

HAND SANITIZER- alcohol liquid
PROBEMEX S.A. 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.

HAND SANITIZER

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. 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.

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



52 ML 42955-004-01

250 ML 42955-004-02

SACHET 1.5ML 42955-004-03

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42955-004
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
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.33 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.001 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.51 mL in 100 mL
WATER (UNII: 059QF0K00R)	27.9 mL in 100 mL
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.22 mL in 100 mL
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	0.14 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42955-004-01	52 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
2	NDC:42955-004-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
3	NDC:42955-004-03	1.5 mL in 1 DOSE PACK; Type 0: Not a Combination Product	07/07/2020	



EARTHZEN
Hand Sanitizer Gel
Kills 99.99% of germs*

Formulated with
70%
of alcohol

With Moisturizers
1.7 OZ (50 gr)

NDC 42955-001-XX
UG0005

DRUG FACTS	ACTIVE INGREDIENT	PURPOSE
	Ethyl Alcohol 70% v/v	Antiseptic
Uses: Hand sanitizer to help reduce germs on the skin. Recommended for repeated use.		
Warnings: FLAMMABLE. Keep away from heat or flame. For external use only. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Do not use: On children less than 2 months of age. On open skin wounds. Avoid contact with broken skin, do not inhale or ingest.		
Step use and ask a doctor if irritation or rash appears and lasts. 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 (59-86 F). Avoid freezing and excessive heat above 40C (104 F). May discolor certain fabrics or surfaces.		
Inactive ingredients: Water (Aqua), Carbomer, Propanediol, Aminomethyl Propanol, PEG-40 Hydrogenated Castor Oil, Glycerin, Fragrance.		
* Effective at eliminating more than 99.99% of many common harmful germs and bacteria.		

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Made in Mexico for: Probemex S.A. de C.V. Residencia 17 Col. Jardines del Sur Ixtachilco, Ciudad de México, México. C.P. 06500
Dist. in the U.S.A. by: Terra Beauty, LLC 1396 Banyan Way Weston FL 33327

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/07/2020	

Labeler - PROBEMEX S.A. DE CV (813566395)

Registrant - PROBEMEX S.A. DE CV (813566395)

Establishment

Name	Address	ID/FEI	Business Operations
PROBEMEX S.A. DE CV		813566395	manufacture(42955-004)

