HAND SANITIZER- alcohol gel Tropicos meticos, S.A. de C.A.

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.

Cleaners 500ML ND

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (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. Carbomer 940 (0.12% v/v).
- d. Triethanolamine Benzoate (0.089% v/v)
- e. 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)

Alcohol 80% 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.

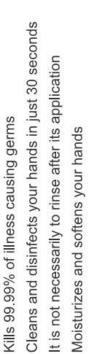
Other information

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

Inactive ingredients

glycerin, Carbomer 940, Triethanolamine Benzoate, purified water USP

Package Label - Principal Display Panel





Uses to decrease bacteria on the skin that could cause disease, I recommended for repeated use Warnings For external use only: hands Flammable, Keep away from heat and 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 skin irritation develops Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Cente Directions wet hands thoroughly with product and allow to dry without wiping. If for children under 6, use only under adult supervision, I not Other Information do not store a 105°F, I may discolor some fabrics, I harmful to wood finishes and plastics. Inactive Ingredients | Purified Water, Glycerin Triethanolamine, Carbom *Effective at eliminating more than 99,99% of many commo harmful germs and bacteria. Made in México Distributed By: Liberty International Distributors, LLC Produced By: Tropicosméticos S.A. de CV. Av Via Morelos No. 60 Bodega 9 Col. Rústica Xulostoc, Ecatepec, Estado de México C.P 55340 DUNS# 814905154

Drug Facts

Active Ingredient

500 mL NDC: 76676-402-07

HAND SANITIZER

alcohol gel

Droduct	Information
Product	Imormation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76676-402
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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

8			
Ingredient Name	Strength		
TRIETHANO LAMINE BENZO ATE (UNII: M3EN4GC19W)	0.089 mL in 100 mL		
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.12 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76676-402- 07	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Tropicosmeticos, S.A. de C.A. (814905154)

Registrant - Tropicosmeticos, S.A. de C.A. (814905154)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tropicosmeticos, S.A. de C.V.		814905154	manufacture(76676-402)	

Revised: 7/2020 Tropicosmeticos, S.A. de C.A.