

SHIELD HAND SANITIZER- isopropyl alcohol liquid
Guangzhou Cluster Mapping Supply Chain Co., Ltd

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

60ml NDC: 77095-310-11

Kills more than 99.99% of most common germs that may cause illness

Drug Facts

Active ingredient Purpoc

Ethyl alcohol 75% w/vAntimicrobial

Use • Hand sanitizer to help reduce bacteria or viruses

Warnings

Flammable. Keep away from fire or flame.

For external use only

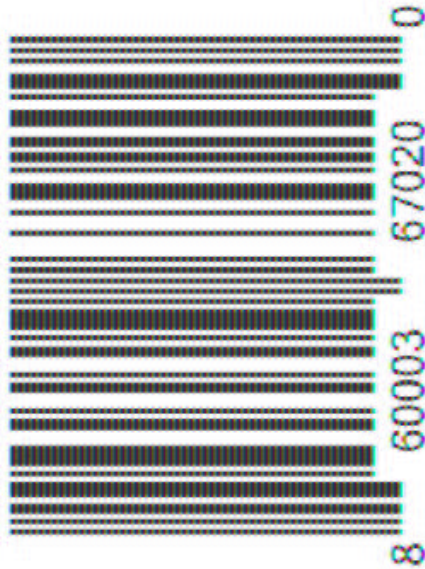
When using this product do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts more than 3 days.

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

Directions

• Put enough product in your palm to cover hand surfaces. Rub hands together briskly until dry.



- Children under 6 years of age should be supervised when using S

Other information

- Store below 110°F (43°C)
- May discolor certain fabrics or

Inactive ingredients

ETHYL ALCOHOL, WATER(AQUA), GLYCERIN, CARBOMER, TRIETHANOLAMINE, TOCOPHERYL ACETATE, ALOE BARBADENSIS LEAF EXTRACT, FRAGRANCE(PARFUM)

Manufactured by: U.S. Federal Pharmaceutical Firm, Inc. Da
 Questions? Tel: 1-617-800-DM+A WWW.USAV.AI
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SHIELD HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90010-310
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:90010-310-02	44160 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	
2	NDC:90010-310-08	9720 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	
3	NDC:90010-310-12	15060 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	
4	NDC:90010-310-10	12 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/31/2020	

Labeler - Guangzhou Cluster Mapping Supply Chain Co., Ltd (554544021)**Establishment**

Name	Address	ID/FEI	Business Operations
Guangzhou Cluster Mapping Supply Chain Co., Ltd		554544021	manufacture(90010-310)

Revised: 7/2020

Guangzhou Cluster Mapping Supply Chain Co., Ltd