

DALAN OCEAN BREEZE ANTIBACTERIAL DEODORANT - triclosan soap

Dalan Kimya Endustri A.S.

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.

dalan OCEAN BREEZE antibacterial soap deodorant soap

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Active Ingredient / Purpose

Triclosan 0.1% Antibacterial

Uses

Antibacterial Soap

Warnings

For external use only

Do not use

- this product on infants under 6 months of age.
- in the eyes. If contact occurs, flush eyes with water.

Stop use and ask a doctor if irritation and redness develops or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

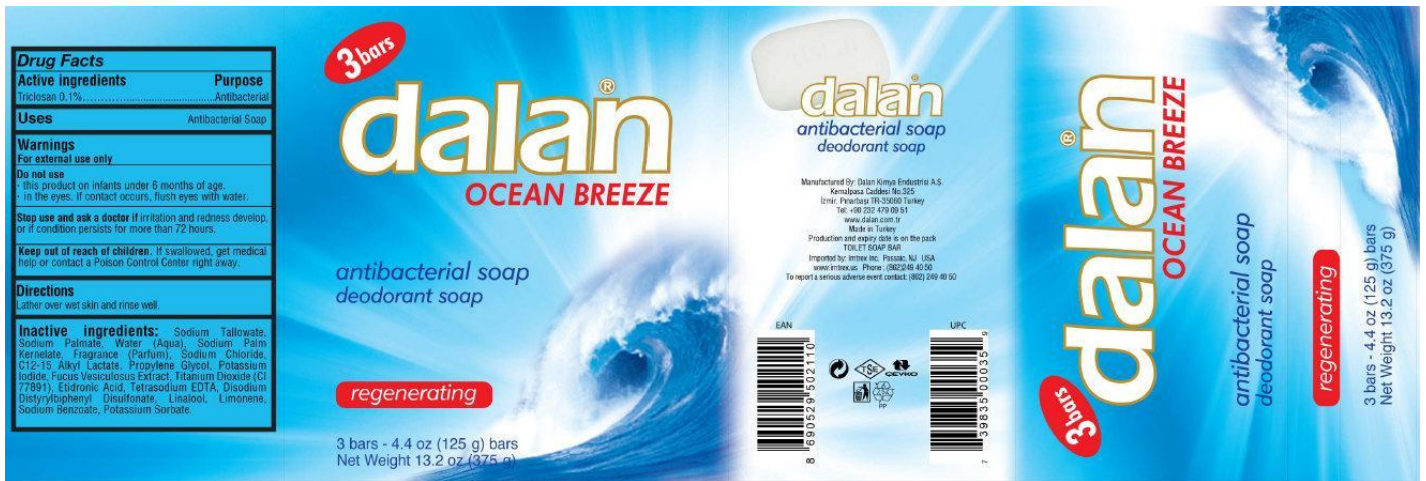
Directions

Lather over wet skin and rinse well

Inactive Ingredients:

Sodium Tallowate, Sodium Palmate, Water (Aqua), Sodium Palm Kernelate, Fragrance, Sodium Chloride, Alkyl Lactate, Propylene Glycol, Potassium Iodide, Fucus Vesiculosus Extract, Titanium Dioxide, Etidronic Acid, Linalool, Limonene, Sodium Benzoate, Potassium Sorbate.

Representative Labeling



DALAN OCEAN BREEZE ANTIBACTERIAL DEODORANT

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51209-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM TALLO WATE, BEEF (UNII: 07RIK6QMEW)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
WATER (UNII: 059QF0K00R)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

ETIDRONIC ACID (UNII: M2F465ROXU)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51209-003-00	3 in 1 BOX		
1		90 g in 1 PACKAGE		
2	NDC:51209-003-01	3 in 1 BOX		
2		125 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/06/2014	

Labeler - Dalan Kimya Endustri A.S. (566219285)

Establishment

Name	Address	ID/FEI	Business Operations
Dalan Kimya Endustri A.S.		566219285	manufacture(51209-003)

Revised: 2/2015

Dalan Kimya Endustri A.S.