PROVON ANTIMICROBIAL LTN SP WITH 0.3% PCMX- 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.

PROVON Antimicrobial Lotion Soap with 0.3% PCMX

Active ingredient

Chloroxylenol 0.3%

Purpose

Antimicrobial

Use

• 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

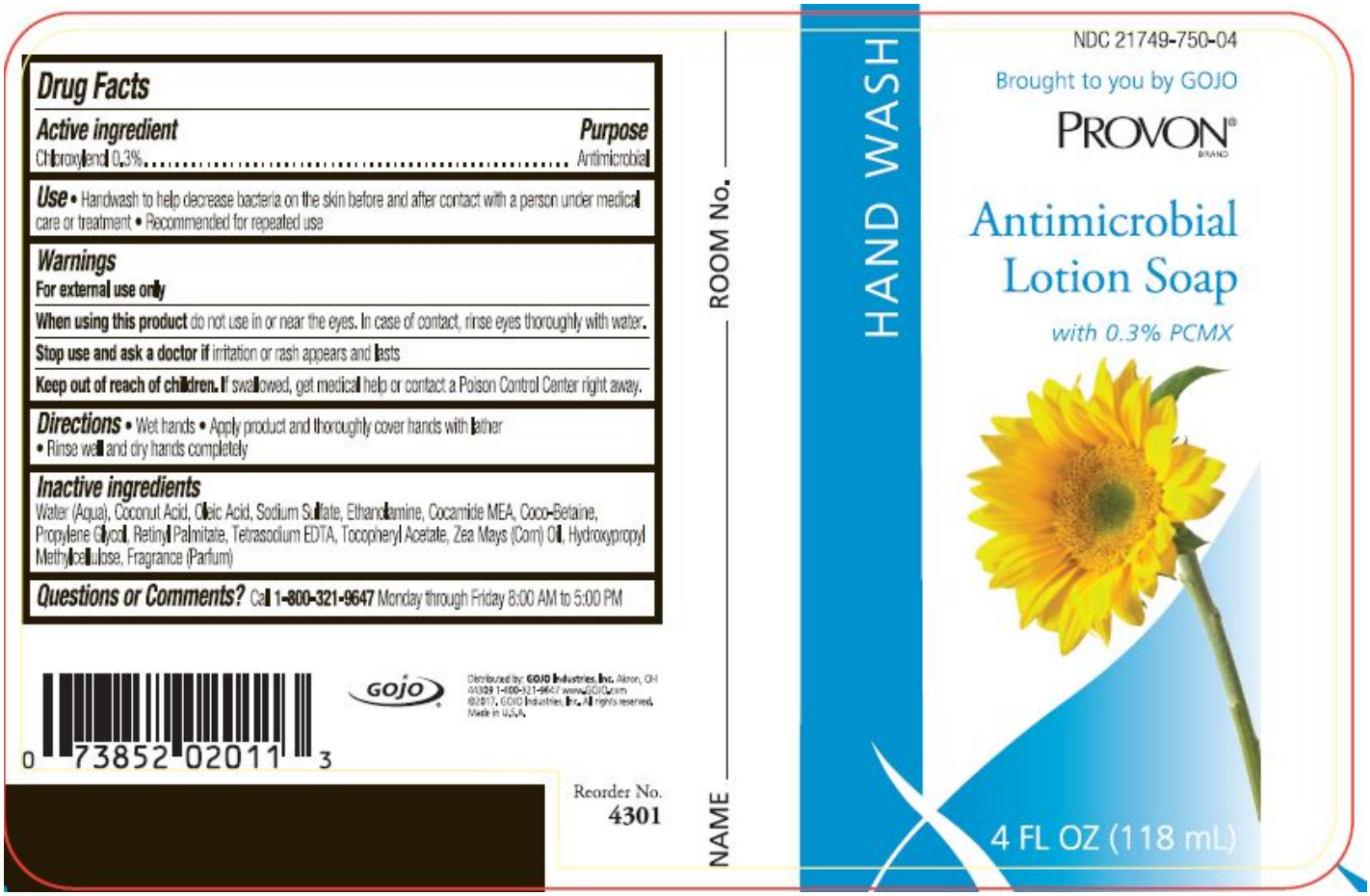
• Wet hands

• Apply a small amount of product and work into a lather

• Rinse well and dry hands completely

Inactive ingredients

Water (Aqua), Coconut Acid, Oleic Acid, Sodium Sulfate, Ethanolamine, Cocamide MEA, Coco-Betaine, Propylene Glycol, Retinyl Palmitate, Tetrasodium EDTA, Tocopheryl Acetate, Zea Mays (Corn) Oil, Hydroxypropyl Methylcellulose, Fragrance (Parfum)



PROVON ANTIMICROBIAL LTN SP WITH 0.3% PCMX

chloroxylenol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21749-750
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)	
Coconut Acid (UNII: 40U37V505D)	
Oleic Acid (UNII: 2UMI9U37CP)	
Sodium Sulfate (UNII: 0YPR65R21J)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
Coco-Betaine (UNII: 03DH2IZ3FY)	
Propylene Glycol (UNII: 6DC9Q167V3)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CORN OIL (UNII: 8470G57WFM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-750-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
2	NDC:21749-750-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
3	NDC:21749-750-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
4	NDC:21749-750-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
5	NDC:21749-750-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
6	NDC:21749-750-80	800 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
7	NDC:21749-750-10	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/31/2013	
8	NDC:21749-750-20	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	
9	NDC:21749-750-37	3784 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/31/2013	

Labeler - GOJO Industries, Inc. (004162038)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	manufacture(21749-750)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	label(21749-750) , pack(21749-750)

Revised: 9/2017 GOJO Industries, Inc.