

CREAMSICLE 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 62%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin that could cause disease

Recommended for repeated use

For external use only-hands

Flammable. Keep away from heat and flame

Keep out of eyes. In case of contact with eyes, flush thoroughly with water

Avoid contact with broken skin

Do not inhale or ingest. Stop use and ask a doctor if skin irritation develops

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision
- Not recommended for infants

Other Information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

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.



FRONT LABEL



BACK LABEL



BACK LABEL



BACK LABEL

CREAMSICLE HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-184
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
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:50563-184-01	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	10/02/2014	
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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(50563-184)

Revised: 10/2014

ENCHANTE ACCESSORIES INC.