

**SOFTIE ANTIBACTERIAL HANDSOAP MILK AND HONEY- 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.

Softie Soap® Antibacterial HAND SOAP Milk & Honey

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

- For handwashing to decrease bacteria on the skin

WARNINGS:

FOR EXTERNAL USE ONLY.

Avoid contact with eyes, if eye contact occurs, flush 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, lather vigorously for at least 15 seconds, rinse and dry thoroughly.

Inactive ingredients

Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Coco-Glucoside (and) Glyceryl Oleate, Cocamide DEA (and) Glycerin, Phenoxyethanol, Sodium Benzoate, Potassium Sorbate, Parfum, Benzyl Alcohol, Coumarin, Hexyl Cinnamal, D- Limonene, Linalool, CI 16035, CI 42090, CI 19140.

Gentle on Skin!

New!

Softsoap® is a registered trademark of Colgate-Palmolive Co. which has not manufactured, distributed or sponsored this product.

FDA APPROVED

Designed & Developed

By: Primax USA LLC

Brooklyn, NY 11204
MADE IN TURKEY

Packaging



DRUG FACTS LABEL

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Cocamidopropyl Betaine, Coco-Glucoside (and) Glyceryl Oleate, Cocamide
DEA (and) Glycerin, Phenoxyethanol, Sodium Benzoate, Potassium
Sorbate, Parfum, Benzyl Alcohol, Coumarin, Hexyl Cinnamal, D-Limonene,
Linalool, CI 16035, CI 42090, CI 19140.

SOFTIE ANTIBACTERIAL HANDSOAP MILK AND HONEY

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74955-050
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: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
COUMARIN (UNII: A4VZ22K1WT)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74955-050-01	400 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/02/2021	

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(74955-050)

Revised: 1/2021

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI