## HAND SANITIZER- alcohol gel Tropicos meticos 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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#### Britz 1000 mL DUNS

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

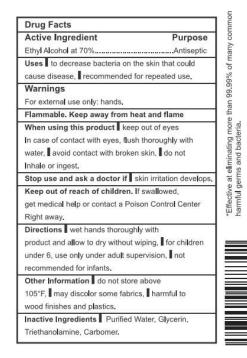


HAND SANITIZER

Ethyl Alcohol 70 %

Eliminates more than 99.99 % of germs and bacteria.

33.8 Oz. (1000 mL)



Distributed By: Soflo Urban Team LLC Produced By: Tropicosméticos S.A. de CV. Av Vía Morelos No. 60 Bodega 9 Col. Rústica Xalostoc, Ecatepec, Estado de México C.P 55340 DUNS# 814905154



1000 mL NDC: 76676-402-02

alcohol gel

Product Type H	HUMAN OTC DRUG	Item Code (Source)	NDC:76676-402
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Route of Administration TOPICAL

# Active Ingredient/Active Moiety

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ı	Ingredient Name	Basis of Strength	Strength
ı	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 WATER (UNII: 059QF0KO0R) CARBOMER 940 (UNII: 4Q93RCW27E) 0.12 mL in 100 mL

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:76676-402- 02	$1000\ mL$ 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: 7/2020 Tropicosmeticos S.A. de C.V.