

HAND SANITIZER WITH ALOE VERA VITAMIN E- alcohol gel
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc

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

Alcohol 70% v/v.

Purpose: Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria on skin. 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 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 old.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, AloeBarbadensis Leaf Juice, Glyceryl Caprylate, Glyceryl Caprate, Isopropyl Myristate, , Aminomethyl Propanol, Caprylic/Capric Glycerides, Tocopherol, Benzophenone-4, Blue 1 /CI 42090, Yellow 5/ CI 19140

Drug Facts

Active ingredient Purpose

Alcohol 70%v/v.....Antiseptic

Use(s) Hand sanitizer to help reduce bacteria on skin. For use when soap and water are not available.

Warnings

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

*Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 30 seconds.

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800.333.3131
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4016758 Rev 1 09/2021
Peel for Drug Facts

Drug Facts (cont'd)

Warnings

Do not use

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- on open skin wounds

When using, 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 poison control center.

Directions

- Place enough product on

HINGE AREA

Drug Facts (cont'd)

hands to cover all surfaces. Rub together until dry.

- Supervise children under 6 years old.

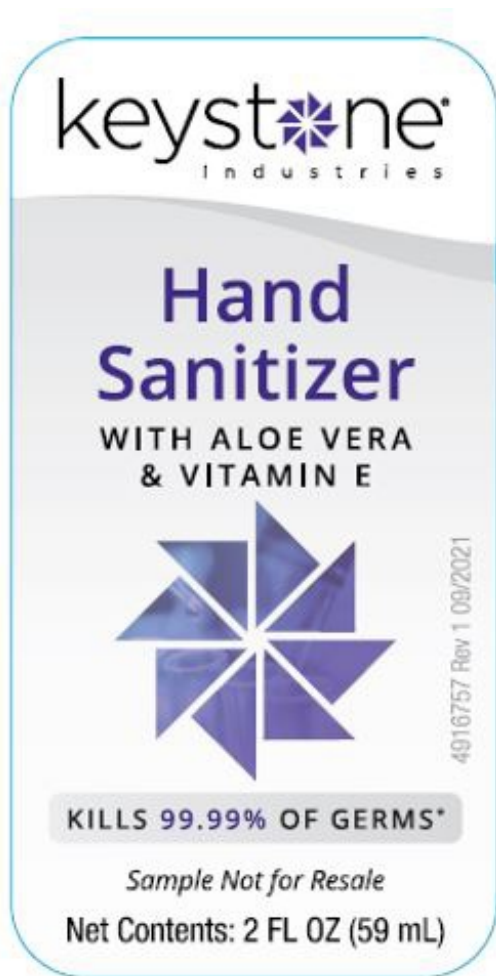
Other information

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HINGE AREA



HAND SANITIZER WITH ALOE VERA VITAMIN E

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-498
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)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SULISOBENZONE (UNII: 1W6L629B4K)	

GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)
GLYCERYL CAPRATE (UNII: 197M6VFC1W)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-498-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/03/2022	

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc (014769301)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	label(68400-498) , manufacture(68400-498)

Revised: 2/2022

Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc