

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% 1 Gallon

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.

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, purified water USP, Aminomethyl Propanol, Carbomer

Package Label - Principal Display Panel

 hydrating & moisturizing hydratant	Drug Facts Active Ingredient: Ethyl Alcohol 80% Purpose: Antiseptic Use: Hand sanitizer to help reduce bacteria on the skin. Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry. Children under 6 years of age should be supervised. Warnings: Flammable. Keep away from fire or flame. 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. If swallowed, call Poison Control Center or get medical help right away. Keep out of reach of children. Other Information: Store below 110°F (43°C). May discolor certain fabrics or furniture. Inactive Ingredients: Sterile Distilled Water, Glycerin, Carbomer, Aminomethyl Propanol.	Manufactured by/ Fabriqué par: Fuego Envasado S.A. de C.V.  8 2 6 0 5 1 9 8 6 2
HAND SANITIZING GEL GEL HYDROALCOOLIQUE	Informations Médicament Ingrédient actif: Alcool Éthylique 80% Utilité: Antiseptique Usage: Pour aider à réduire les bactéries sur la peau. Bien frotter pendant au moins 30 secondes. Laisser sécher. Les enfants de moins de 6 ans doivent être surveillés. Avertissements: Inflammable. Tenir le produit à l'écart du feu. 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. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale. Garder hors de la portée des enfants. Autres informations: A conserver en dessous de 43°C (110°F). Peut décolorer certains tissus ou surfaces. Ingrédient Inactifs: Eau distillée purifiée, Glycérine, Carbomer, 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 MFG: 11/05/2020 EXP: 11/05/2023
kills harmful bacteria & germs éliminer les bactéries & germes nocifs		
80% Alcohol Antiseptic Antiseptique D'alcool		
1 US Gallon (3.78 L)		
NPN # 80100043	SG80-1G4	

3.78 L NDC: 78082-015-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78082-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3.02 L in 3.78 L

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.001 L in 3.78 L
GLYCERIN (UNII: PDC6A3C0OX)	0.053 L in 3.78 L
WATER (UNII: 059QF0K00R)	0.7 L in 3.78 L
CARBOMER 940 (UNII: 4Q93RCW27E)	0.002 L in 3.78 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78082-015-01	3.78 L in 1 BOTTLE; 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(78082-015)

Revised: 12/2021

PICO INC.