PALM - chloroxylenol soap
Certus Medical, 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.

Florens 6739 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, methylchloroisothiazolinone, methylisothiazolinone, fragrance, FD and C yellow no.5, food red 10

Floren 6739 1000mL

CERTUS MEDICAL

Florens Antiseptic Hand Soap

CAUTION: KEEP OUT OF REACH OF CHILDREN

This product is an effective antibacterial hand soap.

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.

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.

Drug Facts

Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic

Uses for hand-washing to decrease bacteria on the skin

Warnings

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

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, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, FD&C yellow no. 5, food red 10

Manufactured for **Certus Medical, Inc.** P. O. Box 16247 Atlanta, GA 30321-0247

www.certusmedical.com

Reorder No.: 6739P6LM

1000 ML (33.8 FL. OZ.)

7 11808 21081 1

6739P6LM.113018

Florens 6739 1000mL label

PALM

chloroxylenol soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75990-6739
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)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 1 (UNII: 3365R6427R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75990-6739-6	1 in 1 BOX	08/19/2016	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:75990-6739-0	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	08/19/2016	
3	NDC:75990-6739-4	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2016	
4	NDC:75990-6739-1	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/19/2016	

Labeler - Certus Medical, Inc. (966433653)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-6739)

Revised: 1/2019

Certus Medical, Inc.