

**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.*

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**Montelegre**

**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.

**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**

water, glycerin, carbomer 940, aminomethyl propanol, phenoxyethanol / iodopropynyl butylcarbamate, tetrasodium EDTA, Ext. Violet 2, aloe vera

**Package Label - Principal Display Panel**

500 mL NDC: 75470-500-01



## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75470-500
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
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75470-500-01	500 mL in 1 TUBE; 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(75470-500)

Revised: 6/2020

Tecnoglobal Ph7, S.a. De C.v.