

HAND SANITIZER- alcohol gel
Tecnoglobal Ph7, 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.

Ecopili 75470-800

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Personal care hand rub to help reduce bacteria that potentially can cause disease.

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.

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)

Inactive ingredients

WATER, GLYCERIN, PROPYLENE GLYCOL, AMINOMETHYLPROPANOL, PHENOXYETHANOL / IODOPROPYNYLBUTYLCARBAMATE, TETRASODIUM EDTA, EXT. VIOLET 2

Package Label - Principal Display Panel

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75470-800
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75470-800-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75470-800-02	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75470-800-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75470-800-04	490 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Tecnoglobal Ph7, S.a. De C.v. (813006665)

Establishment

Name	Address	ID/FEI	Business Operations
Tecnoglobal Ph7, S.a. De C.v.		813006665	manufacture(75470-800)