

HAND SANITIZER- alcohol gel

PICO INC.

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.

PICO Hand Sanitizer 75% 500mL

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 75% 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, trolamine, purified water USP, Aminomethyl Propanol, Carbomer, tocoheryl acetate, albe vera

Package Label - Principal Display Panel

Drug Facts	
Active Ingredients	Propose
Ethyl Alcohol 75%	antiseptique
Use this product only when necessary on hands. Adults only.	
Warnings: Flammable. Keep away from fire or flame. If swallowed, get medical help right away. Report any reaction to Canada.ca/1-877-325-8909. Do not use in children or damaged skin. Stop use and ask a doctor if irritation appears on face. For external use only. Keep out of eyes. In case of contact with eyes, rinse with water. Do not inhale or ingest. Do not use if you are pregnant or breastfeeding.	
Questions: Call 1-800-272-2242 to report any adverse reaction.	
Other information: Store at 15-30°C (59-86°F). May become carbonated.	
Contains ingredients: Ethyl Alcohol, Glycerin, Carbomer, Aloe Vera, Polysorbate, Aminomethyl Propanol, Water.	
Hydroalcoholic Maltreatment	
Hydroalcoholic Maltreatment	Usage:
Alcool Ethylique 75%	Antiseptique
Usage: Pour une action antiseptique sur la peau. À l'usage externe.	
Avvertenze: Infiammabile. Tener a portata di mano. Per uso d'igiene personale. Immediatamente lavare con acqua abbondante, se ingerito. Evitare l'uso in bambini o su pelli danneggiate o irritate. Evitare l'uso in caso di irritazione o di reazione allergica. Per uso esterno. Evitare il contatto con gli occhi. In caso di contatto con gli occhi, lavare immediatamente con acqua. Non inalare e non ingerire. Non usare se si è incinta o si sta allattando.	
Questions? Appelez le 1-800-272-2242 pour signaler tout effet indésirable.	
Autres informations: À conserver en dessous de 30°C (86°F). Peut devenir carbonaté au stockage.	
Ingredients: antiseptique: Eau distillée purifiée, Glycérine, Carbomer, Aloe Vera, Polysorbate, Aminométhyle propanol, Eau.	
Hydroalcoholic Maltreatment	
Hydroalcoholic Maltreatment	
500 mL (16.9 Fl. Oz.)	
NDC 78082-008-01	

500 mL NDC: 78082-008-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78082-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	375 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.15 mL in 500 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.15 mL in 500 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	6 mL in 500 mL
GLYCERIN (UNII: PDC6A3C0OX)	6 mL in 500 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.05 mL in 500 mL
WATER (UNII: 059QF0KOOR)	116.2 mL in 500 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1.5 mL in 500 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78082-008-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

Labeler - PICO INC. (203063060)

Registrant - PICO INC. (203063060)

Establishment

Name	Address	ID/FEI	Business Operations
LMZ (Jiangsu) Industrial Co.,Ltd		546645164	manufacture(78082-008)