

HAND SANITIZER- alcohol gel

Tropicosmeticos, SA de CV

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.

WAVE 1 galon

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) (80%, 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.

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.

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

Triethanolamine Benzoate, Carbomer, glycerin, purified water USP

Package Label - Principal Display Panel

3790 mL NDC: 76676-402-20

KILLS 99.9% OF GERMS

wave

Hand GEL Sanitizer
ANTI-BACTERIAL
FRAGRANCE-FREE

70% ALCOHOL

DRIES QUICKLY!

1 Gallon/3.79 L

ANTIBACTERIAL HAND SANITIZER

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70%	Antiseptic

Uses
For reducing bacteria on skin

Warnings
For external use only

Flammable
Keep away from fire and heat

When using this product
Avoid contact with eyes, and if eye contact occurs, flush thoroughly with water and seek medical advice

Stop use and ask a doctor if
Irritation and redness occurs

Keep out of reach of children

Directions
• Dispense into dry hands and rub until dry
• Children under 6 years of age should be supervised by an adult when using this product

Other Information
Do not store above 105°F. It may discolor some fabrics and may be harmful to wood finishes and plastics

Inactive ingredients
Purified water, glycerin, carbomer

wave

- + ETHYL ALCOHOL 70%
- + KILLS 99.9% OF GERMS
- + FRAGRANCE-FREE
- + DRIES QUICKLY

Distributed by:
C&A Marketing, Inc.
wavessentials.com

For sales inquiries:
848.244.2343
wave@caglobal.com

WARNING:
Extremely flammable.
Keep away from flame.

SKU# WVMX1GL70TC

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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
CARBOMER 940 (UNII: 4Q93RCW27E)	0.12 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	0.089 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76676-402-20	3790 mL in 1 BOTTLE; 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, SA de CV (814905154)**Registrant** - Electronica Audiocode SA de CV (812868313)**Establishment**

Name	Address	ID/FEI	Business Operations
Tropicosmeticos, SA de CV		814905154	manufacture(76676-402)

Revised: 6/2020

Tropicosmeticos, SA de CV