

**SOFTLIPS CHERRY- dimethicone, octinoxate, octisalate,  
oxybenzone ointment**  
**The Mentholatum Company**

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**Drug Facts - Softlips Cherry SPF 20**

**Active ingredients**

Dimethicone 2%

Octinoxate 7.5%

Octisalate 3%

Oxybenzone 3%

**Purpose**

Dimethicone - Skin protectant

Octinoxate - Sunscreen

Octisalate - Sunscreen

Oxybenzone - Sunscreen

**Uses**

- helps prevent sunburn
- temporarily protects chapped or cracked lips

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

**For external use only**

**Do not use**

on damaged or broken skin

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

- rash occurs
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

## Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months of age: ask a doctor

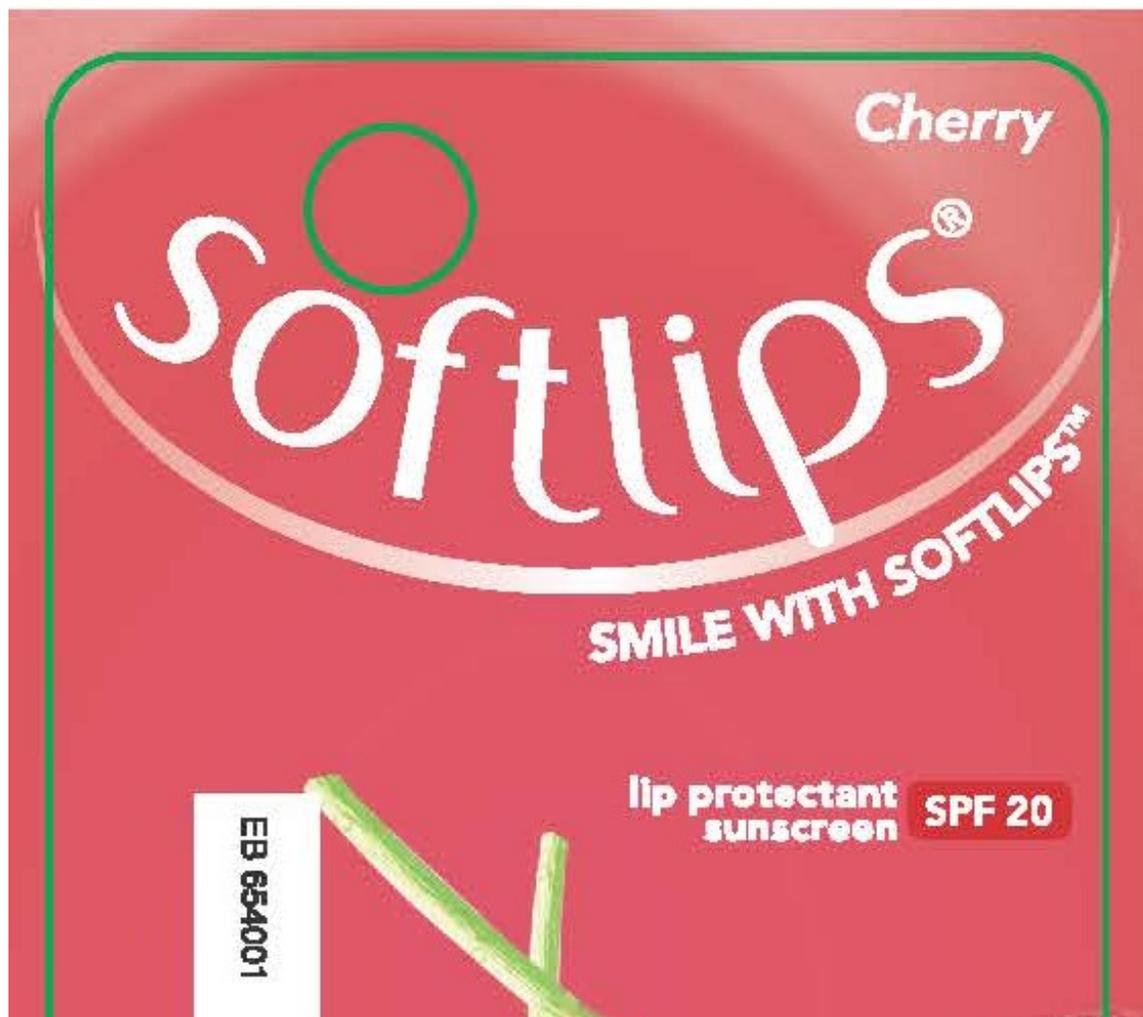
## Inactive ingredients

ozokerite, squalane, ethylhexyl palmitate, petrolatum, myristyl myristate, myristyl lactate, flavor, cetyl alcohol, myristyl laurate, myristyl alcohol, BHT, menthol, tocopheryl acetate [vitamin E]

## Questions?

Toll free **1-877-636-2677** MON-FRI 9 AM to 5 PM (EST) **softlips.com**

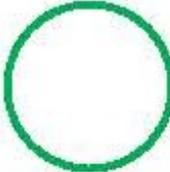
## Package/Label Principal Display Panel





Package/Label Principal Display Panel





All Softlips®  
products are  
gluten-free.

| <b>Drug Facts</b>         |                 |
|---------------------------|-----------------|
| <b>Active Ingredients</b> | <b>Purpose</b>  |
| Dimethicone 2%.....       | Skin protectant |
| Octinoxate 7.5%.....      | Sunscreen       |
| Octisalate 3%.....        | Sunscreen       |
| Oxybenzone 3%.....        | Sunscreen       |

**Uses**

- helps prevent sunburn ■ temporarily protects chapped or cracked lips

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**Softlips® has a lip balm for your every mood and moment. Just glide it on, and it's instant happiness! With essential moisturizers plus SPF protection— it's so smart. So irresistible. So you.™**

party with proof of purchase for a refund or exchange.

GUARANTEE OF SATISFACTION: If this item is unsatisfactory, return it to The Mentholatum Company

**For external use only**

**Do not use on damaged or broken skin**

**When using this product keep out of eyes. Rinse with water to remove.**

**Stop use and ask a doctor if** ■ rash occurs ■ condition worsens  
 ■ symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor

**Other information**

- protect this product from excessive heat and direct sun

