pour cuvette, des acides ni avec des produits qui contiennent de l'ammoniac. Il est recommandé de rincer avec de l'eau potable toutes surfaces dures et/ou les objets qui viennent en contact avec des enfants au niveau de développement buccal. Évitez tout contact avec la nourriture.

**Premiers Soins:** En cas d'ingestion, appelez le centre antipoison ou votre médecin immédiatement. Ne pas faire vomir. En cas de contact avec les yeux, rincez-les avec de l'eau pendant 15 minutes. En cas de contact avec la peau, bien rincez avec de l'eau. Au cas où le produit est inspiré et vous avez du mal à respirer, sortez dehors pour de l'air fraîche. Obtenir des soins médicaux si les symptômes durent. Apportez l'étiquette du contenant ou notez le nom du produit et le DIN (Numéro d'identification d'un médicament) lorsque vous cherchez de l'aide médicale.

Pour obtenir l'information concernant les produits qui n'ont pas été utilisés ou inutilisés, veuillez contacter le fabricant, l'agence territoriale/provincial/municipal ou l'organisation de la gestion des produits.

**Ingredient actif (p/p)** peroxyde d'hydrogène 0,6%

**Ingédients inactifs** Eau, Poly(sorbate) 20, Parfum, Cocobétaine, Glucoside de caprylyl/capryl, Acide citrique.

Conservez bien fermé dans un endroit sec et frais (15-30°C). Bien rincez le contenant vide avant de jeter.

Fabriqué par Trade Management | [www.doverhunt.com](http://www.doverhunt.com)  
631 Rivermede Road, Concord, ON, L4K 2G8

Questions ou commentaires? 1-888-760-2291

ATTENTION: IRRITANT

Fabriqué au Canada

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light lime to dark forest green. These shapes are primarily located on the right side of the slide, creating a modern, layered effect.

# Thank you

Shahin Kalantari

[shahink@davicenna.com](mailto:shahink@davicenna.com)