

**SATIN FOAM HIGH FOAMING ANTISEPTIC HAND WASH- 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.

Satin Foam High Foaming Antiseptic Hand Wash Drug 6914

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, DMDM hydantoin, methylchloroisothiazolinone, methylisothiazolinone, fragrance, aloe barbadensis, acid red 1

Satin Foam High Foaming Antiseptic Hand Wash Drug 6914

Satin Foam

High foaming antiseptic
hand wash

PACKAGED FOR USE IN
A WALL MOUNT DISPENSER

Drug Facts

Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic

Use 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, acid red 1

6914M3PM.113018
Manufactured for Certus Medical, Inc.
P. O. Box 16247 Atlanta, GA 30321-0247
www.certusmedical.com

750 ml (25.4 fl. oz.)

Reorder No.: 6914M3PM



SATIN FOAM HIGH FOAMING ANTISEPTIC HAND WASH

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-914
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)	
ACID RED 1 (UNII: 3365R6427R)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-914-03	750 mL in 1 BAG; Type 0: Not a Combination Product	10/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/05/2022	

Labeler - Certus Medical, Inc. (118806847)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-914)

