ANTIBACTERIAL - triclosan liquid
FRED'S 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 0.115%

PURPOSE

ANTIBACTERIAL

USES

HELPS ELIMINATE GERMS ON HANDS.

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 DOCTOR IF

IRRITATION AND REDNESS DEVELOP.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

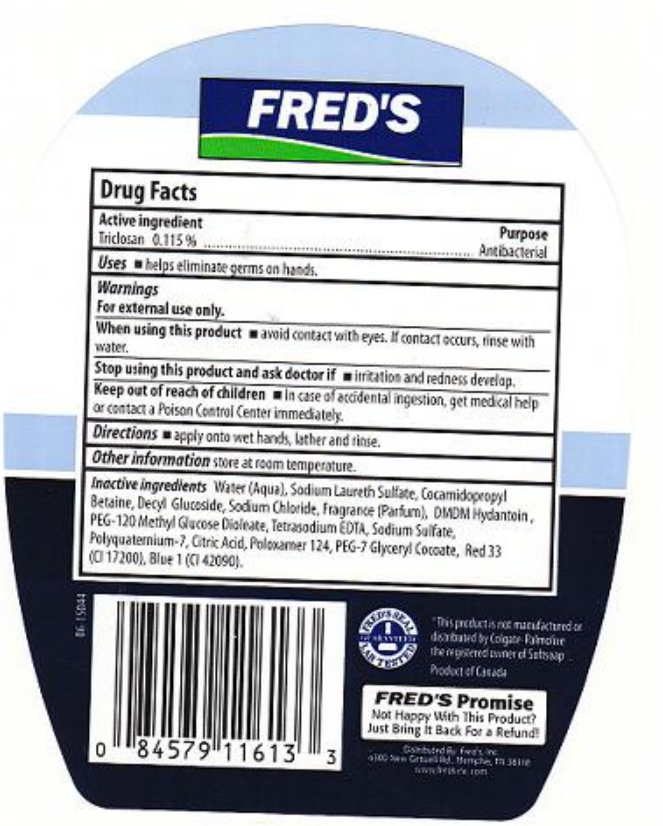
APPLY ONTO WET HANDS, LATHER, AND RINSE.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, DECYL GLUCOSIDE, SODIUM CHLORIDE, FRAGRANCE, DMDM HYDANTOIN, PEG-120 METHYL GLUCOSE DIOLEATE, TETRASODIUM EDTA, SODIUM SULFATE, POLYQUATERNIUM-7, CITRIC ACID, POLOXAMER 124, PEG- 7 GLYCERYL COCOATE, RED 33 (CI 17200), BLUE 1 (CI 42090).



ANTIBACTERIAL

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-720
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.115 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
POLOXAMER 124 (UNII: 1S66E28KXA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-720-08	222 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/26/2011	

Labeler - FRED'S INC (005866116)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 7/2011 FRED'S INC