FRESH N UP - benzalkonium chloride solution
Rockline 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.

Drug Facts

Active Ingredient

Benzalkonium chloride 0.115%

Purpose

Antibacterial

Uses
For hand washing to decrease bacteria on the skin

Warnings
For external use only

When using this product
avoid the eyes and mucous membranes
If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if
if irritation develops and persists for more than 72 hours.

Keep out of reach of children

Keep out of reach of children. If swallowed contact a doctor or Poison Control Center right away.

Other Information
May be used on face, arms and legs.

Directions

- **For use** apply thoroughly to hands and face as desired. Allow to dry without wiping. Discard wipe in trash receptacle after use. Do not flush.
- **For dispensing** tear open package at notch. Dispose of wrapper in trash. Do not flush

Inactive Ingredients
Acrylates Copolymer, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, FDC Yellow 5, FDC Blue 1, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Chloride, Sodium Laureth Sulfate, Water

Package Label
Package label

FRESH N UP

benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57624-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.115 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57624-601-15	0.115 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2010	

Labeler - Rockline Industries, Inc (066886102)

Establishment

Name	Address	ID/FEI	Business Operations
Hgiene Salud, S.A. de C.V.		814608832	manufacture

Revised: 9/2010 Rockline Industries, Inc