

ANTIBACTERIAL ORANGE CLEMENTINE- 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.

Purpose Antibacterial liquid hand soap- Refill

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, Tetra Sodium EDTA, Methylchloroisothiazolinone, Methylthiazolinone, Yellow 5, Red 4, Polyquaternium-7, Fragrance (Parfum)

PURPOSE
Antibacterial
Liquid
Hand Soap
Orange Clementine



No Triclosan
 50 FL OZ (1.48L) **REFILL**

PURPOSE
 Orange Clementine
 Antibacterial Liquid Hand Soap
 50 FL OZ (1.48L)

Drug Facts

Active Ingredient.....Purpose
 Benzalkonium Chloride 0.13% w/w.....Antibacterial

Uses for handwashing or decrease bacteria to the skin.

Warnings For external use only.
 Stop use and ask a doctor if irritation or redness develops.

When using this product ■ do not get into eyes, if contact occurs, rinse eye thoroughly with water

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

Directions ■ wet hands ■ apply palmful to hands ■ scrub thoroughly ■ rinse

Inactive ingredients Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium chloride, Citric Acid, Fragrance (Parfum), Polyquaternium-7, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (CI 19140), Red 4 (CI 14700).



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Manufactured by:
 Brands International Corp.
 Newmarket, ON, L3X 2S2
www.brandscorp.com

ANTIBACTERIAL ORANGE CLEMENTINE			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-454
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
FD&C RED NO. 4 (UNII: X3W0AM1JLX)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			

EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-454-15	1480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/06/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/06/2022	

Labeler - Brands International Corporation (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(50157-454)

Revised: 9/2022

Brands International Corporation