

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

HELPS REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

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

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY ONTO WET HANDS, WORK INTO A LATHER. RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, SODIUM CHLORIDE, COCAMIDOPROPYL HYDROXYSULTAINE, GLYCERIN, FRAGRANCE (PARFUM), POLYQUATERNIUM-7, PPG-2 HYDROXYETHYL COCO/ISOSTEARAMIDE, DMDM HYDANTOIN, TETRASODIUM EDTA, CITRIC ACID, YELLOW 5 (CI 19140), RED 4 (CI 14700).

LABEL COPY



DG BODY ANTIBACTERIAL			
triclosan liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-29 4
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TRICLOSAN (UNII: 4NM50 39 Y5X) (TRICLOSAN - UNII:4NM50 39 Y5X)		TRICLOSAN	0.15 mL in 100 mL
Inactive Ingredients			

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-294-08	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	05/02/2012	

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

Revised: 5/2012

DOLGENCORP INC.