PRO-CARE- chloroxylenol soap Apple 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.

Pro-Care 6890 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

Pro-Care 6890 1 gal



Pro-Care 6890

PRO-CARE

chloroxylenol soap

Product Information	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67147-544		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength
l	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: BPV390 UAP0)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0 VTB1)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
ACID RED 1 (UNII: 3365R6427R)			
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67147-544- 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		09/09/2019		
	NDC -6 7147 544				

2	110-50 / 147-544- 06	1 in 1 BOX		09/09/2019	
2	NDC:67147-544- 13	800 mL in 1 BAG; Type 0: Not a Con	mbination Product		
Marketing Information					
	Marketing Categ	ory Application Number or M	Monograph Citation	Marketing Start Date	Marketing End Date
О	TC monograph not	final part333E	0	09/01/2010	

Labeler - Apple Products, Inc. (965982544)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Co., Inc.		003284353	manufacture(67147-544)	

Revised: 9/2019 Apple Products, Inc.