ANTIBACTERIAL- benzalkonium chloride liquid
Brands International Corporation

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 - Antibacterial

Use for handwashing to decrease bacteria on skin

for external use only - hands only

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or redness develops and 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 immediately

Direction

* wet hands

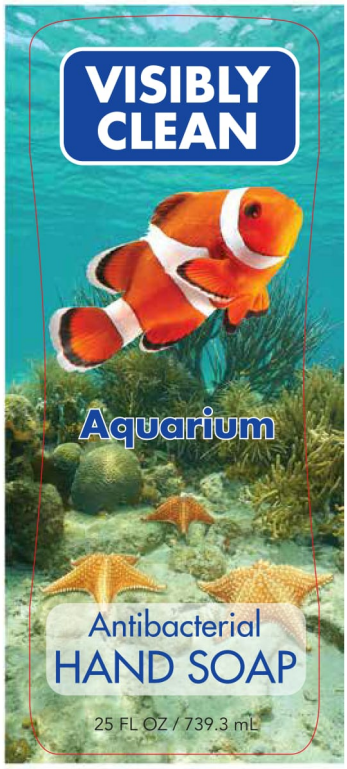
* apply to hands

* scrub thoroughly

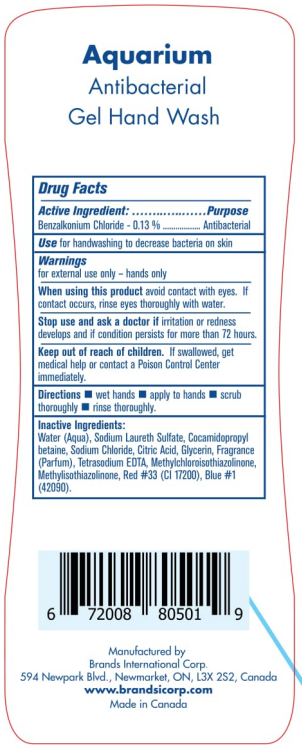
* rinse thoroughly

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Tetra Sodium EDTA, Methylchloroisothiazolinone, Methylisthiazolinone, Red # 33 (Cl 17200), Blue# 1(42090), Fragrance (Parfum)

die 5.75x2.25



BACK LABEL CLEAR FILM



label:
PMS 293 Blue
White & Black

white box under UPC

ANTIBACTERIAL

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50157-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-207-25	739 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/07/2017	

Labeler - Brands International Corporation (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(50157-207)

Revised: 7/2017 Brands International Corporation