OSCEOLA SUPPLY INC 6176- chloroxylenol soap
OSCEOLA 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.

Medicated Lotion Soap 6176 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.6%

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, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, propylene glycol, sodium chloride, PEG-75 lanolin, sodium styrene/PEG-10 maleate/nonoxynol-10 maleate/acrylates copolymer, boric acid, fragrance, methylparaben, propylparaben, aloe barbadensis

Medicated Lotion Soap 6176 Label

Medicated Lotion Soap 6176
6176M4P5136.jpg

OSCEOLA SUPPLY INC 6176

chloroxylenol soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62672-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62672-300-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
2	NDC:62672-300-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
3	NDC:62672-300-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/22/2016	
4	NDC:62672-300-03	350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/22/2016	
5	NDC:62672-300-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
6	NDC:62672-300-07	700 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2016	
7	NDC:62672-300-09	2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/22/2016	
8	NDC:62672-300-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/22/2016	
9	NDC:62672-300-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
10	NDC:62672-300-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2016	
11	NDC:62672-300-13	800 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2016	
12	NDC:62672-300-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
13	NDC:62672-300-15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
14	NDC:62672-300-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
15	NDC:62672-300-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/22/2016	
16	NDC:62672-300-55	2082 mL in 1 DRUM; Type 0: Not a Combination Product	07/22/2016	
	NDC:62672-300	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		

17	NDC:62672-300-16	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
18	NDC:62672-300-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2016	
19	NDC:62672-300-19	1890 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/22/2016	
20	NDC:62672-300-20	7560 mL in 1 DRUM; Type 0: Not a Combination Product	07/22/2016	
21	NDC:62672-300-35	1325 mL in 1 DRUM; Type 0: Not a Combination Product	07/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/22/2016	

Labeler - OSCEOLA SUPPLY, INC. (809050479)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62672-300)

Revised: 7/2016 OSCEOLA SUPPLY, INC.