ADVANCED HAND SANITIZER GEL- alcohol gel Bozhou Xunhetang Biological Technology 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.

ADVANCED HAND SANITIZER GEL

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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

Water aloe
CARBOMER HOMOPOLYMER
Trolamine
Tocopheryl Acetate
(Vitamin E)

Package Label - Principal Display Panel







Drug Facts (continued)

Warnings For external use only

Flammable. Keep away from heat and flame

When using this product avoid contact with face, eyes, and broken skin. In case of eye contact, flush with plenty of water and seek medical advice.

Stop use and ask a doctor if irritation or redness develops

Drug Facts

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

Directions

- Wet hands thoroughly with product and rub into skin until dry
- Children under 6 years of age should be supervised by an adult when using this product

Inactive ingredients

water (aqua), glycerin, carbomer, aloe barbadensis leaf juice, tocopheryl acetate (Vitamin E)

ADVANCED HAND SANITIZER GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78254-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE (UNII: V5VD430 YW9)		
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 9O3K93S3TK)		

.ALPHA.-TO COPHEROL ACETATE, D- (UNII: A7E6112E4N)

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:78254-111-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	02/01/2021		

Labeler - Bozhou Xunhetang Biological Technology Co., Ltd. (554533192)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bozhou Xunhetang Biological Technology Co., Ltd.		554533192	manufacture (78254-111)	

Revised: 2/2021 Bozhou Xunhetang Biological Technology Co., Ltd.