

BREEZE ANTIBACTERIAL HANDSOAP LAVENDER AND JASMINE- benzalkonium chloride liquid

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI

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.

Breeze ANTIBACTERIAL hand soap LAVENDER JASMINE

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

- For handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product • Avoid contact with eyes. In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develops.

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

Directions

- Pump into hands, wet as needed
- Lather vigorously for at least 15 seconds
- Wash skin, rinse thoroughly and dry

Inactive ingredients

Aqua, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, DMDM Hydantoin, FD&C Blue No:1, FD&C Red No. 40, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

Extra Soft

CLEANSING

MOISTURIZING

REFRESHING

UNAC GROUP KOZMETİK SAN. TİC. LTD. ŞTİ

Trump Towers Residence No: 12/238 D.No:606 Şişli, İstanbul- TURKEY - Tel: +90 212 526 68 69
www.unac.com.tr

USA DISTRIBUTOR: UNAC INTERNATIONAL INC. / info@unacusa.com

Made in TURKEY

Packaging



DRUG FACTS LABEL

ANTIBACTERIAL HAND SOAP / LAVENDER-JASMINE

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0.13%	Antibacterial

55-031-01

BENZALKONIUM CHLORIDE 0.13% ANTIBACTERIAL

NDC: 749

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BREEZE ANTIBACTERIAL HANDSOAP LAVENDER AND JASMINE

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74955-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74955-031-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/03/2020	

Labeler - COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (595671824)

Establishment			
Name	Address	ID/FEI	Business Operations
COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		595671824	manufacture(74955-031)