

AFFEX ANTIMICROBIAL FOAMING HAND SO AP- chloroxylenol liquid
Afflink, 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.

AFFEX® Antimicrobial Foaming Hand Soap

Active ingredient

Chloroxylenol 0.3%

Purpose

Antimicrobial

Uses

- Handwash to help decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands
- Apply a small amount of product and work into a lather
- Rinse well and dry hands completely

Inactive ingredients

Water (Aqua), Alcohol, Ammonium Laureth Sulfate, Ammonium Lauryl Sulfate, Propylene Glycol, Ammonium Xylenesulfonate, Cocamide MEA, Glycerin, Isopropyl Alcohol, Lactic Acid, Retinyl Palmitate, Simmondsia Chinensis (Jojoba) Seed Oil, Tetrasodium EDTA, Tocopheryl Acetate, Zea Mays (Corn) Oil, Ammonium Sulfate, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, Red 4 (CI 14700), Yellow 6 (CI 15985)



Drug Facts	
Active Ingredient	Purpose
Chloroxylenol 0.3%	Antimicrobial
Uses	
<ul style="list-style-type: none"> Handwash to help decrease bacteria on the skin Recommended for repeated use 	
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Stop use and ask a doctor if irritation or rash appears and lasts	
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Directions	
<ul style="list-style-type: none"> Wet hands Apply product and thoroughly cover hands with lather Rinse well and dry hands completely 	

Drug Facts (continued)	
Directions	
<ul style="list-style-type: none"> Wet hands Apply product and thoroughly cover hands with lather Rinse well and dry hands completely 	
Inactive Ingredients	
Water (Aqua), Alcohol, Ammonium Laureth Sulfate, Ammonium Lauryl Sulfate, Propylene Glycol, Ammonium Xylenesulfonate, Cocamide MEA, Glycerin, Isopropyl Alcohol, Lactic Acid, Retinyl Palmitate, Simmondsia Chinensis (Jojoba) Seed Oil, Tetrasodium EDTA, Tocopheryl Acetate, Zea Mays (Corn) Oil, Ammonium Sulfate, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, Red 4 (CI 14700), Yellow 6 (CI 59885)	

Datos Farmacológicos	
Ingrediente activo	Propósito
Cloroxileno 0,3%	Antimicrobiano
Usos	
<ul style="list-style-type: none"> Lavado de manos empleado para disminuir la cantidad de bacterias en la piel Recomendado para uso reiterado 	
Advertencias	
Sólo para uso externo	
Al utilizar este producto, evitar el contacto con los ojos o con la zona alrededor de los ojos. En caso de contacto, enjuagar completamente los ojos con agua.	
Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea	
Mantener fuera del alcance de los niños. En caso de ingestión, de inmediato acudir a un médico o ponerse en contacto con un centro para el control de tóxicos.	
Modo De Uso	
<ul style="list-style-type: none"> Moje las manos Aplice el producto hasta cubrir completamente sus manos con la espuma Enjuague bien y seque las manos completamente 	
Ingredientes inactivos	
Agua, Alcohol etílico, Lauret sulfato de amonio, Lauril sulfato de amonio, Propilenglicol, Xilenosulfonato de amonio, MEA cocamida, Glicerina, Alcohol isopropílico, Acido láctico, Palmitato de retinilo, Aceite de Simmondsia Chinensis, EDTA tetrasódico, Acetato de tocoferilo, Aceite de maíz (Zea Mays), Sulfato de amonio, Fragancia, Metilcloroisotiazolinona, Metilisotiazolinona, Rojo 4, Amarillo 6	

AFFEX ANTIMICROBIAL FOAMING HAND SOAP			
chloroxylenol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54057-082
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		CHLOROXYLENOL	0.003 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0K00R)			
ALCOHOL (UNII: 3K9958V90M)			
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)			

AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
AMMONIUM XYLENESULFONATE (UNII: 4FZY6L6XCM)
COCO MONOETHANOLAMIDE (UNII: C80684146D)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
LACTIC ACID (UNII: 33X04XA5AT)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
JOJOBA OIL (UNII: 724GKU717M)
EDETATE SODIUM (UNII: MP1J8420LU)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
CORN OIL (UNII: 8470G57WFM)
AMMONIUM SULFATE (UNII: SU46BAM238)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
FD&C RED NO. 4 (UNII: X3W0AM1JLX)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54057-082-42	1250 mL in 1 PACKAGE; Type 0: Not a Combination Product	08/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/15/2013	

Labeler - Afflink, Inc. (023121150)