HAND SANITIZER- isopropyl alcohol spray Maple Holistics, 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

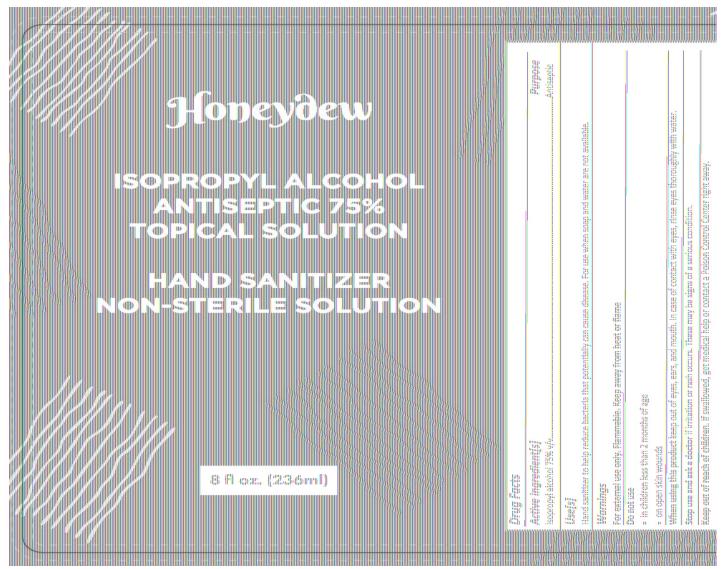
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

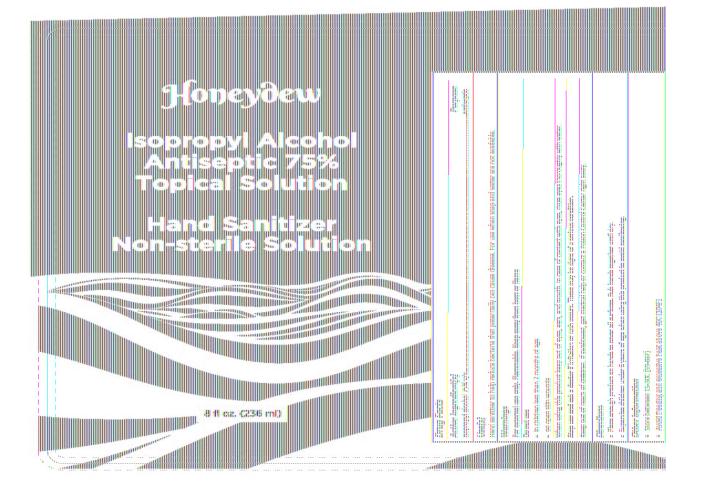
glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236 ml NDC: 75030-075-08



236 ml NDC: 75030-075-46



236 ml NDC: 75030-075-35

APLE FOISTIGS REAL INGREDIENTS REAL RESULTS. ISOPTOPVI Alcohol	Purpose	not available.	व्यांचे भवाक. '.
Isopropyl Alcohol Antiseptic 75% Topical Solution		ise when soap and water are	with eyes, imse eyes trioro erlous condition.
Hand Sanitizer Non-sterile Solution		iaily ca n cause disease. For t m has ar an ana	in incent to manue ind mounth, in Case of contact its. These may be signs of a : tedical help of contact a Pol
	[5] 6 V	<i>Licejs]</i> Hand canitter to help reduce bacteria that potentially can cause disease. For use when soap and water are not available <i>Wernings</i> For evenanty reacher Flammahis. <u>Fron</u> aven from heat or frame.	rea cure me une vong, rammoure, neep everg mum neet on meme De ned use e on chen sex man 2 months of age e on open skin wounds When using this product keep out of eyes, ears, and mouth. In take of contact with eyes, imse eyes unoroughly with ward Stop use and ask a doctor if irritation or rach occurs. These may be signs of a serious condition. Keep out of reach of children. If swellowed, get medical help or contact a Poison Control Center right away.
8 fl oz. (236 ml)	Drug Facts Active ingredient[s] Isopropyl alcohol 75% v/v.	Contract of help by Warnings	For curant use vary manuments are benefities than 2 months of age on open skin wounds When uning this product keep out of a Stop use and ask a doctor if inflation o Keep out of reach of children. If swallth Futerwitzers

HAND SANITIZER					
isopropyl alcohol spray					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce) NDC	NDC:75030-075	
Route of Administration	TOPICAL				
Active Ingredient/Active N	Moiety				
	Ingredient Name		Basis of Strengt	h Strength	
ISOPROPYL ALCOHOL (UNII: N UNII:ND2M416302)	D2M416302) (ISOPROPYL ALCC)HOL -	ISOPROPYL ALCOHOL	75 mL in 100 mL	

C ERIN (UNII: PDC)	Ingredient Name					
C ERIN (UNII: PDC	0	Ingredient Name				
	GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)						
Packaging						
Item Code	Package Description	Marketing	g Start Date	Marketing End Date		
C:75030-075-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020				
C:75030-075-46	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020				
C:75030-075-35	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020				
Marketing Information						
rketing Categor	y Application Number or Monograph Citation	Marketing	g Start Date	Marketing End Date		
monograph not fin	al part333A	04/30/2020				
k])(0))(0))(1) 1)	xaging Item Code C:75030-075-08 C:75030-075-46 C:75030-075-35	KagingItem CodePackage DescriptionC:75030-075-08236 mL in 1 BOTTLE; Type 0: Not a Combination ProductC:75030-075-46236 mL in 1 BOTTLE; Type 0: Not a Combination ProductC:75030-075-35236 mL in 1 BOTTLE; Type 0: Not a Combination ProductC:75030-075-35236 mL in 1 BOTTLE; Type 0: Not a Combination ProductC:75030-075-35236 mL in 1 BOTTLE; Type 0: Not a Combination ProductC:75030-075-35Application Number or Monograph Citation	Kaging Item Code Package Description Marketing C:75030-075-08 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 04/30/2020 C:75030-075-46 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 rketing Information Marketing Category Application Number or Monograph Citation Marketing	Marketing Start Date Marketing Start Date Item Code Package Description Marketing Start Date C:75030-075-08 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 04/30/2020 C:75030-075-46 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-35 236 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/12/2020 C:75030-075-36 246 mL i		

Labeler - Maple Holistics, LLC (095735306)

Establishment

Name	Address	ID/FEI	Business Operations
Maple Holistics, LLC		095735306	manufacture(75030-075)

Revised: 6/2020

Maple Holistics, LLC