ANTIBACTERIAL CUCUMBER MELON- triclos an liquid HYVEE 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 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 AND REDNESS DEVELOP.

KEEP OUT REACH OF CHILDREN

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

DIRECTIONS

PUMP ONTO WET HANDS. WORK INTO A LATHER RINSE THROUGHLY.

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, CITRIC ACID, SODIUM SULFATE, TETRASODIUM EDTA, BENZOPHENONE-4, POLYQUATERNIUM-7, PEG-7 GLYCERYL COCOATE, YELLOW 5 (CI 19140), BLUE 1 (CI 42090).



ANTIBACTERIAL CUCUMBER MELON

triclosan liquid

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Prod	ист	INIO	rmation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42507-295

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of 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: BPV390 UAPO)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)				
DMDM HYDANTO IN (UNII: BYR0546 TOW)				
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)				
EDETATE SO DIUM (UNII: MP1J8420LU)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
SULISOBENZONE (UNII: 1W6L629B4K)				
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)				
GLYCERYL CO CO ATE (UNII: WVK1CT5994)				

ED & C	VELLO	W NO	E (LINIII)	I753WB2F1M)
FD&C	YELLU	W NU.	o (UNII:	1/33WB2F1W]

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:42507-295-08	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	06/09/2011		

Labeler - HYVEE INC (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment					
Name	Address	ID/FEI	Business Operations		
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture		

Revised: 6/2011 HYVEE INC