

## **ANTIBACTERIAL SKIN CLEANSER 82 - antibacterial hand soap soap**

**Penco Products, 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.*

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### **Active Ingredient**

Chloroxylenol 1% w/w

### **Purpose**

Health Care Personnel Hand Wash

### **Uses**

- Hand Wash to help reduce bacteria that cause disease
- Repeated usage suggested

### **Warnings**

For external use only.

Keep out of reach of children.

Avoid contact with eyes and mouth.

If redness or irritation develops, discontinue use immediately. If condition persists for more than 72 hours, consult a physician.

Not for use on children under 6 months of age.

### **Directions**

- Wash hands and forearms.
- Apply 5 mL of product to hands.
- Scrub well for 30 seconds.
- Rinse and repeat.

### **Inactive Ingredients**

Water, Sodium C14-16 Olefin Sulfonate, Sodium Laureth Sulfate, Lauramide DEA, Isopropyl Alcohol, Polyquaternium-7, Fragrance, Styrene Acrylates/Copolymer, Tetrasodium EDTA, Citric Acid

### **In Case of Emergency**

Call: (800) 228-5635 ext. 167

LOT #

EXP.

<b>Drug Facts</b>		<b>Antibacterial Skin Cleanser #82</b>	
<p><b>Active Ingredient</b> Chloroxylenol 1% w/w</p> <p><b>Purpose</b> Health Care Personnel Hand Wash</p>		<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• Wash hands and forearms.</li> <li>• Apply 5 mL of product to hands.</li> <li>• Scrub well for 30 seconds.</li> <li>• Rinse and repeat.</li> </ul>	
<p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• Hand Wash to help reduce bacteria that cause disease</li> <li>• Repeated usage suggested</li> </ul>		<p><b>Inactive Ingredients</b> Water, Sodium C14-16 Olefin Sulfonate, Sodium Laureth Sulfate, Lauramide DEA, Isopropyl Alcohol, Polyquaternium-7, Fragrance, Styrene/Acrylates Copolymer, Tetrasodium EDTA, Citric Acid</p>	
<p><b>Warnings</b> For external use only. Keep out of reach of children. Avoid contact with eyes and mouth.</p>		<p><b>In Case of Emergency</b> Call: (800) 228-5635 ext. 167</p>	
<p>If redness or irritation develops, discontinue use immediately. If condition persists more than 72 hours, consult a physician.</p> <p>Not for use on children under 6 months of age.</p>		<p>Manufactured For: <b>Penco Products, Inc.</b> Skippack, PA 19474 Tel: (800) 562-1000 Fax: (800) 248-1555</p>	

500 mL

LBL0794-3.0

**ANTIBACTERIAL SKIN CLEANSER 82**

antibacterial hand soap soap

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42497-822
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Chloroxylenol (UNII: 0F32U78V2Q) (Chloroxylenol - UNII:0F32U78V2Q)	Chloroxylenol	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Isopropyl Alcohol (UNII: ND2M416302)	
Edetate Sodium (UNII: MP1J8420LU)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Lauric Diethanolamide (UNII: I29I2VHG38)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	

## Product Characteristics

Color	white (opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42497-822-14	503 g in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	03/04/2010	

**Labeler** - Penco Products, Inc. (808679773)

Revised: 3/2010

Penco Products, Inc.