

HAND SANITIZER- isopropyl alcohol aerosol, spray

Gentell

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.

Spray Hand Sanitizer

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

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

Warnings

Do not use if you are allergic to any ingredients. For external use only. Flammable. Keep away from heat or flame

Do not use

in children less than 2 months of age or 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

Gentell We make it better

Spray Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Non-Sterile Solution

2 oz 68 mL

GEN-41020

Gentell

2701 Bartram Road

Bristol, PA 19007

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www.gentell.com

Rev. April 2020

 **Gentell®**
We make it better

Spray
Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution • Non-Sterile Solution



2 oz • 68 ml

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Drug Facts

Active Ingredient	Purpose
Isopropyl Alcohol 75% v/v	Antiseptic

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

Warnings: Do not use if you are allergic to any ingredients. For external use only. Flammable. Keep away from heat or flame. Do not use in children less than 2 months of age or 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 below 110°F (43°C). May discolor certain fabrics or surfaces.

Inactive Ingredients: Glycerin, Hydrogen Peroxide, Purified Water

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HAND SANITIZER

isopropyl alcohol aerosol, spray

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:6 1554-410
Route of Administration		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: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 1554-410-02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/08/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/08/2020	

Labeler - Gentell (170967876)

Establishment			
Name	Address	ID/FEI	Business Operations
Gentell, Inc.		170967876	manufacture(6 1554-410)