

**PRIME SOURCE ANTIMICROBIAL FOAMING HAND SO AP- chloroxylenol liquid
BUNZL**

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.

PRIME SOURCE® 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)



PRIME SOURCE®

ANTIMICROBIAL FOAMING HAND SOAP
JABÓN DE MANOS ANTIMICROBIANO ESPUMANTE



Distributed by, Distribuido por:
Prime Source, LLC
11434 Moog Drive
Saint Louis, MO 63146
Made in U.S.A., Hecho en los E.E.U.U.

1.25L (42 FL OZ)

5162-643-GET-F

Drug Facts	
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 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, Tocopherol Acetate, Zea Mays (Corn) Oil, Ammonium Sulfate, Fragrance (Parfumi), Methylchloroisothiazolinone, Methylisothiazolinone, Red 4 (CI 14700), Yellow 6 (CI 5985)	

Datos Farmacológicos	
Ingrediente activo Chloroxylenol 0,3%	Propósito Antimicrobiano
Usos • Lavado de manos empleado para disminuir la cantidad de bacterias en la piel • Recomendado para uso reiterado	
Advertencias Solo 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 • Moje las manos • Aplique 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	

5362-644-ES-B

PRIME SOURCE ANTIMICROBIAL FOAMING HAND SOAP

chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66294-080
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: Q7A02R1M0B)	

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:66294-080-42	1250 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/15/2002	
2	NDC:66294-080-67	2000 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/15/2002	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/15/2002	

Labeler - BUNZL (799540588)