

PALM - 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.

Palm 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, DMDM hydantoin, citric acid, fragrance, FD and C yellow no.5, food red 10

Palm 6544 Drug Facts and Label



CAUTION: KEEP OUT OF REACH OF CHILDREN
 Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand this label, find someone to explain it to you in detail.)

NET CONTENTS: 1 GALLON (3.8 L)

PALM 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 Chloroxylenol 0.3%	Purpose Antiseptic
Uses For handwashing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water 	
<ul style="list-style-type: none"> ■ 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, distyl glucoside, sodium lauryl sulfate, cocamide MB9, 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.

Manufactured by:
 ABC COMPOUNDING CO., INC.
 P. O. Box 16247
 Atlanta, GA 30321

BATCH NO. 333X
 654411A.121918



6544 Palm Label

PALM				
chloroxylenol soap				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-544	
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)				
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:62257-544-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/21/1998	
2	NDC:62257-544-07	700 mL in 1 BAG; Type 0: Not a Combination Product	12/21/1998	

3	NDC:62257-544-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	12/21/1998	
4	NDC:62257-544-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/21/1998	
5	NDC:62257-544-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	12/21/1998	
6	NDC:62257-544-06	1 in 1 BOX	12/21/1998	
6	NDC:62257-544-13	800 mL in 1 BAG; Type 0: Not a Combination Product		
7	NDC:62257-544-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/21/1998	
8	NDC:62257-544-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	12/21/1998	
9	NDC:62257-544-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	12/21/1998	
10	NDC:62257-544-35	132500 mL in 1 DRUM; Type 0: Not a Combination Product	12/21/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/21/1998	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62257-544)

Revised: 12/2018

ABC Compounding Co., Inc.