

**ANTIBACTERIAL - chloroxylenol soap**  
**ABC Compounding Co., 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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**Antibacterial 6544 Drug Facts and Label**

**Drug Facts Box OTC-Active Ingredient Section**

Chloroxylenol 0.3%

**Drug Facts Box OTC-Purpose Section**

Antiseptic

**Drug Facts Box OTC-Indications & Usage Section**

for hand-washing to decrease bacteria on the skin

**Drug Facts Box OTC-Warnings Section**

For external use only

**Drug Facts Box OTC-When Using Section**

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

**Drug Facts Box OTC-Stop Use Section**

irritation and redness develop

**Drug Facts Box OTC-Keep Out of Reach of Children Section**

if swallowed, get medical help or contact a Poison Control Center right away

**Drug Facts Box OTC-Dosage & Administration Section**

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

**Drug Facts Box OTC-Inactive Ingredient Section**

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, fragrance, FD and C yellow no.5, food red 10

**Antibacterial 1200 ml**

6544N3PA.jpg Antibacterial 1200 ml

# ANTIBACTERIAL

## Antiseptic Hand Soap

ANTIBACTERIAL is an effective antibacterial hand soap for use in food processing plants and restaurants by personnel prior to handling food and/or food processing equipment. This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against Staphylococcus aureus, E. Coli, and Pseudomonas aeruginosa. Formulated with skin conditioners for extra mildness.

**CAUTION:** KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: 41.0 fl. oz. (1200 ML)

batch # 0311 6544N3PA

Manufactured By:  
ABC Compounding Co., Inc.  
P.O. Box 16247  
Atlanta, GA 30321  
800-795-9222

6544N3PA.1403

### Drug Facts

Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic

**Uses** for hand-washing to decrease bacteria on the skin

### Warnings

For external use only

#### When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

#### Stop use and ask a doctor if

- irritation and redness develop

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

### Directions

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

**Inactive Ingredients** water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, fragrance, FD&C yellow no. 5, food red 10

## ANTIBACTERIAL

chloroxylenol soap

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-770
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>CO CO MONOISOPROPANOLAMIDE</b> (UNII: 21X4Y0VTB1)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-770-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:62257-770-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:62257-770-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:62257-770-01	1200 mL in 1 CARTRIDGE		
5	NDC:62257-770-03	350 mL in 1 CARTRIDGE		
6	NDC:62257-770-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:62257-770-07	700 mL in 1 BAG		
8	NDC:62257-770-09	2000 mL in 1 CARTRIDGE		
9	NDC:62257-770-10	1000 mL in 1 CARTRIDGE		
10	NDC:62257-770-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:62257-770-12	1000 mL in 1 BAG		
12	NDC:62257-770-13	800 mL in 1 BAG		
13	NDC:62257-770-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:62257-770-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:62257-770-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:62257-770-27	800 mL in 1 CARTRIDGE		
17	NDC:62257-770-55	208200 mL in 1 DRUM		
18	NDC:62257-770-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:62257-770-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:62257-770-18	50 mL in 1 BOTTLE, PLASTIC		
21	NDC:62257-770-19	18900 mL in 1 CONTAINER		
22	NDC:62257-770-20	75600 mL in 1 DRUM		
23	NDC:62257-770-35	132500 mL in 1 DRUM		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/09/2014	

**Labeler** - ABC Compounding Co., Inc. (003284353)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 4/2014

ABC Compounding Co., Inc.