SOFTLIPS RASPBERRY- dimethicone, octinoxate, octisalate, oxybenzone ointment 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.

Drug Facts

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

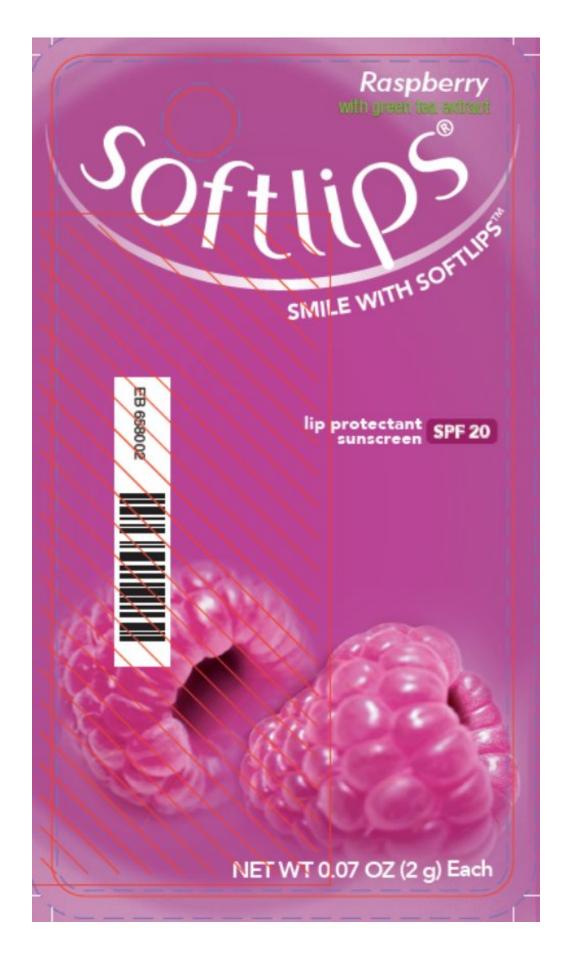
Inactive ingredients

ozokerite, squalane, ethylhexyl palmitate, petrolatum, myristyl myristate, myristyl lactate, cetyl alcohol, myristyl laurate, flavor, myristyl alcohol, BHT, camellia sinensis (green tea) leaf extract, carthamus tinctorius (safflower) seed oil, menthol, oenothera biennis (evening primrose) oil, punica granatum (pomegranate) seed extract, tocopheryl acetate [vitamin E]

Questions?

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

Package/Label Principal Display Panel



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softlips

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All Softing® products are gluten-free.

Softlips® has a stick 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.

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Other information

protect this product from excessive heat and direct sun

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The Mentholatum Company Orchard Park, NY 14127



SOFTLIPS RASPBERRY

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8470
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 1 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	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)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
SAFFLOWER OIL (UNII: 65UEH262IS)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)			
POMEGRANATE SEED (UNII: 7294Z34NS7)			
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742- 8470-1	1 in 1 BLISTER PACK	01/12/2007	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742- 8470-9	2 in 1 BLISTER PACK	01/12/2007	
2		2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part352	01/12/2007	
IIIIai			

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment			
Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8470)

Revised: 2/2023 The Mentholatum Company