

AFIA FOAMING ANTI-BACTERIAL HAND CLEANER- chloroxylenol soap
National Chemical Laboratories, 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.

Listing of Afia Foaming Anti-Bacterial Hand Cleaner

Drug Facts

Active Ingredient. Purpose

Chloroxylenol 0.3%.....Antimicrobial

Drug Facts		 7 52610 70446 4	National Chemical Laboratories, Inc. 401 N. 10th Street Philadelphia, PA 19123
Active Ingredient.	Purpose		
Chloroxylenol 0.3%.....	Antimicrobial		
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. If swallowed, get medical help or contact a Poison Control Center right away.			
Directions • Wet a hand. Pump one or two stokes of foam into palm of hand • Rub thoroughly over all surfaces of both hands for 30 seconds • Rinse hands and dry thoroughly.			
Inactive ingredients Water, Sodium Methyl 2-Sulfolaurate, Disodium 2-Sulfolaurate, Decyl glucoside, Cocamidopropyl Betaine, Lauric Monoethanolamide, Centrimonium Chloride, PEG-150 Distearate, Phenoxyethanol, fragrance, Methychloroisothiazolinone, Methylisothiazolinone, FD&C yellow #5, FD&C Blue #1			

**Foaming
 Anti-Bacterial**



NDC 71023-446-57
 LB1000-0001-0446-01i

1000mL (33.8 fl. oz.)
 Product #0446

Uses

For hand washing to decrease bacteria on the skin

Warnings:

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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.

Directions

- Wet a hand. Pump one or two strokes of foam, into palm of hand.
- Rub thoroughly over all surfaces of both hands for 30 seconds
- Rinse hands and dry thoroughly.

Inactive ingredients

Water, Sodium Methyl 2-Sulfolaurate, Disodium 2-Sulfolaurate, Decyl glucoside, Cocamidopropyl Betaine, Lauric Monoethanolamide, Cetrimonium Chloride, PEG-150 Distearate, Phenoxyethanol, fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C yellow #5, FD&C blue #1

Warnings:

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Product #0446

AFIA FOAMING ANTI-BACTERIAL HAND CLEANER

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71023-446
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
LAURIC MONOETHANOLAMIDE (UNII: 098P2IGT76)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DISODIUM 2-SULFOLAURATE (UNII: 329M3829G2)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM METHYL 2-SULFOLAURATE (UNII: I39GGJ23HV)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71023-446-57	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/24/2016	
2	NDC:71023-446-29	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/24/2016	

Labeler - National Chemical Laboratories, Inc. (002289619)

Registrant - National Chemical Laboratories, Inc. (002289619)

Establishment

Name	Address	ID/FEI	Business Operations
National Chemical Laboratories, Inc.		002289619	manufacture(71023-446)

Revised: 1/2022

National Chemical Laboratories, Inc.