

HAND SANITIZER- alcohol gel
Tropicosméticos, 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

The image shows the principal display panel of a hand sanitizer package. The label is primarily green and white. At the top, it says 'FRAGRANCE FREE'. Below that, a green oval contains the word 'Cleaner'. To the left of this oval is a circular seal that says 'ELIMINATES UP TO 99.99% OF BACTERIA'. The main body of the label features the words 'HAND SANITIZER' in large white letters on a green background, with 'rinse free' in a white oval below it. At the bottom, it says 'FORMULATED WITH 70% ALCOHOL'. On the left side, there are four bullet points with green circular icons: 'Kills 99.99% of illness causing germs', 'Cleans and disinfects your hands in just 30 seconds', 'It is not necessarily to rinse after its application', and 'Moisturizes and softens your hands'. On the right side, there is a 'Drug Facts' table. Below the table, it says '*Effective at eliminating more than 99.99% of many common harmful germs and bacteria.', 'Made in Mexico', and 'Distributed By: Liberty International Distributors, LLC'. At the bottom right, there is a 'Lote:' field, a barcode, and the number '7 47356 64224 8'.

FRAGRANCE FREE

Cleaner

ELIMINATES UP TO 99.99% OF BACTERIA

HAND SANITIZER

rinse free

FORMULATED WITH 70% ALCOHOL

16.9 Oz (500 mL)

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol at 70%.....	Antiseptic
Uses ■ to decrease bacteria on the skin that could cause disease. ■ 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 Center Right away.	
Directions ■ wet hands thoroughly with product and allow to dry without wiping. ■ for children under 6, use only under adult supervision, ■ not recommended for infants.	
Other Information ■ do not store above 105°F. ■ may discolor some fabrics. ■ harmful to wood finishes and plastics.	
Inactive Ingredients ■ Purified Water, Glycerin, Triethanolamine, Carbomer.	

*Effective at eliminating more than 99.99% of many common harmful germs and bacteria.

Made in Mexico

Distributed By: Liberty International Distributors, LLC
Produced By: Tropicosméticos S.A. de CV.
Av Via Morelos No. 60 Bodega 9
Col. Rústica Xalostoc, Ecatepec,
Estado de México C.P 55340
DUNS# 814905154

Lote:

7 47356 64224 8

500 mL NDC: 76676-402-07

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76676-402
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
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	0.089 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	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

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.