

CHARLIE GIRL GRAPE 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:

Deionized Water, Triethanolamine, Carbomer, 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





Antiseptic

Uses

- To decrease bacteria on the skin

Warnings

For external use only.



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

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

CHARLIE GIRL GRAPE ANTIBACTERIAL HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-131
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)	36.109948 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: HBR47K3TBD)	
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:50563-131-01	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	05/09/2013	

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(50563-131)

Revised: 5/2013

ENCHANTE ACCESSORIES INC.