1012 ANTIMICROBIAL - 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.

1012 Antimicrobial 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

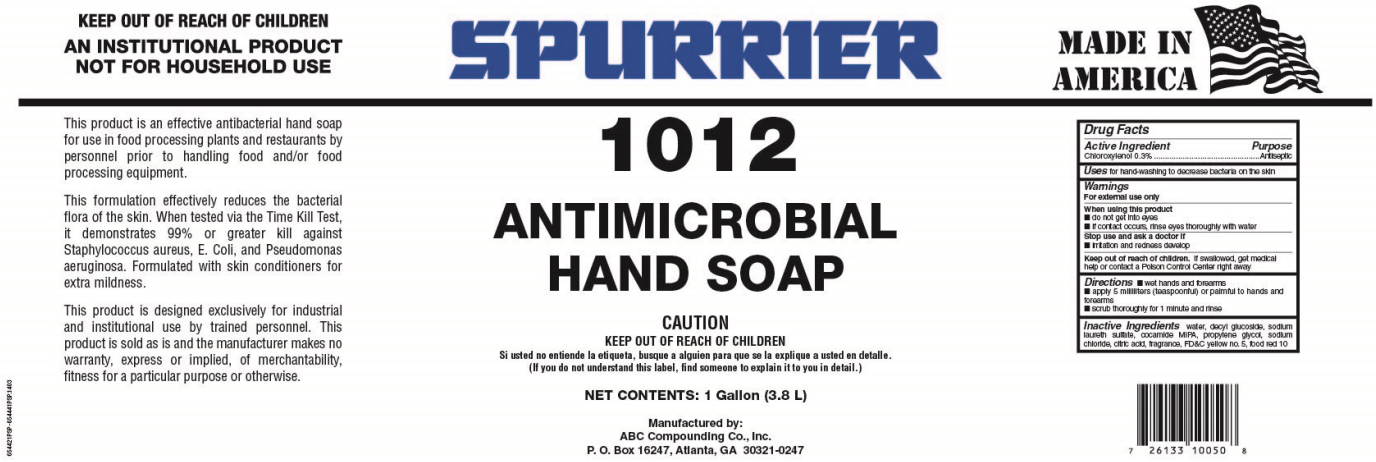
scrub thoroughly for 1 minute and rinse

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

1012 Antimicrobial 6544 1 gallon bottle

654441PSP.jpg 1012 Antimicrobial 1 gallon bottle



1012 ANTIMICROBIAL

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62257-012
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
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)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-012-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:62257-012-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:62257-012-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:62257-012-01	1200 mL in 1 CARTRIDGE		

5	NDC:62257-012-03	350 mL in 1 CARTRIDGE		
6	NDC:62257-012-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:62257-012-07	700 mL in 1 BAG		
8	NDC:62257-012-09	2000 mL in 1 CARTRIDGE		
9	NDC:62257-012-10	1000 mL in 1 CARTRIDGE		
10	NDC:62257-012-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:62257-012-12	1000 mL in 1 BAG		
12	NDC:62257-012-13	800 mL in 1 BAG		
13	NDC:62257-012-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:62257-012-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:62257-012-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:62257-012-27	800 mL in 1 CARTRIDGE		
17	NDC:62257-012-55	208200 mL in 1 DRUM		
18	NDC:62257-012-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:62257-012-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:62257-012-18	50 mL in 1 BOTTLE, PLASTIC		
21	NDC:62257-012-19	18900 mL in 1 CONTAINER		
22	NDC:62257-012-20	75600 mL in 1 DRUM		
23	NDC:62257-012-35	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	05/01/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62257-012)

Revised: 3/2014 ABC Compounding Co., Inc.