

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.

250 mL Parabola

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 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, Triethanolamine Benzoate, Carbomer 940, purified water USP

Package Label - Principal Display Panel

| 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. | |



HAND SANITIZER

ETHYL ALCOHOL 70%

Eliminates more than 99.99% of germs and bacteria.

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

Made in México

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



Lote:



8.45 Oz. (250 mL)

NDC: 76676-402-09

250 mL

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: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76676-402-09 | 250 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 - Tropicometicos, SA de CV (814905154)

Registrant - Tropicometicos, SA de CV (814905154)

Establishment

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

Revised: 7/2020

Tropicometicos, SA de CV