SOFTIE ANTIBACTERIAL HANDSOAP CHERRY BLOSSOM- 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 Cherry Blossom

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, Hexylcinnamal, Linalool.

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

MADE IN TURKEY

Packaging



DRUG FACTS

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SOFTIE ANTIBACTERIAL HANDSOAP CHERRY BLOSSOM

benzalkonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74955-045

Route of Administration TOPICAL

Active Ingredient/Active Moiety

8		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (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)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)		
COCO GLUCOSIDE (UNII: ICS790225B)		
GLYCERYL OLEATE (UNII: 4PC054V79P)		
COCO DIETHANO LAMIDE (UNII: 92005F972D)		
GLYCERIN (UNII: PDC6A3C0OX)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)		
LINALOOL, (+/-)- (UNII: D81QY6188E)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:74955-045- 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 sanayı ve ticaret anonım sirketi (595671824)

Establishment				
Name	Address	ID/FEI	Business Operations	
COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		595671824	manufacture(74955-045)	

Revised: 1/2021 COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI