

**SOFTIE ANTIBACTERIAL HANDSOAP LAVENDER AND CHAMOMILE- 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.*

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**Softie Soap® Antibacterial HAND SOAP Lavender & Chamomile**

***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, Coumarin, Eugenol, D-Limonene, Linalool, CI 16035, CI 42090.

***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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**Inactive ingredients** Aqua, Sodium Laureth Sulfate,  
Cocamidopropyl Betaine, Coco-Glucoside (and) Glyceryl Oleate,  
Cocamide DEA (and) Glycerin, Phenoxyethanol, Sodium Benzoate,  
Potassium Sorbate, Parfum, Coumarine, Eugenol, D-Limonene,  
Linalool, CI 16035, CI 42090.

## SOFTIE ANTIBACTERIAL HANDSOAP LAVENDER AND CHAMOMILE

benzalkonium chloride liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74955-047
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>COUMARIN</b> (UNII: A4VZ22K1WT)	
<b>EUGENOL</b> (UNII: 3T8H1794QW)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74955-047-01	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(74955-047)

Revised: 1/2021

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI