

HAND SANITIZER- alcohol gel gel

PurCel Labs 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.

Active Ingredient(s)

Alcohol 70% v/v

Purpose

Antiseptic

Uses

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

- On children less than 2 months of age.
- On open skin wounds.

When using this product do not use in or near the eyes. In case of contact, 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

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using products.

Other information

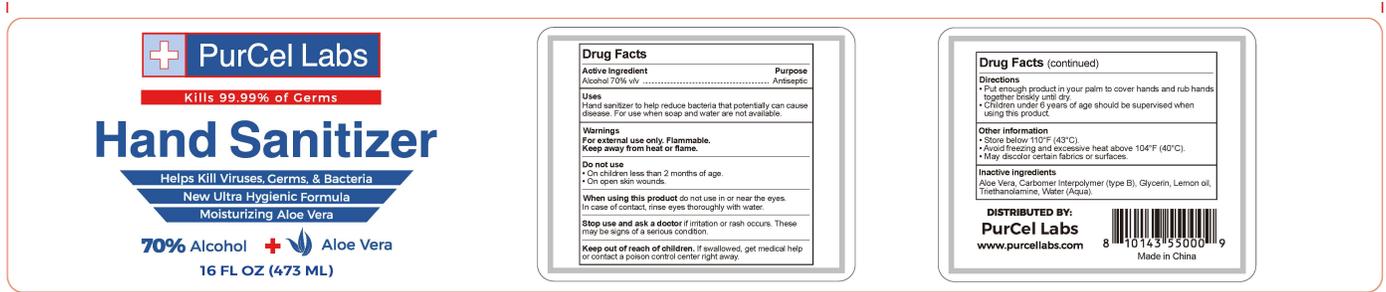
- Store below 110°F (43°C).

- Avoid freezing and excessive heat above 104°F (40°C).
- May discolor certain fabrics or surfaces.

Inactive ingredients

Aloe Vera, Carbomer Interpolymer (type B) □ Lemon oil □ Glycerin, Triethanolamine, Water (Aqua).

Package label.principal display panel



HAND SANITIZER

alcohol gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83584-016
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
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
WATER (UNII: 059QF0KO0R)	
LEMON OIL (UNII: I9GRO824LL)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:83584-016-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/26/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333E		07/25/2023	

Labeler - PurCel Labs LLC (127672531)

Registrant - Jiangsu Intco Medical Products Co., Ltd (529128686)

Establishment			
Name	Address	ID/FEI	Business Operations
Jiangsu Intco Medical Products Co., Ltd		529128686	manufacture(83584-016)

Revised: 7/2023

PurCel Labs LLC