

HAND SANITIZER- alcohol gel
Fuego Envasado, S.A. de C.V.

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.

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

Package Label - Principal Display Panel

Drug Facts

Active Ingredient:
Ethyl Alcohol 80%

Purpose:
Antiseptic

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

Warnings: Flammable. Keep away from fire or flame. 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 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.

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

Ingrédient actif:
Alcool Éthylique 80%

Utilité:
Antiseptique

Usage: Pour aider à réduire les bactéries sur la peau

Avertissements: Infammable. Tenir le produit à l'écart du feu. Garder hors de la portée des enfants. En cas d'ingestion communiquez immédiatement avec votre médecin ou un centre antipoison. Si une irritation apparaît et persiste, cesser d'utiliser le produit et consulter un praticien de soins de santé. 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.

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

Ingrédient Inactifs: Eau distillée purifiée, Glycérine, Peroxyde d'hydrogène, 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

Manufactured by/
Fabriqué par
Fuego Envasado
S.A. de C.V.



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76800-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	800 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE (UNII: QCD5R22RNT)	3 mL in 1000 mL
CARBOMER 934 (UNII: Z135WT9208)	2.52 mL in 1000 mL
GLYCERIN (UNII: PDC6A3C0OX)	14.5 mL in 1000 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.83 mL in 1000 mL
WATER (UNII: 059QF0K00R)	179.15 mL in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76800-102-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/23/2020	

Labeler - Fuego Envasado, S.A. de C.V. (812932655)

Registrant - Fuego Envasado, S.A. de C.V. (812932655)

Establishment

Name	Address	ID/FEI	Business Operations
Fuego Envasado, S.A. de C.V.		812932655	manufacture(76800-102)

Revised: 5/2020

Fuego Envasado, S.A. de C.V.