

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 Gel

Antibacterial



Extra Moisturizer + Glycerin

Bamboo

www.productoszapien.com

12 BOTTLES OF 33.8 FL. OZ (1000 ml)
TOTAL 405.6 FL. OZ (144 LTS)
LOT. 2730

MADE BY GAZA S.A. DE C.V.
Castilla St. #1473-A
ZIP 45410
Tonala, Jalisco, México.



DRUG FACTS

Active Ingredient: Ethyl Alcohol 70% (v/v)
Purpose: Antimicrobial

Uses:
Helps reduce bacteria on skin.
Repeated use is recommended.

Warnings
For external use only: hands
Flammable. Keep away from fire or flame.

When using this product:
• keep out of eyes.
• in case of contact with eyes flush thoroughly with water.
• avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if redness or irritation develops & condition persists for more than 72 hours.

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

Directions:
• Wet hands thoroughly with product and allow to dry without wiping.
• Children under 6 years of age, use only under adult supervision.
• Not recommended for infants.

Other information:
• Do not store above 110°F (43°C).
• May discolor some fabrics and surfaces.

Inactive Ingredients:
water, ethyl alcohol, carbomer, triethanolamine, glycerin, tween 20, fragrance.

*These statement have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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: 059QF0K00R)	
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