

HAND SANITIZER- isopropyl alcohol solution

Griffin Chemical company llc

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.

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.

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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

Drug Facts	
Active Ingredients: Isopropyl Alcohol 75% w/v.....	Purpose: Antiseptic
Uses: • For hand washing to decrease bacteria on skin. • Recommended for repeated use.	
Warnings: • Flammable. Keep away from fire or flame. • For external use only. • Do not use in eyes. If contact occurs, flush thoroughly with water. • Stop use and ask a doctor if redness and irritation develop and persist for more than 72 hours. • Keep out of reach of children if swallowed, get medical help or contact the Poison Control Center right away.	
Directions: • Apply a palmful of alcohol based handrub and cover all surfaces of hands. Rub hands until dry.	
Other information: • Store at room temperature 20°- 25°C (66 - 77°F) • May discolor certain fabrics.	
Inactive Ingredients: Water, Glycerin, Hydrogen Peroxide.	

Effective at eliminating more than 99.99% of many common harmful germs in as little as 15 seconds.

Manufactured in USA by Griffin Chemical Co., LLC
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CLEAN HANDS™

Hand Sanitizer

WHO Recommended Formula

Kills 99.99% of Germs

16 fl. oz. (500ml)

HAND SANITIZER

isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73881-334
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:73881-334-00	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73881-334-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:73881-334-02	3785 mL in 1 BOTTLE; 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 - Griffin Chemical company llc (602426046)

Establishment

Name	Address	ID/FEI	Business Operations
Griffin Chemical Company llc		602426046	manufacture(73881-334)

Revised: 4/2020

Griffin Chemical company llc