

**HAND SANITIZER- alcohol solution**  
**Guardian Chemicals Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**hand sanitizer 10L and 1000L package size**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

205000 mL NDC: 76787-001-05



A DIVISION OF GUARDIAN CHEMICALS INC  
155-55202 SH 825 STURGEON INDUSTRIAL PARK  
STURGEON COUNTY, ALBERTA, CANADA, T8L 5C1  
PHONE: TOLL FREE (800) 661-6544

## Alcohol Antiseptic 80% Topical Solution

### Hand Sanitizer Non-Sterile Solution

[ 205,000 mL ]

GTIN: [REDACTED]

Lot Number: [REDACTED]  
Net Contents: 205 L  
NDC: 76787-001-05

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80%w/v	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b>	
<ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

Read the Safety Data Sheet for further information.  
FOR EMERGENCY SPILL INFORMATION, CALL CANUTEC AT 1-613-996-6666  
TO REORDER: CALL TOLL FREE 1-800-661-6544. READ THE LABEL BEFORE USING.

In accordance with TDG  
UN1170 ETHANOL SOLUTION  
3- Flammable liquids, PG II

20000 mL NDC: 76787-001-04



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# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer  
Non-Sterile Solution

[ 20,000 mL ]

GTIN: [REDACTED]

Lot Number: [REDACTED]  
 Net Contents: 20 L  
 NDC: 76787-001-04

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80%v/v	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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In accordance with TDG  
 UN1170 ETHANOL SOLUTION  
 3- Flammable liquids, PG II

10000 mL NDC: 76787-001-03



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 ALBERTA, CANADA, T8L 5C1  
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# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer  
Non-Sterile Solution

[10,000mL]

Lot Number: [REDACTED]  
 Net Contents: 10 LITERS  
 NDC: 76787-001-03  
 GTIN: [REDACTED]

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80%v/v	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
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<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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In accordance with TDG  
 UN1170 ETHANOL SOLUTION  
 3- Flammable liquids, PG II

100000 mL NDC: 76787-001-06



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# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer  
Non-Sterile Solution

[ 1,000,000 mL ]

GTIN: [REDACTED]

Lot Number: [REDACTED]  
 Net Contents: 1000 L  
 NDC: 76787-001-06

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80%v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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Directions	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
Other information	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	

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In accordance with TDG  
 UN1170 ETHANOL SOLUTION  
 3- Flammable liquids, PG II

## HAND SANITIZER

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76787-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76787-001-03	10000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

2	NDC:76787-001-06	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76787-001-04	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76787-001-05	205000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Guardian Chemicals Inc. (254092356)

**Registrant** - Guardian Chemicals Inc. (254092356)

## Establishment

Name	Address	ID/FEI	Business Operations
Guardian Chemicals Inc.		254092356	manufacture(76787-001)

Revised: 5/2020

Guardian Chemicals Inc.