

PURELL HEALTHCARE HEALTHY SP 0.5PCT PCMX ANTIMICROBIAL FOAM-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.

PURELL Healthcare HEALTHY SOAP 0.5% PCMX Antimicrobial Foam

Active ingredient

Chloroxylenol 0.5%

Purpose

Antimicrobial

Use

- Handwash to help reduce 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, Lauric Acid, Ethanolamine, Dipropylene Glycol, Lactic Acid, Poloxamer 124, Isopropyl Alcohol, Sodium Metabisulfite, Sodium Sulfite, Tetrasodium EDTA, Sodium Sulfate, Fragrance (Parfum), Methylparaben, Propylparaben



Reorder No. / Código Nº 5178



Healthcare HEALTHY SOAP®
0.5% PCMX Antimicrobial Foam

Lavado de Manos Antimicrobiano
en Espuma con 0.5% PCMX

Distributed by, Distribuido por:
GOJO Industries, Inc. Akron, OH 44309
800-321-9647 • 330-255-6000 • www.GOJO.com
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Made in U.S.A., Hecho en los E.E.U.U.

5178-640-ES-B

SOAP
CS4

1250 mL (42 US/ÉU FL OZ)

Drug Facts

Active ingredient

Chloroxyleneol 0.5%.....Antimicrobial

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

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Drug Facts (continued)

Directions

- Wet hands
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Inactive ingredients

Water (Aqua), Alcohol, Lauric Acid, Ethanolamine, Dipropylene Glycol,
Lactic Acid, Poloxamer 124, Isopropyl Alcohol, Sodium Metabisulfite,
Sodium Sulfite, Tetrasodium EDTA, Sodium Sulfate, Fragrance
(Parfum), Methylparaben, Propylparaben

Other Information Store below 110°F (43°C)

DSP-OH-36

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Datos Farmacológicos

Ingrediente activo

Cloroxileno 0,5%.....Antimicrobiano

Propósito

Usos • 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.

Datos Farmacológicos (continuado)

Modo de uso

- Mojar las manos
- Aplicar una pequeña cantidad del producto y frotar las manos hasta
producir una espuma abundante
- Enjuagar bien • Secarse las manos completamente

Ingredientes inactivos

Agua, Alcohol etílico, Ácido láurico, Etilandamina, Dipropilenglicol, Ácido
láctico, Poloxámero 124, Alcohol isopropílico, Metabisulfito de sodio,
Sulfito de sodio, EDTA tetrasódico, Sulfato de sodio, Fragancia,
Metilparabeno, Propilparabén

Información adicional Almacenar a temperaturas
inferiores a 43°C (110°F)

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PURELL HEALTHCARE HEALTHY SP 0.5PCT PCMX ANTIMICROBIAL FOAM
chloroxyleneol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-522
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.005 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
LAURIC ACID (UNII: 1160N9NU9U)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-522-53	535 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/14/2017	
2	NDC:21749-522-89	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/14/2017	
3	NDC:21749-522-90	1250 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/14/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/14/2017	

Labeler - GOJO Industries, Inc. (004162038)

Establishment			
Name	Address	ID/FEI	Business Operations

GOJO Industries, Inc.		036424534	manufacture(21749-522)
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Establishment			
Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	label(21749-522) , pack(21749-522)