

ANTIMICROBIAL CLEANSER- chloroxyleneol soap
AFFLAB, Affiliated Laboratories, a Division of AFFLINK

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.

Active ingredient

Chloroxyleneol 0.3% w/w

Purpose

Antimicrobial

Keep out of reach of children

If swallowed, get medical attention or contact a poison control center immediately.

Uses

- Handwash to help decrease bacteria on the skin. Recommended for repeated use.

Warnings

For external use only

When using this product do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Directions

□ wet hands □ apply small amount of product and work into a lather □ rinse well and dry hands completely

Inactive ingredients:

Water, Sodium laureth sulfate, Sodium chloride, Cocamidopropyl betaine, PEG-120 Methyl glucose dioleate, DMDM hydantoin, Linear alcohol ethoxylate, Propylene glycol, Methylchloroisoithiazolinone, Methylisothiazolinone, Fragrance, Tetrasodium EDTA, Isopropyl myristate, Citric acid, FD&C Red #40, FD&C Red #33.

PRINCIPAL DISPLAY PANEL - 3785 mL Bottle Label

AFFLAB™

Antimicrobial Lotion Cleanser

Antimicrobiano Loción Limpiadora

CAUTION/PRECAUCION

Keep out of reach of children.

See back panel for further precautions and first aid.

Net Contents 1 U.S. GALLON (3.78 Liters) Instrucciones Atras

All Hands™ Hand Care Products

Antimicrobial Lotion Cleanser

ANTIMICROBIAL CLEANSER			
chloroxylenol soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54057-524
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		CHLOROXYLENOL	3 g in 1000 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0K00R)			
C9-11 PARETH-6 (UNII: KCE0V8JT7W)			
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)			
DMDM HYDANTOIN (UNII: BYR0546TOW)			
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)			
EDETATE SODIUM (UNII: MP1J8420LU)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
Product Characteristics			
Color	pink	Score	
Shape		Size	

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54057-524-28	3785 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	10/16/2013		

Labeler - AFFLAB, Affiliated Laboratories, a Division of AFFLINK (023121150)

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