RUE 21 SUGAR COOKIE ANTI BACTERIAL 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 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.





Antiseptic

Uses

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Warnings
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Drug Facts (continued)

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if skin irritation develops

When using this product

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- Do not ingest

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If swallowed, get medical assistance

Directions

 Rub a dime size drop into hands

Drug Facts (continued)

Other



 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

RUE 21 SUGAR COOKIE ANTI BACTERIAL HAND SANITIZER

alcohol liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-169		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	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: 1753WB2F1M)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				

Packaging						
#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date
1	NDC:50563-169-01	29 mL in 1 BOTTLE				
Marketing Information						
	Marketing Category	Application Number or Monogr	raph Citation	Marketing Star	t Date	Marketing End Date
O'	CC monograph not final	part333E		11/09/2013		

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(50563-169)	

Revised: 11/2013 ENCHANTE ACCESSORIES INC.