APRIL BATH AND SHOWER CUCUMBER MELON SCENTED HAND SANITIZER ANTI-BACTERIAL - chloroxylenol 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

Chloroxylenol 0.5%

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:

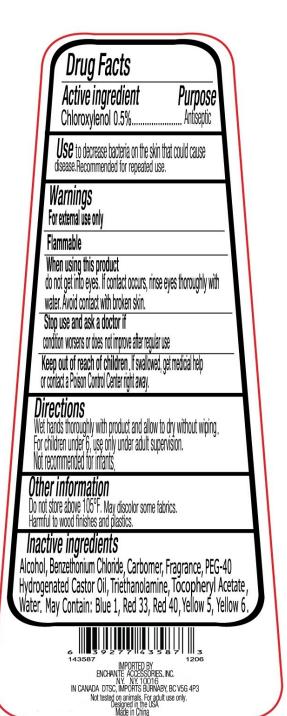
- Do not store above 105F
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive Ingredient:

Benzethonium Chloride, 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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APRIL BATH AND SHOWER CUCUMBER MELON SCENTED HAND SANITIZER ANTI-BACTERIAL

chloroxylenol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.5 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
TROLAMINE (UNII: 9O3K93S3TK)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
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)		
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744)		

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-113-01	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.