

**PRIME SOURCE E2 FOAM 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 SOURC®E E2 Foam Soap

Active ingredient

Chloroxylenol 0.5%

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 product and thoroughly cover hands with 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, Methylparaben, Propylparaben



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| Drug Facts | |
| Active ingredient Chloroxylenol 0.5% | Purpose Antimicrobial |
| Uses | |
| <ul style="list-style-type: none"> 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. | |

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| Datos Farmacológicos | |
| Ingrediente activo Cloroxileno 0.5% | Propósito 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. | |

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| 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 |

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| Modo de uso |
| <ul style="list-style-type: none"> 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, Acido láurico, Etanolamina, Dipropilenglicol, Acido láctico, Poloxámero 124, Alcohol isopropílico, Metabisulfito de sodio, Sulfito de sodio, EDTA tetrasódico, Sulfato de sodio, Metilparabeno, Propilparabén |

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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, Methylparaben, Propylparaben |

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| ¿Preguntas o comentarios? |
| Llame al 1-800-321-9647 de lunes a viernes de 8:00 AM a 5:00 PM |

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| Questions or comments? |
| Call 1-800-321-9647 Monday through Friday 8:00 AM to 5:00 PM |

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| PRIME SOURCE E2 FOAM SOAP | | | |
| chloroxylenol liquid | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66294-523 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | Chloroxylenol (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q) | Chloroxylenol | 0.5 mg in 100 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |

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| WATER (UNII: 059QF0K00R) |
| ALCOHOL (UNII: 3K9958V90M) |
| LAURIC ACID (UNII: 1160N9NU9U) |
| MONOETHANOLAMINE (UNII: 5KV86114PT) |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) |
| LACTIC ACID, UNSPECIFIED FORM (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) |
| METHYL PARABEN (UNII: A2I8C7HI9T) |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:66294-523-42 | 1250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/15/2015 | |
| 2 | NDC:66294-523-67 | 2000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/30/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 04/15/2015 | |

Labeler - BUNZL (799540588)