HAND SANITIZER- alcohol gel
Universal Distributors 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 rub hand sanitizer (leave in product) which is intended to be used when soap and water are not available, and are left on and not rinsed off with water. It complies with the final rule on consumer antiseptic rubs, using alcohol in a percentage between 65 and 90%. The product is made with

a. Alcohol (ethanol) (70%, volume/volume (v/v)) in an aqueous solution denatured.
b. Glycerol (10% v/v).
c. Isopropyl alcohol (1.33% v/v).
d. Sterile distilled water or boiled cold water.
e. Carbomer 940 (0.25% m/v)
f. Polysorbate 20 (3.33% m/v)

The firm add only fragrance (0.002%) as an inactive ingredient, and realizes it may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% 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, isopropyl alcohol, carbopol 940, polysorbate 20, fragrance, purified water USP

Package Label - Principal Display Panel

1000 mL NDC: 76540-100-01

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76540-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	10 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 g in 100 mL
WATER (UNII: 059QF0KO0R)	
THIOGLYCOLIC ACID TRIETHANOLAMINE (UNII: JPH0S6Q77R)	1.336 mL in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	3.33 g in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76540-100-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

Labeler - Universal Distributors LLC (080748869)

Registrant - Universal Distributors LLC (080748869)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Distributors LLC		080748869	relabel(76540-100) , repack(76540-100) , manufacture(76540-100)

Revised: 4/2020 Universal Distributors LLC