

HAND SANITIZER- alcohol gel
AAA COSMETICA S.A. DE C.V.

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.

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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 940, triethanolamine, purified water USP

Package Label - Principal Display Panel

250 mL NDC: 76987-250-01

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 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.

Other Information

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

Directions

■ Wet hands thoroughly 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.

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AREA SIN IMPRESION



QualitaMed

Advance Hand Sanitizer



Ethyl Alcohol 70%

UNSCENTED

Eliminates more than 99% of
germs and bacteria.

Net Cont. 08.45 FL. OZ. (250 mL)

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
Export only		03/30/2020	

Labeler - AAA COSMETICA S.A. DE C.V. (813075470)

Revised: 5/2020

AAA COSMETICA S.A. DE C.V.