

OCEAN MIST 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.

lab



Drug Facts

Active ingredient	Purpose
Benzethonium Chloride 0.13%	Antiseptic

Use to decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings
For external use only

Flammable
When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if condition worsens or does not improve after regular use

Keep out of reach of children. If swallowed, get medical help 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 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.

Inactive ingredients
Alcohol, Carbomer, Fragrance, PEG-40 Hydrogenated Castor Oil, Triethanolamine, Tocopheryl Acetate, Water.
May Contain: Blue 1, Red 33, Red 40, Yellow 5, Yellow 6.

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Not tested on animals. For adult use only.
Designed in the USA
Made in China
Formulated exclusively and distributed by:
Enchanté Accessories Inc.
NY, NY 10016

OCEAN MIST

OCEAN MIST SCENTED HAND SANITIZER ANTI-BACTERIAL

benzethonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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)	
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	Marketing End Date
1	NDC:50563-109-01	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.