

HAND SANITIZER- alcohol gel
Valor Fractal, LLC

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.

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.

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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

Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, triethanolamine (Trolamine), water.

Package Label - Principal Display Panel

251 mL NDC: 79047-002-01

Blueberry

HAND sanitizer

ALCOHOL GEL ANTIBACTERIAL

70% VOL.

NOT GREASY - WITHOUT RINSING
NO GRASO - SIN ENJUAGUE

HAND SANITIZER
DESINFECTANTE DE MANOS
KILLS GERMS
ELIMINA GÉRMENES

251 ml (8.5 Fl. Oz)

EN

DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 70% w/v	Antiseptic

Uses: to decrease bacteria on the skin that could cause diseases.

Warnings:
For external use only. Flammable product. Keep out of reach of children. Keep at a temperature not higher than 105°F. May discolor some fabrics, harmful to wood finishes.
When using this product: Keep out of eyes. In case of contact, flush thoroughly with water. Do not inhale or ingest.
Stop using and ask a doctor: if irritation and redness develop and persists for more than 24 hours.
Keep out of reach of children: if swallowed, get medical help or contact a Poison Control Center right away.

Directions: apply a small amount in your hands and rub until it dries, for children under 6, use only under adult supervision.

Inactive ingredients: Aqua/Water, Triethanolamine, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer.

ES

Modo de uso: aplique en sus manos y frote hasta que seque.
Advertencias: solo para uso externo. Producto inflamable. Evitar el contacto con los ojos, en caso de contacto enjuague con abundante agua. En niños menores de 6 años usar bajo la supervisión de un adulto. Conservar a temperaturas menores a 40°C.
Ingredientes: Alcohol Denat., Aqua/Water, Triethanolamine, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer.

En El Salvador Reg. San.: LUC0380509
No. Lote y Fecha de vencimiento: Ver envase

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AL0320-002
Made in El Salvador for Distribuidora Cuscatlán S.A. de C.V.
Hecho en El Salvador para Distribuidora Cuscatlán S.A. de C.V.

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79047-002
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
TROLAMINE (UNII: 9O3K93S3TK)	0.7 mL in 100 mL
CARBOMER 1342 (UNII: 809Y72KV36)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	28.8 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79047-002-01	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2020	

Labeler - Valor Fractal, LLC (114617374)**Registrant** - Valor Fractal, LLC (114617374)**Establishment**

Name	Address	ID/FEI	Business Operations
Valor Fractal, LLC		114617374	relabel(79047-002)

Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Cuscatlan		851247924	manufacture(79047-002)