PRIMORY ANTIBACTERIAL PLUM FOAM HANDWASH- benzalkonium chloride 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.

Primory Antibacterial Plum 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

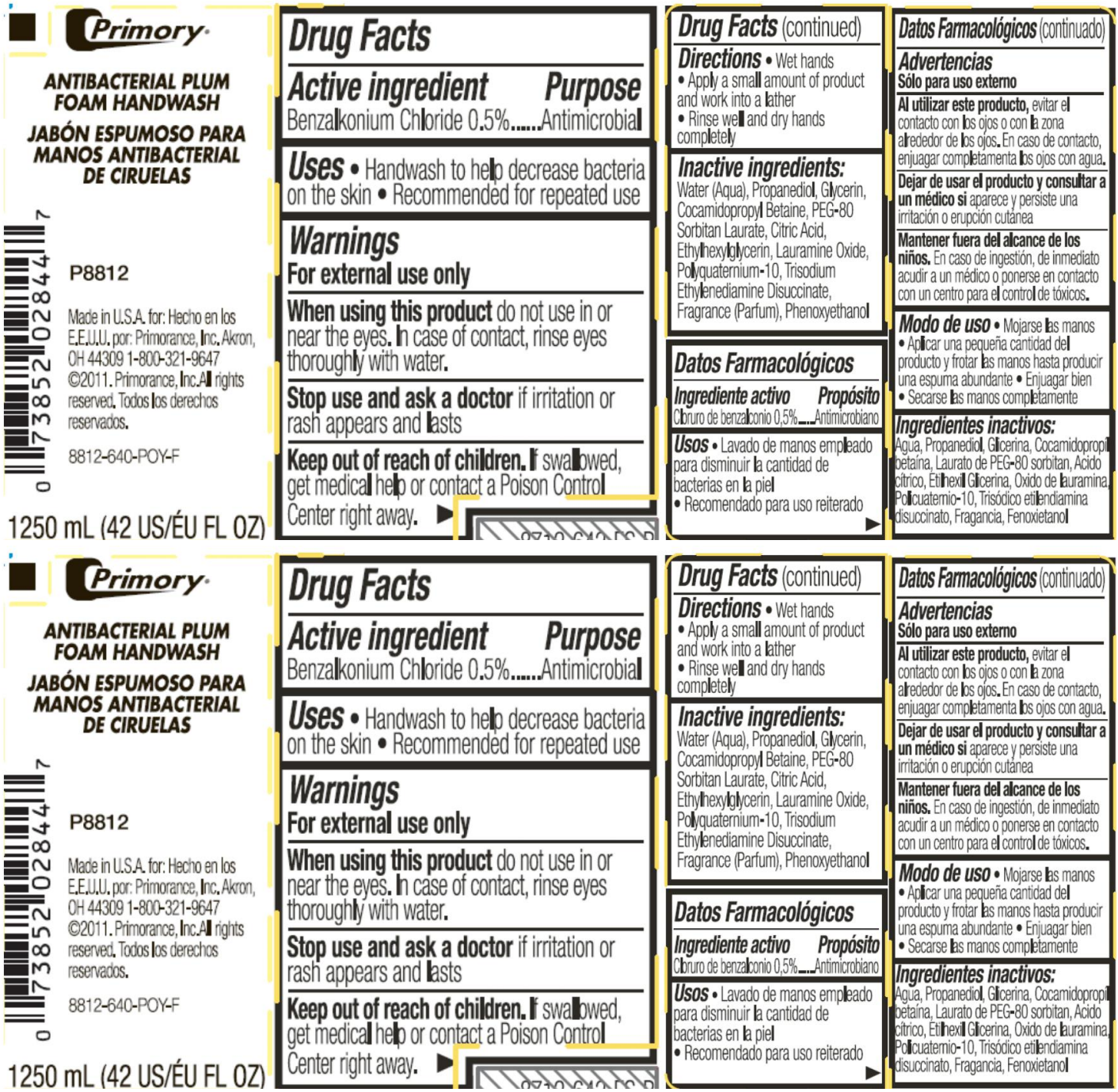
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

Inactive Ingredients

Water (Aqua), Propanediol, Glycerin, Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Citric Acid, Ethylhexylglycerin, Lauramine Oxide, Polyquaternium-10, Trisodium Ethylenediamine Disuccinate, Fragrance (Parfum), Phenoxyethanol



Primory
ANTIBACTERIAL PLUM FOAM HANDWASH
JABÓN ESPUMOSO PARA MANOS ANTIBACTERIAL DE CIRUELAS
P8812
Made in U.S.A. for: Hecho en los E.E.U.U. por: Primorance, Inc. Akron, OH 44309 1-800-321-9647
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8812-640-POY-F
1250 mL (42 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
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Drug Facts (continued)
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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
Datos Farmacológicos (continuado)
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 completamenta 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 • 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, Propanediol, Glicerina, Cocamidopropil betaína, Laurato de PEG-80 sorbitan, Acido cítrico, Etilhexil Glicerina, Oxido de lauramina, Policuaternio-10, Trisódico etilendiamina disuccinato, Fragancia, Fenoxietanol

PRIMORY ANTIBACTERIAL PLUM FOAM HANDWASH

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21749-454
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzalkonium Chloride (UNII: F5UM2KM3W7) (BENZALKONIUM -	Benzalkonium	0.5 mg

UNII:7N6JUD5X6Y)	Chloride	in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
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)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-454-08	236 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/14/2017	
2	NDC:21749-454-97	700 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/14/2017	12/31/2023
3	NDC:21749-454-89	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/14/2017	
4	NDC:21749-454-90	1250 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/14/2017	

Labeler - GOJO Industries, Inc. (004162038)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	manufacture(21749-454)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	manufacture(21749-454) , label(21749-454) , pack(21749-454)