

PURE SAFER GEL(ETHANOL)- hand sanitizer gel
Sinbad Co.,Ltd

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

Ethyl Alcohol 70.0% v/v

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria on skin.

Warnings

For external use only. Flammable. Keep away from heat or flame.

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 doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients

Water(Aqua), Carbomer, Aloe Barbadensis Leaf Juice, Glycerin, Tocopherol, Triethanolamine, Propylene Glycol, FD&C Blue No.1, FD&C Yellow No.5

Directions:

- Place enough Product in your palm to thoroughly spread on both hands and rub into the skin until dry.
- Children under 6 years of age should be supervised when using this product.

Other Information:

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

Package Label - Principal Display Panel



PURE SAFER GEL(ETHANOL)

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74142-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE (UNII: V5VD430YW9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74142-201-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

Labeler - Sinbad Co.,Ltd (693900611)

Registrant - Sinbad Co.,Ltd (693900611)

Establishment

Name	Address	ID/FEI	Business Operations
CAREPHARM		694639821	manufacture(74142-201)

Revised: 5/2020

Sinbad Co.,Ltd