

**SOFTIE ANTIBACTERIAL HANDSOAP STRAWBERRY AND KIWI- 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 Strawberry & Kiwi**

***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, Linalool, 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**

|  |                |
|--|----------------|
| <b>Drug Facts</b>  |                |
| <b>Active Ingredient</b>   | <b>Purpose</b> |
| Benzalkonium Chloride 0.13%.....   | Antibacterial  |
| <b>Use</b> • For handwashing to decrease bacteria on the skin  |                |
| <b>WARNINGS: FOR EXTERNAL USE ONLY.</b><br>Avoid contact with eyes, if eye contact occurs, flush with water. |                |

Wash 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, Linalool, CI 16035.

## SOFTIE ANTIBACTERIAL HANDSOAP STRAWBERRY AND KIWI

benzalkonium chloride liquid

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:74955-053 |
| 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<br>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)        |          |
| LINALOOL, (+/-)- (UNII: D81QY6I88E)         |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)          |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74955-053-01 | 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(74955-053) |

Revised: 1/2021

COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI