

## **GENERATIONS ANTIMICROBIAL- chloroxylenol soap**

### **Cole Papers**

*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.*

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### **Active ingredient**

Chloroxylenol 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, Methylchloroisothiazolinone, Methylisothiazolinone, Fragrance, Tetrasodium EDTA, Isopropyl myristate, Citric acid, FD&C Red #40, FD&C Red #33.

## **PRINCIPAL DISPLAY PANEL - 3785 mL Bottle Label**

### **GENERATIONS**

**The Power of Experience Since 1918**

### **Antimicrobial Lotion Soap**

**Keep out of reach of children.**

**CAUTION:**

**See back panel for additional precautions.**

# NET CONTENTS: 1 U.S. GALLON (3.78 LITERS)

Drug Facts	
<b>Active Ingredient</b> Chloroxylenol 0.3%	<b>Purpose</b> Antimicrobial
<b>Uses</b> ■ Handwash to help decrease bacteria on the skin. Recommended for repeated use.	
<b>Warnings</b> 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. Keep out of reach of children. If swallowed, get medical attention or contact a Poison Control Center immediately.	
<b>Directions</b> ■ Wet hands. Apply small amount of product and work into a lather. Rinse well and dry hands completely.	
<b>Inactive Ingredients</b> Water, Sodium Laureth Sulfate, Sodium chloride, Cocamidopropyl betaine, PEG-120 Methyl glucose dioleate, DMDM hydantoin, Linear alcohol aminoxyate, Propylene glycol, Fragrance, Methylol bisisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Isopropyl myristate, Citric acid, FD&C Red #40, FD&C Red #33.	



## GENERATIONS ANTIMICROBIAL

chloroxylenol soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69554-524
<b>Route of Administration</b>	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)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISO THIAZOLINONE (UNII: 229D0E1QFA)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PEG-120 METHYL GLUCOSE DOLEATE (UNII: YM0K64F20V)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69554-524-28	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	01/26/2015	

**Labeler** - Cole Papers (006221444)

Revised: 1/2015

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