HAND SANITIZER- alcohol gel
Tropicosmeticos S.A. de C.V.

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.

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420 ml Britz

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 (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)

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, carbomer, Thrienalonamine, purified water USP

Package Label - Principal Display Panel

Eliminates more than
99.99 % of germs and bacteria.

14.2 Oz. (420 ml)

420 mL NDC: 76676-402-03

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 México

Distributed By: Viking Sales Group LLC.
750 N Dixie Hwy, Hollywood, FL 33020
Exported By: E. Audiocode S.A. de C.V.
Produced By: Tropicosméticos S.A. de CV.
Av Vía Morelos No. 60 Bodega 9
Col. Rústica Xalostoc, Ecatepec,
Estado de México C.P 55340

Lote:

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**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	0.089 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76676-402-03	420 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.V. (814905154)

Registrant - Electronica Audiocode SA de CV (812868313)

Establishment

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

Revised: 4/2020 Tropicosmeticos S.A. de C.V.