

**FOAMFRESH DYE FREE ANTIBACTERIAL HAND WASH - chloroxylenol solution**  
**Woodbine Products Company**

*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.*

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**Drug Facts**

Active Ingredient

Chloroxylenol 0.25%

Purpose

Antibacterial

Uses:

For hand washing to decrease bacteria on the skin.

Warnings:

For external use only

When using this product avoid contact with eyes.

In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

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

Directions:

For maximum efficiency, pump foam into dry hands, lather vigorous for 30 seconds, rinse and dry.

Other Information:

Store at 20 to 25C.(68 to 77F)

Inactive Ingredients:

Water, Sodium Lauryl Sulfate, Lauryl Glucoside, Cocamidopropyl Betaine, Decyl Glucoside.  
Potassium Hydrolyzed Collagen, DMDM Hydantoin, Propylene Glycol and Fragrance

FOAMFresh

DYE FREE

ANTIBACTERIAL

Hand WASH

Sense the

Difference

Stock # 5110DF

1250 ml (42 fl.oz.)

# FRONT LABEL

**FOAMFresh**<sup>®</sup>

DYE FREE  
ANTIBACTERIAL  
HAND WASH

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Difference!*

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**Dye Free Antibacterial Hand Wash**

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<b>Other information:</b> Store at 20 to 25°C. (68 to 77°F)	
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Made in the U.S.A.

# BACK LABEL

## FOAMFRESH DYE FREE ANTIBACTERIAL HAND WASH

chloroxylenol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11429-10 10
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	2.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11429-10 10-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2018	
2	NDC:11429-10 10-7	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2018	
3	NDC:11429-10 10-3	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2018	
4	NDC:11429-10 10-8	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/20/2018	

**Labeler** - Woodbine Products Company (004220323)

### Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture(11429-10 10)

Revised: 11/2018

Woodbine Products Company