**Inactive ingredients**

ozokerite, squalane, ethylhexyl palmitate, petrolatum, myristyl myristate, myristyl lactate, cetyl alcohol, myristyl laurate, myristyl alcohol, BHT, flavor, menthol, tocopheryl acetate [vitamin E]

**Questions?**

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 softlips.com

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The Mentholatum Company  
 Orchard Park, NY 14127

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**SOFTLIPS CHERRY**

dimethicone, octinoxate, octisalate, oxybenzone ointment

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10742-8512 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE       | 20 mg in 1 g |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | OCTINOXATE        | 75 mg in 1 g |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 30 mg in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)   | OXYBENZONE        | 30 mg in 1 g |

## Inactive Ingredients

| Ingredient Name                              | Strength |
|--|----------|
| CERESIN (UNII: Q1LS2UJO3A)                   |          |
| SQUALANE (UNII: GW89575KF9)                  |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)      |          |
| PETROLATUM (UNII: 4T6H12BN9U)                |          |
| MYRISTYL MYRISTATE (UNII: 4042ZC00DY)        |          |
| MYRISTYL LACTATE (UNII: 1D822OC34X)          |          |
| CETYL ALCOHOL (UNII: 936JST6JCN)             |          |
| MYRISTYL LAURATE (UNII: 58U0NZN2BT)          |          |
| MYRISTYL ALCOHOL (UNII: V42034O9PU)          |          |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)  |          |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) |          |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)        |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10742-8512-1 | 1 in 1 BLISTER PACK                              | 04/20/2000           |                    |
| 1 |                  | 2 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:10742-8512-9 | 2 in 1 BLISTER PACK                              | 04/20/2000           |                    |
| 2 |                  | 2 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 04/20/2000           |                    |

**Labeler** - The Mentholatum Company (002105757)

**Registrant** - The Mentholatum Company (002105757)

## Establishment

| Name                    | Address | ID/FEI    | Business Operations     |
|-------------------------|---------|-----------|-------------------------|
| The Mentholatum Company |         | 002105757 | manufacture(10742-8512) |