

FOAMFRESH ANTIBACTERIAL HAND WASH - chloroxylenol liquid
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.

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 vigorously for 30 seconds, rinse and dry.

Other Information:

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

Inactive Ingredient:

Water, Sodium Lauryl Sulfate, C10-16 Alkyl Glucoside, Cocamidopropyl Betaine, Lauryl Glucoside, Potassium Hydrolyzed Collagen, DMDM Hydantoin, Propylene Glycol, Fragrance and FDC Blue #1, FDC Yellow #5, FDC Yellow #6.

FoamFresh

Antibacterial Hand Wash

The easiest way to clean

hands. A fragranced, luxuriant foam,
it is easily dispensed for an enjoyable
hand wash. Sense the difference.

Woodbine Products Company

915 West Smith Road

Medina, OH 44256

www.woodbineproducts.com

Made in USA

Stock #4510 1000 ml. (34 fl. oz.)

FoamFresh Antibacterial

Fortified with Collagen

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chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11429-1005
Route of Administration	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
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11429-1005-1	59 mL in 1 BOTTLE, PLASTIC		
2	NDC:11429-1005-2	250 mL in 1 BOTTLE, PLASTIC		
3	NDC:11429-1005-3	1000 mL in 1 BOTTLE, PLASTIC		
4	NDC:11429-1005-4	2125 mL in 1 BOTTLE, PLASTIC		
5	NDC:11429-1005-5	3785 mL in 1 BOTTLE, PLASTIC		
6	NDC:11429-1005-6	1500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/28/2012	

Labeler - Woodbine Products Company (004220323)

Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture(11429-1005)

