

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 80% 500 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) (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 80% 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, hydrogen peroxide, purified water USP, Aminomethyl Propanol, Carbomer

Package Label - Principal Display Panel



PICO
Hand Sanitizing Gel
Gel Hydroalcoolique

80%
advanced formula
formule avancée

kills 99.9% of
bacteria & germs

élimine 99,9% des
bactéries et germes

NPN #80100043 500 mL (16.9 fl oz) SG-500ML

Drug Facts

Active Ingredient:	Purpose:
Ethyl Alcohol 80%	Antiseptic
Ethanol 99.55% technical grade	

Use: Hand sanitizer to help reduce bacteria on the skin. Adults only.

Warnings: Flammable. Keep away from fire or flame. If swallowed, get medical help right away. Report any incident to Canada.ca/drug-device-reporting. Do not use on broken or damaged skin. Stop use and ask a doctor if irritation appears and lasts. 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 1-866-234-2345 to report any adverse reaction.

Other Information: Store below 110°F (43°C). May discolor certain fabrics or furniture.

Inactive Ingredients: Sterile Distilled Water, Glycerin, Hydrogen Peroxide, Carbomer, Aminomethyl Propanol.

Informations Médicament

Ingédient actif:	Utilité:
Alcool Éthylque 80%	Antiseptique
Éthanol 99,55% qualité technique	

Usage: Pour aider à réduire les bactéries sur la peau. Adultes seulement.

Avvertissements: Inflammable. Tenir le produit à l'écart du feu. En cas d'ingestion communiquez immédiatement avec votre médecin, signaler tout incident à Canada.ca/medicament-instrument-declaration. Ne pas utiliser sur peau endommagée ou présentant des lésions. Si une irritation apparaît et persiste, cesser d'utiliser le produit. Pour usage externe seulement. Éviter le contact avec les yeux. En cas de contact avec les yeux, laver immédiatement avec de l'eau. Ne pas inhaler ou ingérer. Ne pas utiliser si vous êtes enceinte ou si vous allaitez.

Questions?: Appelez le 1-866-234-2345 pour signaler tout effet indésirable.

Autres informations: À conserver en dessous de 43°C (110°F). Peut décolorer certains tissus ou surfaces.

Ingédient inactif: Eau distillée purifiée, Glycérol, Peroxyde d'hydrogène, Carbomère, Aminométhyl propanol.

Distributed by/Distribué par: PICO Inc.
180 John St, Toronto, ON, M5T 1X5, Canada
www.picohospitality.com
Made in/Fabriqué en: Mexico
Lot # 20051101 Manufactured by/
MFG: 11/05/2020 Fabriqué par: F&G
EXP: 11/05/2023 Enzasso S.A. de C.V.



500 mL NDC: 78082-002-01

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78082-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	400 mL in 500 mL
Inactive Ingredients			
Ingredient Name			Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			1.5 mL in 500 mL
GLYCERIN (UNII: PDC6A3C0OX)			7 mL in 500 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.6 mL in 500 mL
WATER (UNII: 059QF0KO0R)			87.5 mL in 500 mL
CARBOMER 940 (UNII: 4Q93RCW27E)			3 mL in 500 mL
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78082-002-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

Labeler - PICO INC. (203063060)

Registrant - PICO INC. (203063060)

Establishment

Name	Address	ID/FEI	Business Operations
Fuego Envasado SA de CV		812932655	manufacture(78082-002)

Revised: 12/2021

PICO INC.