

## **ANTISEPTIC HAND- chloroxylenol soap**

**Image Supply, 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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### **Antiseptic Hand Soap 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, DMDM hydantoin, fragrance, FD and C yellow no.5, food red 10

### **Antiseptic Hand Soap 1 gallon**



**Antiseptic Hand Soap**

This product 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.

Drug Facts	
Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic
<b>Uses</b> For hand-washing to decrease bacteria on the skin	
<b>Warnings</b>	
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.	
<b>Directions</b> ■ wet hands and forearms	
■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms	
■ scrub thoroughly for 1 minute and rinse	
<b>Inactive Ingredients</b> water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, sodium chloride, citric acid, fragrance, FD&C yellow no. 5, food red 10	

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise.

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Antiseptic Hand Soap 1 gallon

**ANTISEPTIC HAND**

chloroxylenol soap

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16496-544
<b>Route of Administration</b>	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
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16496-544-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2005	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2005	

**Labeler** - Image Supply, Inc. (070632435)

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

## Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(16496-544)

Revised: 12/2018

Image Supply, Inc.