

ANTIBACTERIAL FOAMING- triclosan solution
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 BOX

ACTIVE INGREDIENT

TRICLOSAN 0.46%

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 WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IF IRRITATION AND REDNESS DEVELOP

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

APPLY ONTO DRY HANDS, WORK INTO LATHER. RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM XYLENE SULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE (PARFUM), DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYL PARABEN, PROPYL PARABEN, RED 4 (CI 14700), YELLOW 5 (CI 19140)

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ANTIBACTERIAL FOAMING			
triclosan solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-177
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.46 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0KO0R)		
	SODIUM XYLENESULFONATE (UNII: G4LZF950UR)		
	DIPROPYLENE GLYCOL (UNII: E107L85C40)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)		
	AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)		
	COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)		

POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-177-08	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	08/08/2011	

Labeler - HYVEE INC (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 8/2011

HYVEE INC