

HAND SANITIZER- alcohol gel
Tropicosméticos, 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.

Kleanz 1000 mL

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. Hydrogen peroxide (0.125% v/v).
- d. triethanolamine benzoate (0.089% v/v)
- e. Carbomer 940 (0.12% v/v)
- f. 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.

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

glycerin, Triethanolamine Benzoate, Carbomer 940, purified water USP

Package Label - Principal Display Panel

<p>Kills 99.99% of illness causing germs</p> <p>Cleans and disinfects your hands in just 30 seconds</p> <p>It is not necessarily to rinse after its application</p> <p>Moisturizes and softens your hands</p>		Drug Facts				
	<p>ANTIBACTERIAL</p> <p><i>Hand Sanitizer</i></p> <p>ADVANCED</p>	<table border="1"><tr><td>Active ingredient(s)</td><td>Purpose</td></tr><tr><td>Ethyl alcohol 70% v/v</td><td>Antiseptic</td></tr></table>	Active ingredient(s)	Purpose	Ethyl alcohol 70% v/v	Antiseptic
	Active ingredient(s)	Purpose				
	Ethyl alcohol 70% v/v	Antiseptic				
<p>KILLS 99.99% OF MOST ILLNESS CAUSING GERMS</p> <p>Alcohol Antiseptic 70% Topical Solution</p> <p>Antiseptic Hand Rub Non-sterile Solution</p> <p>33.8 FL OZ (1000 mL)</p>	<p>Use(s)</p> <p>Health care personnel hand rub to help reduce bacteria that potentially cause disease.</p> <p>Warnings</p> <p>For external use only. Flammable. Keep away from heat or flame.</p> <p>Do not use</p> <ul style="list-style-type: none">• In children less than 2 months of age.• On open skin wounds. <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none">• 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. <p>Other information</p> <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) <p>Inactive ingredients</p> <p>Water, Carbomer, Triethanolamine, Glycerin.</p>					
<p> UP IN THE LAB DISTRIBUTED BY UP IN THE LAB BEVERLY HILLS, CA 90212 www.Kleanzhands.com MADE IN MEXICO</p>						

1000 mL NDC: 76676-406-06

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: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.12 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76676-402-06	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 - Tropicosmeticos, S.A.de C.V. (814905154)

Establishment

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