PINK GRAPEFRUIT SCENTED HAND SANITIZER ANTI-BACTERIAL - benzethonium chloride 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

Benzethonium Chloride 0.13%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin that could cause diseases

Recommended for repeated use

For external use only

Flammable

When using this product: 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 right away

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:

Alcohol, Carbomer, Fragrance, PEG-40 Hydrogenated Castor Oil, Triethanolamine, Tocopheryl Acetate, may contain D and C Red No. 33, D 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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PINK GRAPEFRUIT

PINK GRAPEFRUIT SCENTED HAND SANITIZER ANTI-BACTERIAL

benzethonium chloride liquid

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-112			
Route of Administration	TOPICAL					

Active Ingredient/Act	tive Moiety						
	Ingredient Name		Basis o	f Streng	gth	Strength	
BENZETHO NIUM CHLO RI UNII:1VU15B70BP)	RIDE (UNII: PH41D05744) (BENZETHONIUM - BENZETHONIUM CHLORIDE				0.13 g in 100 mL		
Inactive Ingredients							
	Ingredient Na	me				Strength	
WATER (UNII: 059QF0KO0R)							
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)							
TROLAMINE (UNII: 903K93S3TK)							
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: I753WB2F1M)							
ALCOHOL (UNII: 3K9958V90M)							
FD&C YELLOW NO.6 (UNII: H77VEI93A8)							
FD&C RED NO. 40 (UNII: WZB9127XOA)							
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)							
Packaging							
# Item Code	Package Description	Marketing Start Date Market		rketing	ting End Date		
1 NDC:50563-112-01	236 mL in 1 BOTTLE						
Marketing Information							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date		
OTC monograph not final	part333E		06/18/2012				

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

Revised: 6/2012

ENCHANTE ACCESSORIES INC.