### RUE21 SUGAR COOKIE 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.

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### **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.

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# **Drug Facts** (continued)

## Stop use and ask a doctor

if skin irritation develops

## When using this product

- Keep out of eyesDo 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

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-135

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

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	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 DISO DIUM (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)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50563-135-01	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(50563-135)	

Revised: 7/2013 ENCHANTE ACCESSORIES INC.