**PRIME SOURCE ANTIBACTERIAL FOAM HANDWASH- benzalkonium chloride 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.*

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**PRIME SOURCE® Antibacterial Foam Handwash**

## Active ingredient

Benzalkonium Chloride 0.5%

## 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

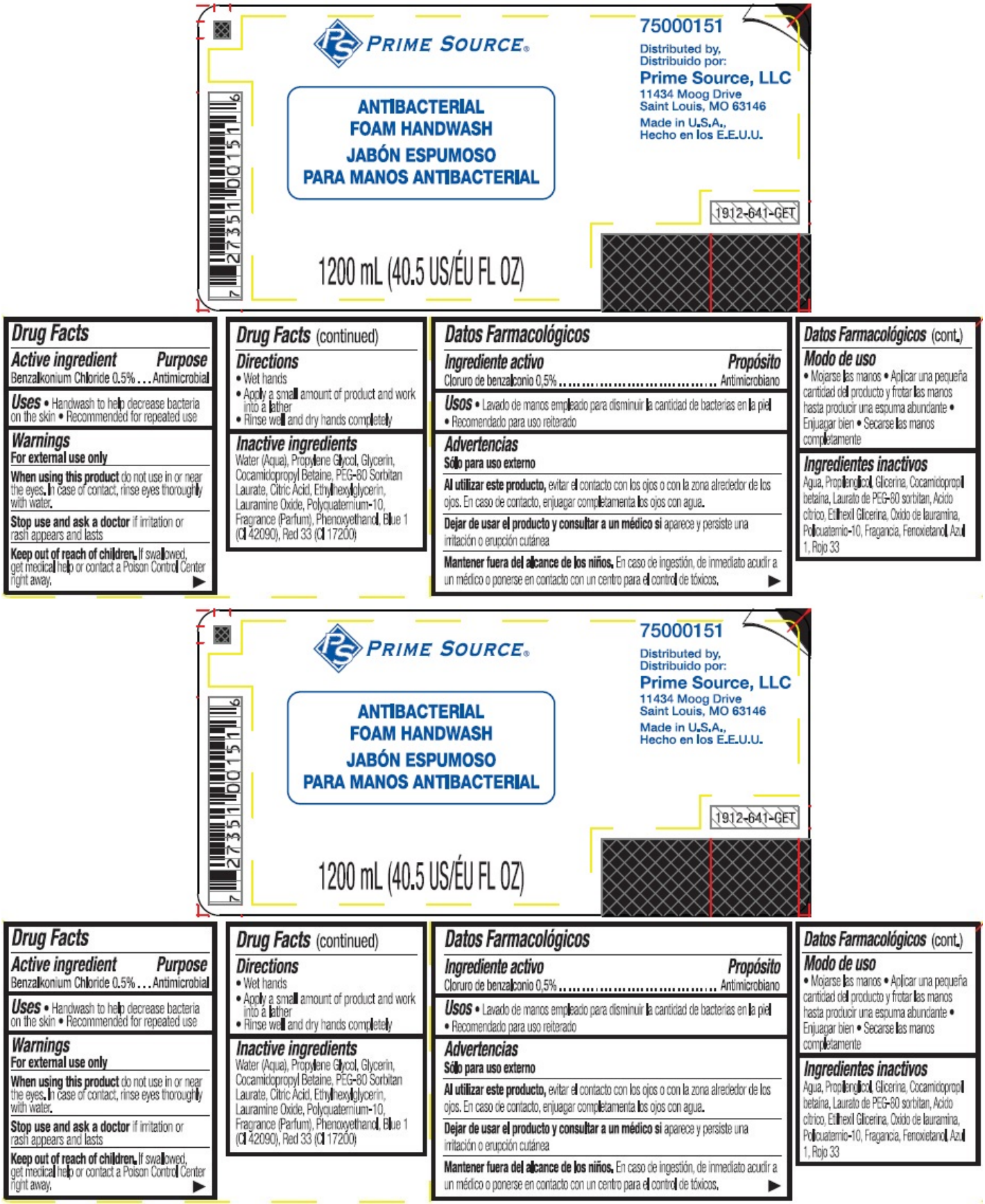
**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Wet hands
- Apply a small amount of product and work into a lather
- Rinse well and dry hands completely

## Inactive Ingredients

Water (Aqua), Propylene Glycol, Glycerin, Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Citric Acid, Ethylhexylglycerin, Lauramine Oxide, Polyquaternium-10, Fragrance (Parfum), Phenoxyethanol, Blue 1 (CI 42090), Red 33 (CI 17200)




PRIME SOURCE
75000151
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.
ANTIBACTERIAL
FOAM HANDWASH
JABÓN ESPUMOSO
PARA MANOS ANTIBACTERIAL
1912-641-GET
1200 mL (40.5 US/ÉU FL OZ)
Drug Facts
Active ingredient Purpose
Benzalkonium Chloride 0.5% ... 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.
Drug Facts (continued)
Directions
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Datos Farmacológicos
Ingrediente activo Propósito
Cloruro de benzalconio 0,5% ..... Antimicrobiano
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 (cont.)
Modo de uso
• Mojarse 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, Propilenglicol, Glicerina, Cocamidopropil betaína, Laurato de PEG-80 sorbitan, Ácido cítrico, Etilhexil Glicerina, Óxido de lauramina, Polyquaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33

# PRIME SOURCE ANTIBACTERIAL FOAM HANDWASH

benzalkonium chloride liquid

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:66294-400 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Benzalkonium Chloride** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | Benzalkonium Chloride | 0.005 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Water** (UNII: 059QF0KO0R) | |
| **Propylene Glycol** (UNII: 6DC9Q167V3) | |
| **Glycerin** (UNII: PDC6A3C0OX) | |
| **Cocamidopropyl Betaine** (UNII: 5OCF3O11KX) | |
| **PEG-80 Sorbitan Laurate** (UNII: 239B50Y732) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **Ethylhexylglycerin** (UNII: 147D247K3P) | |
| **Lauramine Oxide** (UNII: 4F6FC4MI8W) | |
| **POLYQUATERNIUM-10 (10000 MPA.S AT 2%)** (UNII: PI1STR9QYH) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:66294-400-23 | 700 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/30/2017 | |
| **2** | NDC:66294-400-40 | 1200 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/30/2017 | |
| **3** | NDC:66294-400-42 | 1250 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/30/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333E | 04/30/2017 | |

## Labeler - BUNZL (799540588)