

INSTANT HAND SANITISER- instant hand sanitiser gel
JinHua Denise Cosmetics 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.

INSTANT HAND SANITISER GEL

Active Ingredient(s)

Ethyl Alcohol 70%

Purpose

Antiseptic

Use

To decrease bacteria on the skin that could cause disease. When water, soap and towel are not available. Recommended for repeated use.

Warnings

For external use only hands. Flammable. Keep away from fire or flame. When using this product Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest. Stop use and ask a doctor if redness or irritation develop. condition persists for more than 72 hours. Keep out of reach of children
Children should be supervised by an adult when using this product. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

Do not inhale or ingest

When using this product Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if redness or irritation develop. condition persists for more than 72 hours.

Keep out of reach of children

Children should be supervised by an adult when using this product. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping. No rinsing required, For children under 6, use only under adult supervision. Not recommended for infants.

Other information

Store below 105°F (40 °C). May discolor certain fabrics. Harmful to wood finishes & plastics

Inactive ingredients

Water(Aqua), Triethanolamine, Carbomer, Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate (Vitamin E).

Package Label - Principal Display Panel



90.3*120MM

31.6*28.6MM

31.6*28.6MM



<p>Drug Facts</p> <p>Active Ingredient Ethyl Alcohol 70%.....Antiseptic</p> <p>Uses To decrease bacteria on the skin that could cause disease. When water, soap and towel are not available. Recommended for repeated use.</p> <p>Warnings For external use only hands. Flammable. Keep away from fire or flame.</p> <p>When using this product Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.</p> <p>Stop use and ask a doctor if redness or irritation develop. condition persists for more than 72 hours</p>	<p>Purpose Antiseptic</p> <p>Keep out of reach of children Children should be supervised by an adult when using this product. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Wet hands thoroughly with product and allow to dry without wiping. No rinsing required. For children under 6, use only under adult supervision. Not recommended for infants.</p> <p>Other information Store below 105oF (40°C). May discolor certain fabrics. Harmful to wood finishes & plastics</p>	<p>Inactive ingredients: Water(Aqua), Triethanolamine, Carbomer, Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate (Vitamin E).</p> <p>Manufactured by: Jinhua Denise Cosmetics Co.,Ltd. ADD NO.198, CaiHong Road, WuCheng District, JinHua City, ZheJiang, China.</p> <p>Made in China</p> <p>6973204930050</p>
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125.7*64.2MM

JDC COSMETICS

INSTANT HAND SANITISER GEL

KILLS 99.9% OF BACTERIA

**EASY APPLICATION
NON-STICKY
FAST DRYING
SOOTHING MINT**

70% Alcohol

INSTANT HAND SANITISER GEL

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Manufactured by:
Jinhua Denise Cosmetics Co.,Ltd.
ADD NO.198, CaiHong Road, WuCheng District, JinHua City, ZheJiang, China.

6 973204 930043
Made in China

NET WT. 3.5 fl. OZ. / 100 ml

INSTANT HAND SANITISER

instant hand sanitiser gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77663-006
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
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77663-006-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77663-006-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77663-006-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - JinHua Denise Cosmetics CO., LTD. (554532652)

Establishment

Name	Address	ID/FEI	Business Operations
JinHua Denise Cosmetics CO., LTD.		554532652	manufacture(77663-006)

Revised: 5/2020

JinHua Denise Cosmetics CO., LTD.