

## **ADVANCED HAND SANITIZER- alcohol gel**

**The Sheek & Co Pty 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.*

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### **Advanced Hand Sanitizer**

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### **Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

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.

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### **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**

carbomer  
Deionized water  
glycerin  
triethanolamine

## Package Label - Principal Display Panel

<p><b>DRUG FACTS:</b></p> <table border="1"><tr><td><b>ACTIVE INGREDIENTS:</b> 75% ETHANOL</td><td><b>PURPOSE:</b> ANTISEPTIC</td></tr></table> <p><b>USES:</b> HAND SANITIZER THAT USES ETHANOL AS THE MAIN ACTIVE INGREDIENT, HAS A HAND SANITIZATION EFFECT, AND CAN ELIMINATE UP TO 99% OF COMMON BACTERIA</p> <p><b>WARNINGS:</b> FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME</p> <p><b>DO NOT USE:</b> IN CHILDREN LESS THAN 2 MONTHS OF AGE, ON OPEN WOUNDS</p> <p>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 YOUR LOCAL POISON CONTROL CENTER RIGHT AWAY</p>	<b>ACTIVE INGREDIENTS:</b> 75% ETHANOL	<b>PURPOSE:</b> ANTISEPTIC	<p><b>DIRECTIONS:</b> PLACE HAND 2CM UNDER AUTOMATED DISPENSER SENSOR FOR 1 SECOND, 2ML WILL DISPENSE ONTO HANDS AND THEN RUB TOGETHER AND ALLOW UP TO 1 MINUTE FOR HANDS TO DRY SUPERVISE CHILDREN UNDER 6 YEARS OF AGE WHEN USING THIS PRODUCT TO AVOID SWALLOWING</p> <p><b>OTHER INFORMATION:</b> PRODUCT VALIDITY IS 2 YEARS, CHECK THE BOTTLE FOR PRODUCTION DATE STORE BETWEEN 15-30C (59-86F) AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)</p> <p><b>INACTIVE INGREDIENTS:</b> GLYCERIN, CARBOMER, TRIETHANOLAMINE, DEIONIZED WATER</p> <p><b>SANITIZER MANUFACTURER:</b> SHENZHEN HYDROXY TECHNOLOGY CO.,LTD SHENZHEN, GUANGDONG PROVINCE, CHINA TEL: +86 21047606 NDC 0000000000000000</p>  
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**INACTIVE INGREDIENTS:**

GLYCERIN, CARBOMER, TRIETHANOLAMINE, DEIONIZED WATER

**SANITIZER MANUFACTURER:**

SHENZHEN HYDROXY TECHNOLOGY CO.,LTD  
SHENZHEN, GUANGDONG PROVINCE, CHINA  
TEL: +86 21047606  
NDC 000000000000000000



**ADVANCED HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:8 1462-10 1
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
WATER (UNII: 059QF0K00R)				
TROLAMINE (UNII: 9O3K93S3TK)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81462-101-01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2021	
2	NDC:81462-101-02	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2021	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/23/2021		

**Labeler** - The Sheek & Co Pty Ltd (747050340)

### Establishment

Name	Address	ID/FEI	Business Operations
SHENZHEN HYDROXY TECHNOLOGY CO.,LTD		552726183	manufacture(81462-101)

Revised: 1/2021

The Sheek & Co Pty Ltd