

ANTI-BACTERIAL BUBBLE GUM HAND - triclosan soap
BB17, LLC

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:

Triclosan 0.3%

Purpose

Antimicrobial

KILLS MORE THAN 99.99% OF COMMON GERMS

FOR EXTERNAL USE ONLY. DO NOT USE IN THE EYES.

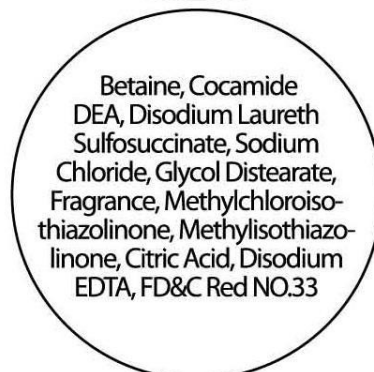
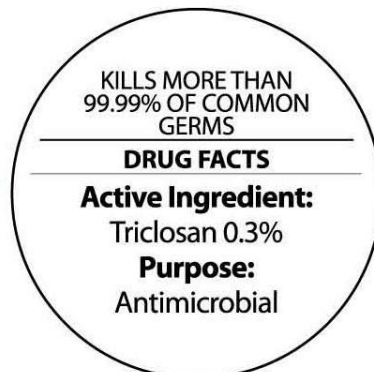
DISCONTINUE USE IF IRRITATION AND REDNESS DEVELOP. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS, CONSULT A DOCTOR.

Keep out of reach of children. CHILDREN CAN ONLY USE THIS PRODUCT WITH ADULT SUPERVISION.

DIRECTIONS:

WET HANDS. APPLY PALMFUL TO HANDS. SCRUB THOROUGHLY. RINISE.
RECOMMENDED FOR REPEATED USE.

INACTIVE INGREDIENTS:Water, Sodium Alkyl Ether Sulphate, Ammonium Lauryl Sulphate, Cocamidopropyl Betaine, Cocamide DEA, Disodium Laureth Sulfosuccinate, Sodium Chloride, Glycol Distearate, Fragrance, Methylchloroiso-thiazolinone, Methylisothiazolinone, Citric Acid, Disodium EDTA, FD&C Red NO. 33



ANTI-BACTERIAL BUBBLE GUM HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53603-2014
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)	
SODIUM C12-15 PARETH-3 SULFATE (UNII: 19Q4RW8UWP)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53603-2014-8	236.6 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/30/2012	

Labeler - BB17, LLC (828378294)

Revised: 11/2012

BB17, LLC