ANTIBACTERIAL OCEAN FRESH- triclocarban soap International Wholesale, 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.

Active Ingredient

Triclocarban 0.30%

Purpose

Antibacterial

Uses

- Helps reduce bacteria on the skin that could cause disease.
- Recommended for repeated use

Warnings

For external use only

When using this product:

do not use in or near the eyes. In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if:

irritation and redness develops and lasts more than 72 hours.

Keeps out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet bar with water
- Lather vigorously and wash skin
- Rinse and dry thoroughly

Other Information

- Store below 110° F (43° C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

Sodium Cocoate, Sodium Palmate, Water, Glycerin, Sodium Chloride, Titanium Dioxide, BHT, Fragrance

Package Display





ANTIBACTERIAL OCEAN FRESH

triclocarban soap

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52862-130

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthTRICLO CARBAN (UNII: BGG1Y1ED0 Y) (TRICLO CARBAN - UNII: BGG1Y1ED0 Y)TRICLO CARBAN0.3 g in 100 g

Inactive Ingredients Ingredient Name Strength SODIUM CO CO ATE (UNII: R1TQH25F4I) SODIUM PALMATE (UNII: S0 A6004K3Z) WATER (UNII: 059QF0 KOOR) GLYCERIN (UNII: PDC6A3C0OX) SODIUM CHLORIDE (UNII: 451W47IQ8X) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K)

Product	Charac	teristics
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Color white Score no score

Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:52862-130-03	3 in 1 PACKET	07/15/2015			
ı	1	90 g in 1 CARTON; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/15/2015		

Labeler - International Wholesale, Inc. (161872676)

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