

**SOFTLIPS CHERRY CORDIAL, MAPLE BUTTER, FROSTED BERRY- dimethicone, octinoxate, octisalate, oxybenzone stick**  
**The Mentholatum Company**

*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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**Drug Facts**

**Active ingredient**

Dimethicone 2%

Octinoxate 7.5%

Octisalate 3%

Oxybenzone 3%

**Purpose**

Dimethicone - Skin protectant

Octinoxate - Sunscreen

Octisalate - Sunscreen

Oxybenzone - Sunscreen

**Keep Out of Reach of Children**

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

**Uses**

- helps prevent sunburn
- temporarily protects chapped or cracked lips

**Warnings**

Skin Cancer/Skin Aging Alert: Spending time in the sun increased 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

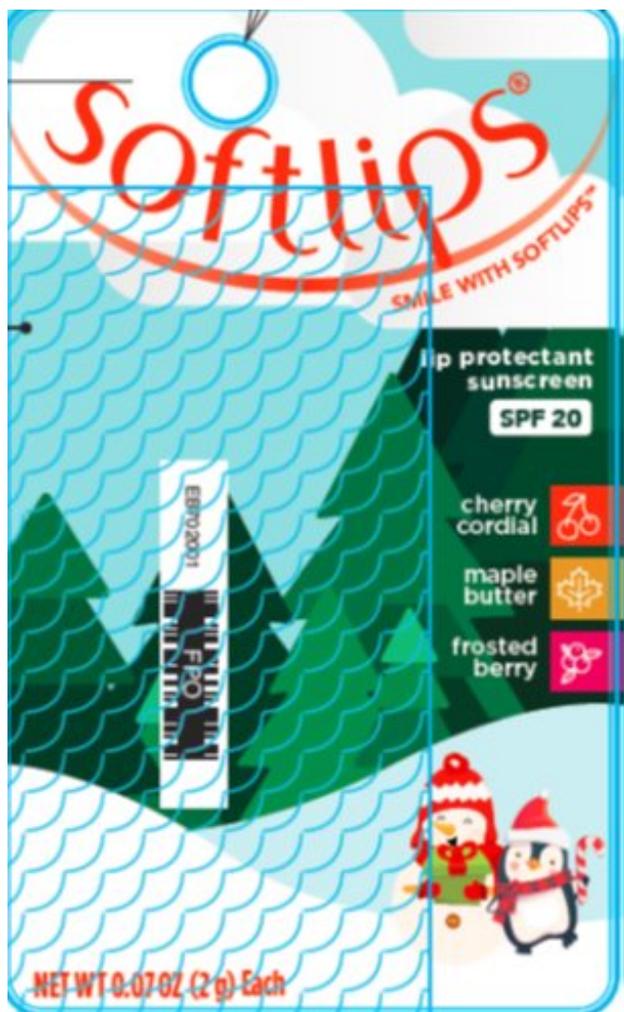
## **Directions**

- 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

## **Inactive ingredients**

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

## **Package/Label Principal Display Panel**



**Principal Display Panel**

Softlips® contains no ingredients made from a gluten-containing grain (wheat, barley, or rye).

**Drug Facts**

Active Ingredients	Purpose
Dimethicone 2%	Skin protectant
Octinoxate 7.5%	Sunscreen
Octisalate 3%	Sunscreen
Oxybenzone 3%	Sunscreen

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.\*

**Uses**

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**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, flavor, cetyl alcohol, myristyl laurate, myristyl alcohol, BHT, menthol, tocopheryl acetate [vitamin E]

**Questions?**

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

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**Mentholatum®**  
The Mentholatum Company  
Orchard Park, NY 14127

## SOFTLIPS CHERRY CORDIAL, MAPLE BUTTER, FROSTED BERRY

dimethicone, octinoxate, octisalate, oxybenzone stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-7001
<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 ug in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CERESIN</b> (UNII: Q1LS2UJ03A)	
<b>SQUALANE</b> (UNII: GW89575KF9)	

<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)	
<b>MYRISTYL LACTATE</b> (UNII: 1D822OC34X)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>MYRISTYL LAURATE</b> (UNII: 58U0NZN2BT)	
<b>MYRISTYL ALCOHOL</b> (UNII: V42034O9PU)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-7001-3	3 in 1 BLISTER PACK	10/15/2018	
1		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 final	part352	10/15/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-7001)

Revised: 2/2023

The Mentholatum Company