

BREEZE ANTIBACTERIAL HANDSOAP PINK ORCHID AND COCONUT- 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 PINK ORCHID COCONUT

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

Styrene/Acrylates Copolymer Aqua, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, DMDM Hydantoin, 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 / PINK ORCHID - COCONUT

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0.13%.....	Antibacterial

4955-030-01

NDC: 7

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16,9 FL.OZ 500ML

BREEZE ANTIBACTERIAL HANDSOAP PINK ORCHID AND COCONUT

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74955-030
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
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
WATER (UNII: 059QF0K00R)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
EDETATE SODIUM (UNII: MP1J8420LU)	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74955-030-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2020	

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Marketing Information

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

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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(74955-030)

Revised: 10/2020

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI