

**PURELL FOODSERVICE HEALTHY SP 0.5PCT BAK ANTIMICROBIAL FOAM-
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.

PURELL Foodservice HEALTHY SOAP™ 0.5% BAK Antimicrobial Foam

Active ingredient

Benzalkonium Chloride 0.5%

Purpose

Antimicrobial

Uses

- Handwash to help decrease bacteria on the skin

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



**Foodservice HEALTHY SOAP®
0.5% BAK Antimicrobial Foam**

Lavado de Manos Antimicrobiano en Espuma con 0.5% BAK

GDUO Industries, Inc., Akron, OH 44329
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Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.5%	Antimicrobial
Use • Handwash to help decrease bacteria on the skin	
Warnings	
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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	
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Datos Farmacológicos	
Ingrediente activo	Propósito
Cloruro de benzalconio 0,5%	Antimicrobiano
Uso • Lavado de manos empleado para disminuir la cantidad de bacterias en la piel	
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.	
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 betaina, Laurato de PEG-80 sorbitan, Acido cítrico, Etihexil Glicerina, Oxido de Lauramina, Poliquaternio-10, Trisódico etilendiamina disuccinato, Fragancia, Fenoxietanol	

**SOAP
ES4**

1200 mL
(40.5 US/ÉU FL OZ)
Reorder No. / Código N° 5080

5080-040-ES-B

PURELL FOODSERVICE HEALTHY SP 0.5PCT BAK ANTIMICROBIAL FOAM			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-686
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)			

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: 4F6FC4M8W)
POLYQUATERNIUM-10 (10000 MPA.S AT 2%) (UNII: P11STR9QYH)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-686-23	222 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/15/2017	
2	NDC:21749-686-89	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/15/2017	

Labeler - GOJO Industries, Inc. (004162038)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	manufacture(21749-686)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	label(21749-686) , pack(21749-686)

Revised: 10/2017

GOJO Industries, Inc.