

ANTISEPTIC HAND SANITIZER ETHYL ALCOHOL- alcohol gel
Corporacion Saint Germain

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.

Antiseptic Alcohol Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70% Purpose:Antiseptic

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin.

Warnings

For external use only. Flammable, keep away from fire or flame.

Do not use

- in the eyes

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping

Other information

- Store below 106°F (41°C). May discolor certain fabrics or surfaces.

Inactive ingredients

Water, Isopropyl alcohol, Carbomer, and Triethanolamine.

Questions or comments?

+1 (305)517-7739

500 ML NDC:79036-000-02



ANTISEPTIC HAND SANITIZER ETHYL ALCOHOL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79036-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79036-000-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
2	NDC:79036-000-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/31/2020	

Labeler - Corporacion Saint Germain (816054674)

Registrant - Corporacion Saint Germain (816054674)

Establishment

Name	Address	ID/FEI	Business Operations
Corporacion Saint Germain		816054674	manufacture(79036-000)

Revised: 8/2020

Corporacion Saint Germain