OPTIMIZE 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

Package Label - Principal Display Panel

ALCOHOL
ANTISEPTIC 70%
TOPICAL
SOLUTION
HAND SANITIZER
NON-STERILE
SOLUTION
Net Contents:
16 fl oz (473.2 ml)
REF 4022052

Drug Facts Active ingredient Purpose Alcohol 70%v/v 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 15-30°C (59-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F) Inactive ingredients water, glycerin, isopropyl myristate, carbomer, tocopheryl acetate, triethanolamine





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Made in USA

4916655 03/2020

OPTIMIZE THICK HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68400-486

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			
Ingred	lient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)			

WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 903K93S3TK)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:68400- 486-15	473.2 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		
Tinai				

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(68400-486), manufacture(68400-486)

Revised: 1/2022 Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc