

HAND SANITIZER- alcohol spray
Zhongshan Sinno Cosmetic 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.

HAND SANITIZER SPRAY

ACTIVE INGREDIENT

ALCOHOL 80% v/v

PURPOSE

ANTISEPTIC

USES

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, RINSE EYES THOROUGHLY WITH WATER.

STOP USE AND 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 15-30°C (59-86°F)
- AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40°C (104°F)

INACTIVE INGREDIENTS

PURIFIED WATER USP, GLYCERIN, DENATONIUM BENZOATE

Drug Facts

Active ingredient *Purpose*
Alcohol 80% v/v.....Antiseptic

Uses 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, 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 15-30°C (59-86°F)
• Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients Purified Water USP, Glycerin, Denatonium Benzoate

WORLD'S LEADING
HYGIENE SOAP™



HAND SANITIZER

ALCOHOL ANTISEPTIC 80%

Topical, Non-sterile solution

500mL 16.9 FL OZ e

MANUFACTURED BY/ DIPRODUKSI OLEH: ZHONGSHAN SINNO COSMETIC CO., LTD. NO.1, WANMEI ROAD, SOUTH CHINA MODERN CHINESE MEDICINE PARK, NANLANG TOWN, ZHONGSHAN CITY, GUANGDONG PROVINCE, PRC. MADE IN PRC. FOR UNILEVER ASIA PRIVATE LIMITED, SINGAPORE. DISTRIBUTED BY: US USA MIDWAY IMPORTING INC. HOUSTON, TX. TEL +1 713 802 9362. CA THAI UNITED FOOD COMPANY LTD., BURNABY, BC.

*CALCULATION BASED ON NIELSEN VOLUME SALES INFORMATION FOR THE TOTAL MARKETS (42 COUNTRIES). LATEST 12 MONTHS. DETAILS AVAILABLE ON REQUEST.

! DANGER
1. HIGHLY FLAMMABLE LIQUID AND VAPOUR
2. CAUSES SERIOUS EYE IRRITATION
3. TOXIC TO AQUATIC LIFE

ONLINE CODING
W150mL.H50m



500mL
16.9 FL OZ e



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HAND SANITIZER

alcohol spray

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75497-10 1 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DENATONIUM BENZOATE (UNII: 4YK5Z54AT2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------------|---|----------------------|--------------------|
| 1 | NDC:75497-10-11 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/23/2020 | |
| 2 | NDC:75497-10-12 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 04/23/2020 | |
| 3 | NDC:75497-10-13 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/23/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
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|-------------------------|----------|------------|--|
| OTC monograph not final | part333E | 04/23/2020 | |
|-------------------------|----------|------------|--|

Labeler - Zhongshan Sinno Cosmetic Co.,Ltd. (543048039)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Zhongshan Sinno Cosmetic Co.,Ltd. | | 543048039 | manufacture(75497-101) |

Revised: 5/2020

Zhongshan Sinno Cosmetic Co.,Ltd.