# ASSURED INSTANT HAND SANITIZER- alcohol gel Gianthope Arts Product (Huizhou) Company Limited

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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## **Drug Facts**

## Active ingredient

Ethyl Alcohol 65%

#### **Purpose**

Antiseptic

#### $\Box$ Use

- Hand sanitizer to help decrease bacteria on the skin
- when water, soap & towel are not available
- Recommended for repeated use.

#### **Warnings**

#### For external use only.

#### Flammable,

Keep away from fire or flame

Do not apply around eyes, do not use in ears and mouth.

#### When using this product

lavoid contact with eyes. In case of contact, rinse eyes with water immediately

#### Stop use and ask a doctor if

redness or irritation develop and persist for more than 72 hours

#### Keep out of reach of children.

Children must be supervised in use of this product.

#### **Directions**

- Pump as needed into your palms and thoroughly spread on both hands
- Rub into skin until dry.

#### **Inactive ingredients**

Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance

#### Other information

• Store between 68-77 (20-25)

May discolor fabrics.

#### **Packaging**



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MANUFACTURED FOR & DISTRIBUTED BY Gianthope Company Limited (Hong Kong SAR, China) MADE IN CHINA



## ASSURED INSTANT HAND SANITIZER

alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78524-002

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 65 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:78524-002-01	$100\ mL$ in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020				
Marketing Information						
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not fi	nal part333E	06/02/2020				

# **Labeler** - Gianthope Arts Product (Huizhou) Company Limited (529306767)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Gianthope Arts Product (Huizhou) Company Limited		529306767	manufacture(78524-002)				

Revised: 6/2020 Gianthope Arts Product (Huizhou) Company Limited