

THICK HAND SANITIZER- 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 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, isopropyl myristate, carbomer, tocopheryl acetate, triethanolamine

Package Label - Principal Display Panel

THICK HAND SANITIZER

NOT FOR RESALE

FOR COLLEAGUE USE

**ALCOHOL ANTISEPTIC 70%
TOPICAL SOLUTION**
HAND SANITIZER NON-STERILE SOLUTION

Net Contents:
128 fl oz (3.78 L)

REF 4022055

Drug Facts	
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Warnings For external use only. Flammable. Keep away from heat or flame.	
Do not use <ul style="list-style-type: none">■ in children less than 2 months of age■ on open skin wounds	
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Directions <ul style="list-style-type: none">■ 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.	
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■ Keystone Industries
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Gibbstown, NJ 08027 USA
800.333.3131 keystoneindustries.com
Made in USA 4916653 04/2020

THICK HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-487
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
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

TROLAMINE (UNII: 9O3K93S3TK)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-487-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	label(68400-487) , manufacture(68400-487)

Revised: 1/2022

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