

**SOFTIE ANTIBACTERIAL HANDSOAP SOFT ROSE- 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 Soft Rose

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 Benzoate, Citral, Geraniol, CI 16035.

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

| Drug Facts | |
|--|----------------|
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Cocamidopropyl Betaine, Coco-Glucoside (and) Glyceryl Oleate,
Cocamide DEA (and) Glycerin, Phenoxyethanol, Sodium Benzoate,
Potassium Sorbate, Parfum, Benzyl Benzoate, Citral, Geraniol, C 16035.

SOFTIE ANTIBACTERIAL HANDSOAP SOFT ROSE

benzalkonium chloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74955-052 |
| 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: 5OCF3O11KX) | |
| COCO GLUCOSIDE (UNII: ICS790225B) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| BENZYL BENZOATE (UNII: N863NB338G) | |
| CITRAL (UNII: T7EU0O9VPP) | |
| GERANIOL (UNII: L837108USY) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:74955-052-01 | 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(74955-052) |

Revised: 1/2021

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI