

FORTRESS- chloroxylenol solution
Kay Chemical Co.

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.

Drug Facts

Active ingredient

Chloroxylenol 0.5%

Purpose

Antiseptic Handwash

Uses

- For handwashing to decrease bacteria on the skin.

Warnings

- **For external use only**

Do not use

- In eyes

When using this product

- If in eyes, rinse promptly and thoroughly with water
- Discontinue use if irritation and redness develop

Stop use and ask a doctor if

- Skin irritation or redness occurs for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands and forearms
- Dispense a palmful of product to hands
- Scrub hands and forearms for 20 seconds
- Rinse thoroughly and dry

Other Information

- for additional information, see Material Safety Data Sheet (MSDS)

- for emergency medical information in USA, call (877) 231-2615 or call collect 0 (952) 853-1713

Inactive ingredients: water (aqua), potassium cocoate, hexylene glycol, sodium sulfate, tetrasodium EDTA, sodium lauryl sulfate, glycerin, citric acid, coco-glucoside, glyceryl oleate, fragrance, methychloroisothiazolinone, CI 19140 (FD&C Yellow No. 5), methylisothiazolinone, CI 14700 (FDC Red No. 4)

Questions? Call 1-800-529-5458

Principal display panel and representative label

FORTRESS® Foaming Antibacterial Hand Soap

KEEP OUT OF REACH OF CHILDREN/FOR INSTITUTIONAL USE ONLY

FORTRESS® Foaming Antibacterial Hand Soap is a rich lather hand soap with a balanced blend of cleaning agents and skin protecting moisturizers.

- Instant foam lathers fast • Mild, pH-balanced formula
- Fresh, clean fragrance

To obtain Spanish instructions, see outer carton.

Para obtener las instrucciones en español, véase la caja exterior.

NDC.: 63146-105-03

KAY CHEMICAL COMPANY

8300 Capital Drive

Greensboro, NC 27409-3790, USA

Customer Service: (800) 529-5458

706402-04

KUSA 706402/8004/0412

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25 US fl OZ (750 ml)

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25 US fl oz (750 ml)

FORTRESS

chloroxylenol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63146-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM COCOATE (UNII: F8U72V8ZXP)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63146-105-03	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/16/2005	

Labeler - Kay Chemical Co. (003237021)

