

**PREMIUM FOAM ANTIBACTERIAL- chloroxylenol liquid**  
**GOJO Industries, 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.*

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**GOJO Premium Foam Antibacterial Handwash**

**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

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**Directions**

- Wet hands
- Apply product and thoroughly cover hands with lather
- Rinse well and dry hands completely

**Drug Facts (continued)**

**Directions**

- 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 15985)

5362-644-ES-B

PREMIUM FOAM ANTIBACTERIAL			
chloroxylenol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-085
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: 059QF0KO0R)			
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)			

<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>AMMONIUM SULFATE</b> (UNII: SU46BAM238)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-085-23	222 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2012	
2	NDC:21749-085-80	800 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2012	
3	NDC:21749-085-89	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2012	
4	NDC:21749-085-46	1360 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/11/2012	

**Labeler** - GOJO Industries, Inc. (004162038)

### Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	MANUFACTURE(21749-085)

### Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	label(21749-085) , pack(21749-085)