RUE 21 APPLE 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.





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Warnings For external use

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Drug Facts (continued)

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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 APPLE ANTI BACTERIAL HAND SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:50563-168	
Route of Administration	TOPICAL	DEA Schedule		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (ALCOHOL)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER	33.79985 mL in 100 mL		
CARBOMER COPOLYMER TYPE A			
TROLAMINE			
EDETATE DISO DIUM			
D&C RED NO. 33			
FD&C BLUE NO. 1			
FD&C YELLOW NO.5			
FD&C YELLOW NO.6			
FD&C RED NO. 40			

Packaging					
# Item Code	Package Description	Marketing Start Date		Marketing End Date	
1 NDC:50563-168-01	29 mL in 1 BOTTLE				
Marketing Information					
Marketing Category	Application Number or Monog	raph Citation	Marketing Start Dat	e Marketing End Date	
OTC 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(50563-168)	

Revised: 11/2013 ENCHANTE ACCESSORIES INC.