

HAND SANITIZER- alcohol gel
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 GEL

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, CARBOMER, AMINOMETHYL PROPANOL, DENATONIUM BENZOATE

Drug Facts

| Active Ingredient | Purpose |
|-------------------|------------|
| Alcohol 80% v/v | Antiseptic |

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: • 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 (59-85°F) • Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients: Purified Water USP, Carbomer, Anisomethyl Propanol, Denatonium Benzoate

WORLD'S LEADING
HYGIENE SOAP*



HAND SANITIZER
ALCOHOL ANTISEPTIC 80%

Topical Gel

50mL 1.69 FL OZ e

MANUFACTURED BY/ DIPRODUKSI OLEH:
ZHONGSHAN SINHO 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 8382. GA 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.



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

50mL
1.69 FL OZ e

ONLINE CODING
W15mm x H5mm



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HAND SANITIZER

alcohol gel

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75497-102 |
|-------------------------|----------------|--------------------|---------------|
| 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: 059QF0K00R) | |
| CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| DENATONIUM BENZOATE (UNII: 4YK5Z54AT2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75497-102-11 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/23/2020 | |
| 2 | NDC:75497-102-12 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 04/23/2020 | |
| 3 | NDC:75497-102-13 | 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 |
|-------------------------|--|----------------------|--------------------|
| 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(75497-102) |

Revised: 5/2020

Zhongshan Sinno Cosmetic Co.,Ltd.