

**HAND SANITIZER- isopropyl 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.*

-----

**hand sanitizer IPA 1000L, 205L, 20L, 10L**

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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% 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.

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.

**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**

1000000 ml NDC: 76787-002-06



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

**Isopropyl Alcohol  
Antiseptic  
75% Topical Solution**  
**Hand Sanitizer  
Non-Sterile Solution  
1,000,000 mL**



Lot Number: [redacted]  
Net Contents: 1000 L  
NDC: 76787-002-06

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl Alcohol 75%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	
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 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>	
• 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.	
<b>Other information</b>	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
<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.

UN1993 Flammable Liquids n.o.s. (isopropanol)  
Class 3 - Flammable Liquids  
Packing Group II  
Flashpoint 66F TCC

205000 ml NDC: 76787-002-05



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

# Isopropyl Alcohol Antiseptic 75% Topical Solution

Hand Sanitizer  
 Non-Sterile Solution  
 205,000 mL



Lot Number:   
 Net Contents: 205 L  
 NDC: 76787-002-05

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl Alcohol 75%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>	
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 1-613-996-8666  
 TO REORDER: CALL TOLL FREE 1-800-661-6544. READ THE LABEL BEFORE USING.

UN1993 Flammable Liquids n.o.s. (isopropanol)  
 Class 3 - Flammable Liquids  
 Packing Group II  
 Flashpoint 66F TCC

20000 ml NDC: 76787-002-04



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

# Isopropyl Alcohol Antiseptic 75% Topical Solution

Hand Sanitizer  
 Non-Sterile Solution  
 20,000 mL



Lot Number:   
 Net Contents: 20 L  
 NDC: 76787-002-04

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl Alcohol 75%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>	
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 1-613-996-8666  
 TO REORDER: CALL TOLL FREE 1-800-661-6544. READ THE LABEL BEFORE USING.

UN1993 Flammable Liquids n.o.s. (isopropanol)  
 Class 3 - Flammable Liquids  
 Packing Group II  
 Flashpoint 66F TCC

10000 ml NDC: 76787-002-03



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

# Isopropyl Alcohol Antiseptic 75% Topical Solution

Hand Sanitizer  
 Non-Sterile Solution  
 [10,000mL]



Lot Number:  
 Net Contents: 10 Litre  
 NDC: 76787-002-03

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl Alcohol 75%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>	
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 1-613-956-6666  
 TO REORDER: CALL TOLL FREE 1-800-661-6544. READ THE LABEL BEFORE USING.

UN1993 Flammable Liquids n.o.s. (isopropanol)  
 Class 3 - Flammable Liquids  
 Packing Group II  
 Flashpoint 66F TCC

## HAND SANITIZER

isopropyl alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76787-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76787-002			

1	NDC:76787-002-03	10000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76787-002-04	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76787-002-05	205000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76787-002-06	1000000 mL in 1 CONTAINER; 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(76787-002)

Revised: 5/2020

Guardian Chemicals Inc.