

DEODORANT - triclocarban soap
Shanghai Kangyi Tourism Products Co., Ltd.

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.

MegaFresh Deodorant Soap

Active Ingredient

Triclocarban 0.29%

Antibacterial

Use

For hand washing to decrease bacteria on the skin. Recommended for repeated use.

WARNINGS

For external use only. Keep out of reach of children.

Children should use only this product under adult supervision.

Not edible. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Avoid contact with broken skin.

When using this product, avoid contact with eyes. In case of eye contact, immediately flush eyes with water, call a doctor.

keep out of reach of children

Directions

Wet hands. Apply to hands. Scrub thoroughly. Rinse.

Recommended for repeated use.

Inactive ingredients

Sodium Palmate, Sodium Cocoate, Calcium Carbonate, Water, Glycerin, Fragrance, Sodium Chloride, Edetate Sodium, Etidronic Acid, Titanium Dioxide.

MegaFresh[®]

ANTIBACTERIAL DEODORANT SOAP

Drug Facts	Purpose	Drug Facts (continued)
Active ingredients Triclocarban(0.29%).....Antibacterial		When using this product , avoid contact with eyes. In case of eye contact, immediately flush eyes with water, call a doctor.
Uses For hand washing to decrease bacteria on the skin. Recommended for repeated use.		Directions Wet hands. Apply to hands.Scrub thoroughly Rinse. Recommended for repeated use.
Warning For external use only. Keep out of reach of children. Children should use only this product under adult supervision. Not edible. In case of accidental ingestion, seek professional assistance, or contact a Poison Control Center immediately. Avoid contact with broken skin.		Inactive Ingredients Sodium Palmate,Sodium Cocoate,Calcium Carbonate, Water, Glycerin,Fragrance,Sodium Chloride, Edetate Sodium, Etidronic Acid,Titanium Dioxide. Manufactured exclusively for American Amenities,Inc. Woodinville, WA 98072 Made in China

DEODORANT

triclocarban soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53507-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLO CARBAN (UNII: BGG1Y1ED0 Y) (TRICLOCARBAN - UNII:BGG1Y1ED0 Y)	TRICLOCARBAN	0.29 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Sodium Palmate (UNII: S0A6004K3Z)	
Sodium Cocoate (UNII: R1TQH25F4I)	
Calcium Carbonate (UNII: H0G9379FGK)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetate Sodium (UNII: MP1J8420LU)	
Etidronic Acid (UNII: M2F465ROXU)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53507-001-01	10 g in 1 PACKAGE		
2	NDC:53507-001-02	13 g in 1 PACKAGE		
3	NDC:53507-001-03	20 g in 1 PACKAGE		
4	NDC:53507-001-04	30 g in 1 PACKAGE		
5	NDC:53507-001-05	35 g in 1 PACKAGE		
6	NDC:53507-001-06	54 g in 1 PACKAGE		
7	NDC:53507-001-07	60 g in 1 PACKAGE		
8	NDC:53507-001-08	75 g in 1 PACKAGE		
9	NDC:53507-001-09	85 g in 1 PACKAGE		
10	NDC:53507-001-10	14.17 g in 1 PACKAGE		
11	NDC:53507-001-11	21.26 g in 1 PACKAGE		
12	NDC:53507-001-12	28.35 g in 1 PACKAGE		
13	NDC:53507-001-13	42.52 g in 1 PACKAGE		
14	NDC:53507-001-14	71 g in 1 PACKAGE		
15	NDC:53507-001-15	99 g in 1 PACKAGE		
16	NDC:53507-001-16	113 g in 1 PACKAGE		
17	NDC:53507-001-17	142 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/24/2012	

Labeler - Shanghai Kangyi Tourism Products Co., Ltd. (531054513)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Kangyi Tourism Products Co., Ltd.		531054513	manufacture(53507-001)

Revised: 5/2014

Shanghai Kangyi Tourism Products Co., Ltd.