

**GUARDEX HAND SANITIZER ANTISEPTIC SOLUTION- isopropyl alcohol 75% liquid
Guardex Labs, 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.

Guardex Hand Sanitizer Antiseptic Topical Solution

Active Ingredient

Isopropyl Alcohol 75%

Purpose

Antiseptic

Uses

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

On 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.

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, Triethanolamine, carbomer, purified water USP

Guardex Hand Sanitizer Antiseptic Topical Solution

GUARDEX
Clean Hands Start Here.

Drug Facts
Active ingredient(s): Isopropyl Alcohol 75%
Purpose: Antiseptic

Warnings
Hand sanitizer is for external use only. Flammable. Keep away from heat or flame.
Do not use:
• on children less than 2 months of age
• on open skin wounds

Directions
Wash thoroughly with soap and water before use, and after. In case of contact with eyes, rinse eyes thoroughly with water. Rinse mouth out with a stream of water if inhaled or used on face. Rinse out the edges of a contact lens. If swallowed, get medical help or contact a Poison Control Center right away.

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

Other Information
• Store between 30°-40°C (86°-104°F)
• Avoid freezing and excessive heat above 40°C (104°F)

Contains/Ingredients
glycerin, hydrogen peroxide, triethanolamine, carbomer, purified water USP

For more information please visit www.guardexlabs.com

GUARDEX LABS
MADE IN USA

GUARDEX
Isopropyl Alcohol 75%
HAND SANITIZER
Antiseptic Topical Solution
Non-Sterile • 4oz

MADE IN USA **PREMIUM QUALITY**

GUARDEX
Isopropyl Alcohol 75%
HAND SANITIZER
Antiseptic Topical Solution
Non-Sterile • 250mL

MADE IN USA **PREMIUM QUALITY**

020-288-1024-0028



Clean Hands Start Here.

Drug Facts

Active Ingredient(s) **Proprietary Antiseptic**
Isopropyl Alcohol 70%

Uses:
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:
• on 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.

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°-40°C (59°-104°F)
• Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients:
glycerin, hydrogen peroxide, 1,1-dihydro-6-hydroxy-3,3-dimethyl-2-pyrone USP

For more information please visit
www.guardexlabs.com



1-800-368-1414



Isopropyl Alcohol 75%

HAND SANITIZER

Antiseptic Topical Solution

Non-Sterile • 500mL



Clean Hands Start Here.

Drug Facts

Active Ingredient(s) **Proprietary Antiseptic**
Isopropyl Alcohol 70%

Uses:
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:
• on 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.

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°-40°C (59°-104°F)
• Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients:
glycerin, hydrogen peroxide, methanolamine, carbomer, purified water USP

For more information please visit
www.guardexlabs.com



019-8904-1000-00020



Isopropyl Alcohol 75%

HAND SANITIZER

Antiseptic Topical Solution



Non-Sterile • 1000 mL

isopropyl alcohol 75% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80307-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	187.5 mL in 250 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE TRISTEARATE (UNII: HOM72YRP1F)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
(3-BROMOPROPYL)BENZENE (UNII: 6 VX623QN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80307-002-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
2	NDC:80307-002-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
3	NDC:80307-002-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
4	NDC:80307-002-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - Guardex Labs, Inc. (117630183)

Registrant - Guardex Labs, Inc. (117630183)