

SHIELD HAND SANITIZER- alcohol gel
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. ethyl 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)

Ethyl Alcohol 75% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial

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.

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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.

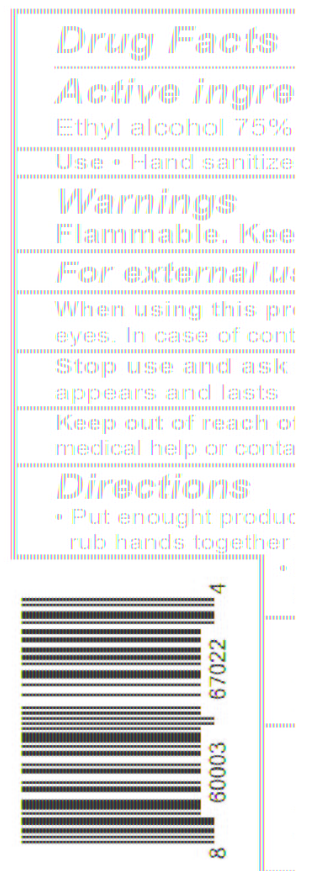
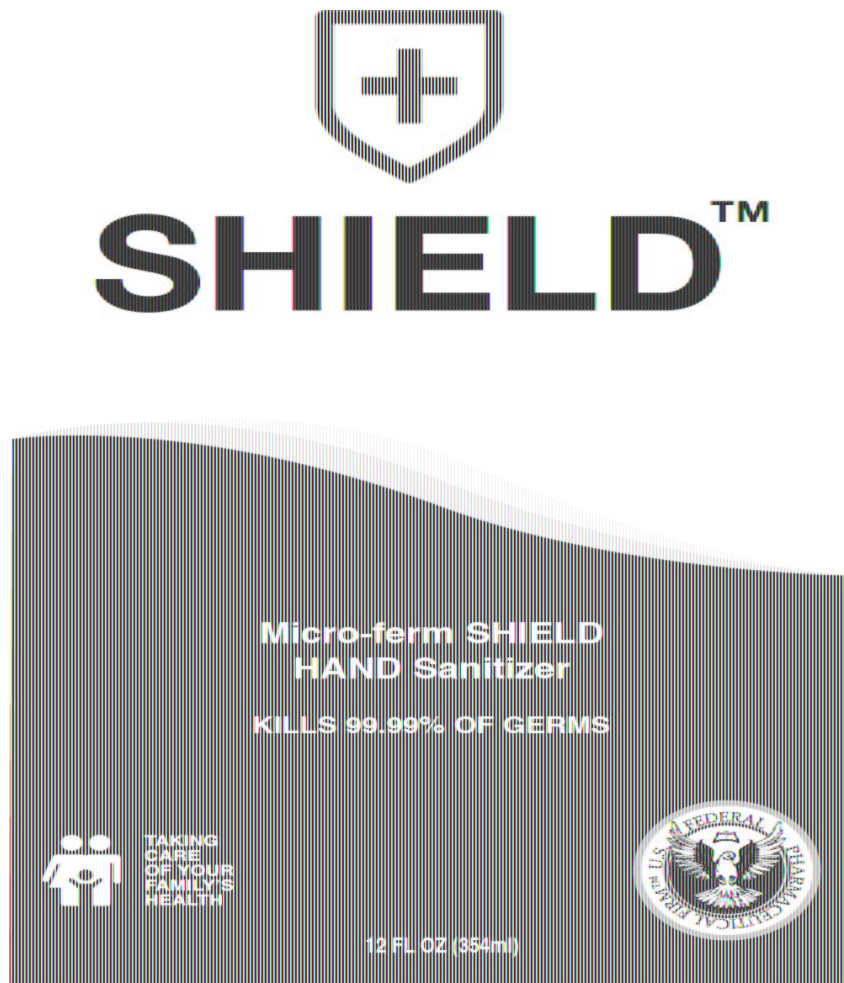
Other information

- 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



MPG: Guangzhou Cluster Mapping Sup
NO.11 of Zhengxin Kuang Road, Nanlin
Guangzhou, Guangdong 510540
Distributed by US PHARMACEUTICAL CO.
926 ATLANTIC AVE, BROOKLYN, NY 1123
Questions? Tel: 1-646-226-1974 | Mail
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2 FL OZ (60 ml) : 90010-646-02



SHIELDTM



8 FL OZ (236 ml) : 90010-646-08

Drug Facts

Active ingre

Ethyl alcohol 75%

Use • Hand sanitize

Warnings

Flammable. Kee

For external u

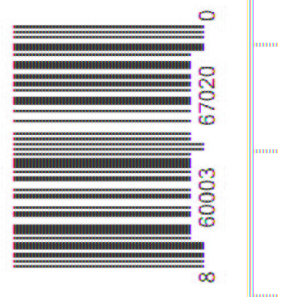
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Stop use and ask
appears and lasts

Keep out of reach o
medical help or conta

Directions

• Put enough produ
rub hands together



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SHIELDTM



12 FL OZ (354 ml) : 90010-646-12
1 Liter (1000 ml) : 90010-646-10

Drug Facts

Active ingre

Ethyl alcohol 75%

Use • Hand sanitize

Warnings

Flammable. Kee

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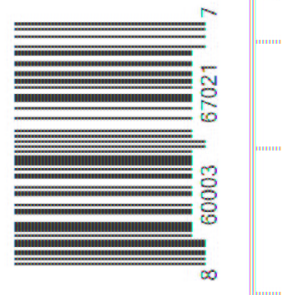
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SHIELD HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90010-646
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	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:90010-646-02	44160 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
2	NDC:90010-646-12	15060 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	
3	NDC:90010-646-08	9702 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	
4	NDC:90010-646-10	12 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/07/2020	

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(90010-646)