

RUE21 OCEAN BREEZE 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

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- 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 OCEAN BREEZE ANTIBACTERIAL HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-139
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:50563-139-01	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(50563-139)