HAND SANITIZER- alcohol gel
AAA COSMETICA 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.

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. 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.

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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, carbomer 940, triethanolamine, 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 fire, flame, or heat.

When using this product
- do not get into eyes
- if contact occurs, rinse eyes throughly 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.

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

Directions
- Wet hands thorughly with product and allow to dry without wiping. Repeat as many times as needed. For children under 6, use only under adult supervision. Not recommended for infants.

Inactive Ingredients Purified Water, Glycerin, Triethanolamine, Carbomer.

*Effective at eliminating more than 99% of many harmful germs and bacteria.

Distributed By: Qualitamed Corp.
11500 NW 123rd ST, Suite 400 Medley FL 33178 USA.email:
info@qualitamed.com
www.qualitamed.com
Manufactured By: AAA Cosmética S.A. de C.V.
Recursos Hidráulicos No. 1 Secc. A,
Col. La Loma Zona Industrial,
Tlalnepantla de Baz, C.P 54060, México.
Made in México.

QualitaMed

Hand Sanitizer

Ethyl Alcohol 70%

UNSCENTED

Eliminates more than 99% of germs and bacteria.

Net Cont. 8.45 FL. OZ. (250 mL)

250 mL NDC: 76987-250-01

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76987-250

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**
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.36 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.14 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76987-250-01	250 mL in 1 TUBE; 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 - AAA COSMETICA S.A. DE C.V. (813075470)

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