

HAND SANITIZER- alcohol liquid
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.

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.

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

Purified Water, Glycerin, Carbomer, Sodium Bicarbonate

Package Label - Principal Display Panel

DISTRIBUTED BY INTERNATIONAL TOLLFREE 877 313 4177 718-9138	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">DRUG FACTS</td> <td style="width: 30%;">PURPOSE</td> </tr> <tr> <td>ACTIVE INGREDIENT(S)</td> <td>ANTISEPTIC</td> </tr> <tr> <td>ETHYL ALCOHOL, 75% V/V</td> <td></td> </tr> <tr> <td>USE(S)</td> <td></td> </tr> <tr> <td>HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.</td> <td></td> </tr> <tr> <td>WARNINGS</td> <td></td> </tr> <tr> <td>FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.</td> <td></td> </tr> <tr> <td>DO NOT USE</td> <td></td> </tr> <tr> <td>• ON CHILDREN LESS THAN 2 MONTHS OF AGE</td> <td></td> </tr> <tr> <td>• ON OPEN SKIN WOUNDS</td> <td></td> </tr> <tr> <td>WHEN USING THIS PRODUCT KEEP OUT OF EYES, EARS AND MOUTH. IN CASE OF CONTACT WITH EYES, RINSE EYES THOROUGHLY WITH WATER.</td> <td></td> </tr> <tr> <td>STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH OCCURS. THESE MAY BE SIGNS OF A SERIOUS CONDITION.</td> <td></td> </tr> <tr> <td>KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.</td> <td></td> </tr> <tr> <td>DIRECTIONS</td> <td></td> </tr> <tr> <td>• PLACE ENOUGH PRODUCT ON HANDS TO COVER ALL SURFACES. RUB HANDS TOGETHER UNTIL DRY.</td> <td></td> </tr> <tr> <td>• SUPERVISE CHILDREN UNDER 6 YEARS OF AGE WHEN USING THIS PRODUCT TO AVOID SWALLOWING.</td> <td></td> </tr> <tr> <td>OTHER INFORMATION</td> <td></td> </tr> <tr> <td>• STORE BETWEEN 15-30C (59-86F)</td> <td></td> </tr> <tr> <td>• AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)</td> <td></td> </tr> <tr> <td>INACTIVE INGREDIENTS PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE</td> <td></td> </tr> </table>	DRUG FACTS	PURPOSE	ACTIVE INGREDIENT(S)	ANTISEPTIC	ETHYL ALCOHOL, 75% V/V		USE(S)		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		• ON 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.		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 PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE		 <h2 style="margin: 0;">Hand Sanitizer</h2> <p style="margin: 0;">75% Ethyl Alcohol</p> <hr/> <p style="margin: 0; color: #0070C0; font-weight: bold;">Kills germs on contact</p> <hr/> <p style="margin: 0;">Contributing to your wellness</p> <div style="background-color: #0070C0; color: white; padding: 5px; text-align: center; font-weight: bold; font-size: 1.2em;">16.9 FL OZ (500 mL)</div>
DRUG FACTS	PURPOSE																																									
ACTIVE INGREDIENT(S)	ANTISEPTIC																																									
ETHYL ALCOHOL, 75% V/V																																										
USE(S)																																										
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																																										
• ON 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.																																										
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 PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE																																										

DISTRIBUTED BY INTERNATIONAL TOLLFREE 877 313 4177 718-9138	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">DRUG FACTS</td> <td style="width: 30%;">PURPOSE</td> </tr> <tr> <td>ACTIVE INGREDIENT(S)</td> <td>ANTISEPTIC</td> </tr> <tr> <td>ETHYL ALCOHOL, 75% V/V</td> <td></td> </tr> <tr> <td>USE(S)</td> <td></td> </tr> <tr> <td>HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.</td> <td></td> </tr> <tr> <td>WARNINGS</td> <td></td> </tr> <tr> <td>FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.</td> <td></td> </tr> <tr> <td>DO NOT USE</td> <td></td> </tr> <tr> <td>• ON CHILDREN LESS THAN 2 MONTHS OF AGE</td> <td></td> </tr> <tr> <td>• ON OPEN SKIN WOUNDS</td> <td></td> </tr> <tr> <td>WHEN USING THIS PRODUCT KEEP OUT OF EYES, EARS AND MOUTH. IN CASE OF CONTACT WITH EYES, RINSE EYES THOROUGHLY WITH WATER.</td> <td></td> </tr> <tr> <td>STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH OCCURS. THESE MAY BE SIGNS OF A SERIOUS CONDITION.</td> <td></td> </tr> <tr> <td>KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.</td> <td></td> </tr> <tr> <td>DIRECTIONS</td> <td></td> </tr> <tr> <td>• PLACE ENOUGH PRODUCT ON HANDS TO COVER ALL SURFACES. RUB HANDS TOGETHER UNTIL DRY.</td> <td></td> </tr> <tr> <td>• SUPERVISE CHILDREN UNDER 6 YEARS OF AGE WHEN USING THIS PRODUCT TO AVOID SWALLOWING.</td> <td></td> </tr> <tr> <td>OTHER INFORMATION</td> <td></td> </tr> <tr> <td>• STORE BETWEEN 15-30C (59-86F)</td> <td></td> </tr> <tr> <td>• AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)</td> <td></td> </tr> <tr> <td>INACTIVE INGREDIENTS PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE</td> <td></td> </tr> </table>	DRUG FACTS	PURPOSE	ACTIVE INGREDIENT(S)	ANTISEPTIC	ETHYL ALCOHOL, 75% V/V		USE(S)		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		• ON 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.		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 PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE		 <h2 style="margin: 0;">Hand Sanitizer</h2> <p style="margin: 0;">75% Ethyl Alcohol</p> <hr/> <p style="margin: 0; color: #0070C0; font-weight: bold;">Kills germs on contact</p> <hr/> <div style="background-color: #0070C0; color: white; padding: 5px; text-align: center; font-weight: bold; font-size: 1.2em;">16.9 FL OZ (500 mL)</div>
DRUG FACTS	PURPOSE																																									
ACTIVE INGREDIENT(S)	ANTISEPTIC																																									
ETHYL ALCOHOL, 75% V/V																																										
USE(S)																																										
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																																										
• ON 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.																																										
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 PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE																																										



Hand Sanitizer

75% Ethyl Alcohol

Kills germs on contact

2 FL OZ (60 mL)

DRUG FACTS

ACTIVE INGREDIENT(S)	PURPOSE
ETHYL ALCOHOL 75% V/V.....	ANTISEPTIC

USE(S)
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

- ON 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.

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 PURIFIED WATER, GLYCERIN, CARBOMER, SODIUM BICARBONATE

MADE IN CHINA EXP 04/2023 XXXXX-IMYYO DISTRIBUTED BY TM INTERNATIONAL, TUCSON,AZ 85713 1-877-776-5136

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74862-275
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
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.03 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.74 mL in 100 mL
WATER (UNII: 059QF0KO0R)	23.7 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74862-275-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
2	NDC:74862-275-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
3	NDC:74862-275-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

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)**Registrant** - Yiwu Shining Cosmetics Co., Ltd. (543002719)**Establishment**

Name	Address	ID/FEI	Business Operations
Yiwu Shining Cosmetics Co., Ltd.		543002719	manufacture(74862-275)

Revised: 4/2020

Yiwu Shining Cosmetics Co., Ltd.