

DG BODY ANTIBACTERIAL- triclosan liquid
DOLGENCORP 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.

DRUG FACTS

ACTIVE INGREDIENT

TRICLOSAN 0.15%

PURPOSE

ANTIBACTERIAL

USES

FOR HAND WASHING TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS MORE THAN 7 DAYS.

KEEP OUT OF REACH OF CHILDREN

IF INGESTED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

APPLY A SMALL AMOUNT ONTO WET HANDS. WORK INTO A RICH LATHER AND RINSE CLEAN.

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM C14-16 OLEFIN SULFONATE, LAURAMIDE DEA, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, FRAGRANCE (PARFUM), CITRIC ACID, DMDM HYDANTOIN, GLYCERIN, TETRASODIUM EDTA, POLYQUATERNIUM-7, HYDROLYZED SILK PROTEIN, ALOE BARBADENSIS LEAF JUICE, RED 40 (CI 16035), YELLOW 5 (CI 19140), RED 33 (CI 17200).

LABEL COPY



DG BODY ANTIBACTERIAL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10 -296
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.15 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
SILK, ACID HYDROLYZED (1000 MW) (UNII: 8549W658QV)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-296-08	222 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/04/2012		

Labeler - DOLGENCORP INC. (068331990)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture