CANDY APPLE ANTI BACTERIAL FOAMING HAND - triclos an 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

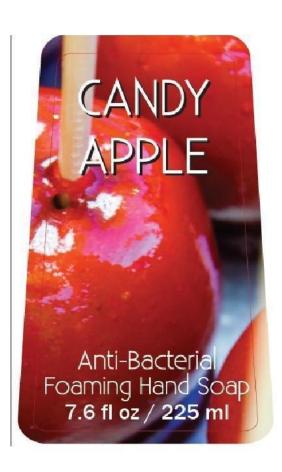
Other Information:

- 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





Candy Apple

CANDY APPLE ANTI BACTERIAL FOAMING HAND

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59021-001
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: 059QF0KO0R)	82.009948 g in 100 mL			
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)				
COCO MONOETHANOLAMIDE (UNII: C80684146D)				
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)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59021-001-01	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	04/12/2013		

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(59021-001)	

Revised: 4/2013 Five Below