HAPPY HANDS HAND SANITIZER- alcohol gel True Chemical Solutions, 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.

Happy Hands Hand Sanitizer

Drug Facts

Active ingredient[s]

Alcohol 70% v/v

Purpose

Antiseptic

Use[s]

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.

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

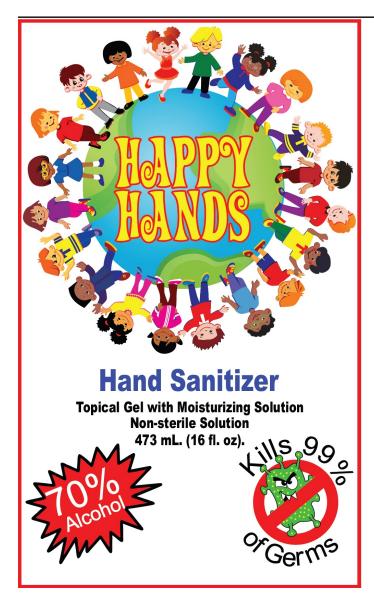
Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone

Package Labeling:118ml



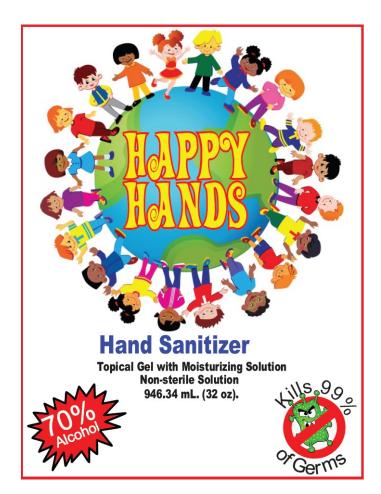
Package Labeling:473ml





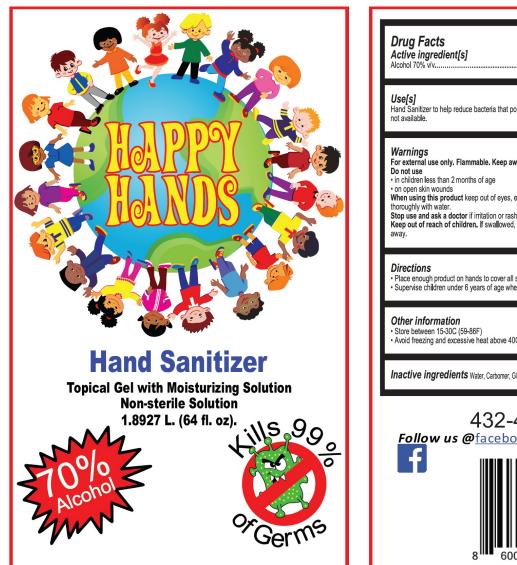


Package Labeling:946.34ml



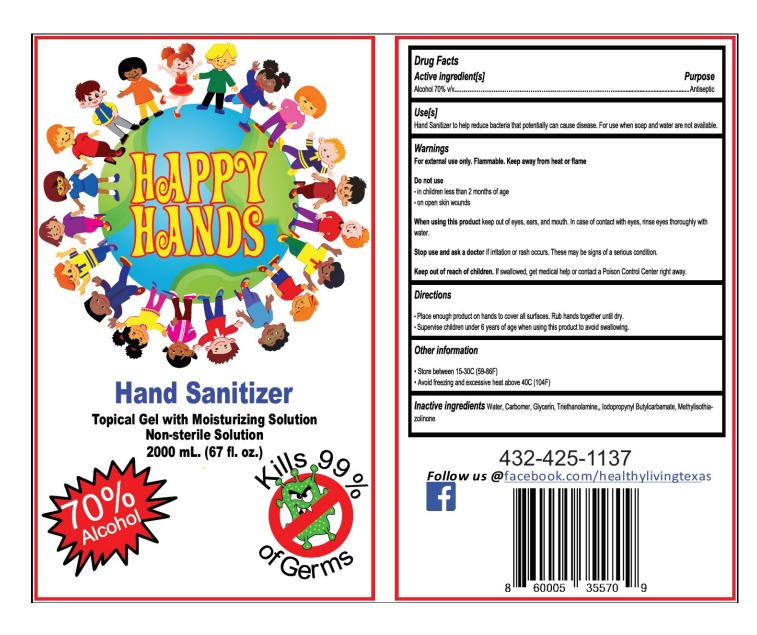


Package Labeling:1.8927L

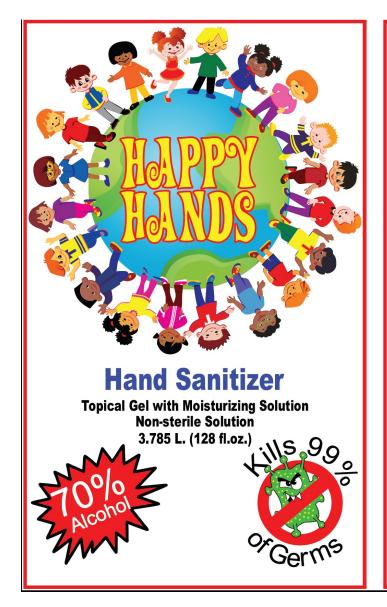




Package Labeling:2000ml



Package Labeling:3.785L



Drug Facts

Active ingredient[s]

Purpose

Alcohol 70% v/v....

Use[s]
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Inactive ingredients Water, Carbomer, Glycerin, Triethanolamine., Iodopropynyl Butylcarbamate, Methylisothiazolinone

432-425-1137

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HAPPY HANDS HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77991-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

GLYCERIN (UNII: PDC6A3C0OX)

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) ALCOHOL 0.7 mL in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

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TROLAMINE (UNII: 9O3K93S3TK)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:77991-004-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			
2	NDC:77991-004- 02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			
3	NDC:77991-004- 03	946.34 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			
4	NDC:77991-004- 04	1892.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			
5	NDC:77991-004- 05	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			
6	NDC:77991-004- 06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	06/01/2020			

Labeler - True Chemical Solutions, LLC (080705292)

Revised: 1/2021 True Chemical Solutions, LLC