

SIMPLY DELICATE- alcohol gel
Yiwu Shining 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.

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, aminomethyl propanol, carbomer, isopropyl alcohol

Package Label - Principal Display Panel

60 mL NDC:74862-061-01



DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
ETHYL ALCOHOL 75% v/v.....	ANTIMICROBIAL
USES	
HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE WHEN SOAP AND WATER IS NOT AVAILABLE.	
WARNINGS	
FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY.	
DO NOT USE	
ON OPEN SKIN WOUNDS	
WHEN USING THIS PRODUCT	
DO NOT USE IN OR NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER.	
STOP USE AND ASK A DOCTOR IF	
IRRITATION OR RASH APPEARS AND LASTS.	
KEEP OUT OF REACH OF CHILDREN.	
IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.	
DIRECTIONS	
<ul style="list-style-type: none"> • PUT ENOUGH PRODUCT IN YOUR PALM TO COVER HANDS AND RUB HANDS TOGETHER UNTIL DRY. • CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT. 	
OTHER INFORMATION	
STORE BELOW 110 ° F (43 ° C). AVOID FREEZING AND EXCESSIVE HEAT. MAY DISCOLOR CERTAIN FABRICS OR SURFACES.	
INACTIVE INGREDIENTS	
WATER (AQUA), ISOPROPYL ALCOHOL, CARBOMER, AMINOMETHYL PROPANOL	
<p>ITEM 48-0006</p>  <p>7 45910 73660 0</p>	
<p>EXP:12/2022 MADE IN CHINA</p>	

SIMPLY DELICATE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74862-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	45 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74862-061-01	60 mL in 1 BOTTLE, DISPENSING; 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 - Yiwu Shining Cosmetics Co Ltd (543002719)

Revised: 5/2020

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