

VANILLA CUPCAKE ANTI BACTERIAL FOAMING HAND - triclosan liquid

Five Below

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

Triclsan 0.3%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin

For external use only

When using this product: Keep out of eyes. Do not 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, Sodium Laurel Sulfate, Cocamide MEA, Fragrance, Citric Acid, Disodium EDTA, Methylisothiazolinone, Methylchloroisothiazolinone, 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



Vanilla Cupcake

VANILLA CUPCAKE ANTI BACTERIAL FOAMING HAND

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59021-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	82.009948 g in 100 mL
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
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)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59021-005-01	225 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/13/2013	

Labeler - Five Below (095446659)

Registrant - Zhejiang Aidi Cosmetics Co., Ltd. (530876820)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Aidi Cosmetics Co., Ltd.		530876820	manufacture(59021-005)

Revised: 4/2013

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