

RUE21 APPLE SPICE ANTIBACTERIAL 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 63%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin

For external use only

When using this product: Keep out of eyes. Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops

Keep out of reach of children. If swallowed, get medical assistance.

Directions

- Rub a dime size drop into hands

Other Information:

- Do not store above 105F
- May discolor some fabrics

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.

lab





Drug Facts
(continued)

Stop use and ask a doctor

- if skin irritation develops

When using this product

- Keep out of eyes
- Do not ingest

Keep out of reach of children

If swallowed, get medical assistance

Directions

- Rub a dime size drop into hands

Drug Facts
(continued)

Other information

- Do not store above 105°F.
- May discolor some fabrics.

Inactive ingredients

Aqua,
Carbomer, Disodium EDTA, Parfum, Triethanolamine. May Contain: Blue 1, Yellow 5, Yellow 6, Red 33, Red 40.

Not tested on animals.
Designed in the USA, Made in China.
Formulated exclusively and distributed by:
Enchanté Accessories Inc. NY, NY 10016

RUE21 APPLE SPICE ANTIBACTERIAL HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50563-138 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 63 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------------|
| WATER (UNII: 059QF0KO0R) | 33.79985 mL in 100 mL |
| 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:50563-138-01 | 29 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333E | 07/09/2013 | |

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(50563-138) |