

COTTON CANDY HAND SANITIZER- alcohol liquid
ENCHANTE ACCESSORIES INC.

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.

Drug Fact

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin that could cause disease

Recommended for repeated use

For external use only-hands

Flammable. Keep away from heat and flame

Keep out of eyes. In case of contact with eyes, flush thoroughly with water

Avoid contact with broken skin

Do not inhale or ingest. Stop use and ask a doctor if skin irritation develops

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision
- Not recommended for infants

Other Information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Inactive Ingredient:

Aqua, Carbomer, Triethanolamine, Parfum, Disodium EDTA, may contain D and C Red No. 33, FD and C Red No. 40, FD and C Blue No. 1, FD and C Yellow No. 5, FD and C Yellow No. 6.



FRONT LABEL



BACK LABEL



BACK LABEL



BACK LABEL

COTTON CANDY HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50563-180 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 62 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:50563-180-01 | 29 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
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|-------------------------|----------|------------|--|
| OTC monograph not final | part333E | 10/02/2014 | |
|-------------------------|----------|------------|--|

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Registrant - Zhejiang Aidi Cosmetics Co., Ltd. (530876820)

| Establishment | | | |
|-----------------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Zhejiang Aidi Cosmetics Co., Ltd. | | 530876820 | manufacture(50563-180) |

Revised: 10/2014

ENCHANTE ACCESSORIES INC.