OPTISOURCE ANTIBACTERIAL FOAM HAND- benzalkonium chloride soap Charlotte Products Ltd.

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.

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

- For hand washing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

When using

this product avoid contact with eyes. In case of eye contact, flush eyes with water.

Stop using and ask doctor if

irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Pump a small amount of foam into palm of hand
- Rub thoroughly over all surfaces of both hands for 15 seconds
- Rinse with potable water

Inactive Ingredients Water/Agua/Eau, Coco-glucoside, Laurtrimonium Chloride, Cocamidopropylamine Oxide, Citric acid



OPTISOURCE®

Antibacterial Foam Hand Soap Jabón antibacterial en espuma para manos

Savoc pour les mains moussant antibactérien

Reorder: 12504

4 x 1250 mL (42.25 fl. oz.)







Drug Facts Active ingredient Purpose
Benzalkonium Chloride,0.13% Antimicrobial

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Instrucciones: Aplíquese una pequeña cantidad de espuma en la palma de la mano - Frote la espuma sobre todas las superficies de ambas manos por 15 segundos - Enjuáguese con agua potable.

Mode d'emploi: Pompez une petite quantité de mousse dans la paume de la main - Frottez bien sur toutes les surfaces des deux mains pendant 15 secondes - Rincez à l'eau potable.

Warnings: For external use only. Avoid eye contact, KEEP OUT OF REACH OF CHILDREN. For industrial

Advertencias: Para uso externo solamente. Evite el contacto con los ojos. MANTENGALA EL PRODUCTO FUERA DEL ALCANCE DE LOS NIÑOS. Para uso industrial y comercial solamente.

Avertissements: Réservé à l'usage externe, Évitez le contact avec les yeux. GARDEZ HORS DE PORTÉE DES ENFANTS, Réservé à l'usage industriel et commercial.

Active Ingredient: Benzalkonium Chloride 0.13%

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OPTISOURCE ANTIBACTERIAL FOAM HAND

benzalkonium chloride soap

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64646-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -BENZALKONIUM 1.3 mg UNII:7N6JUD5X6Y) **CHLORIDE** in $1\,\text{mL}$

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
COCAMIDO PRO PYLAMINE O XIDE (UNII: M4SL82J7HK)			
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS 10 FIC)			
COCO GLUCOSIDE (UNII: ICS790225B)			

]	Packaging						
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:64646-001- 02	4 in 1 CASE	12/22/20 15				
1		1250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	11/03/2015			

Labeler - Charlotte Products Ltd. (248293359)

Registrant - Charlotte Products Ltd. (248293359)

Establishment						
Name	Address	ID/FEI	Business Operations			
Charlotte Products Ltd.		248293359	manufacture(64646-001)			

Revised: 12/2019 Charlotte Products Ltd.