

SOFTLIPS OASIS PEACH MANGO- dimethicone, oxybenzone, octinoxate 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.

Drug Facts

Active ingredient

Dimethicone 2%

Octinoxate 7.5%

Oxybenzone 4%

Purpose

Dimethicone - Skin protectant

Octinoxate - 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: ask a doctor

Other information

- protect this product from excessive heat and direct sun

Inactive ingredients

ozokerite, petrolatum, mineral oil, octyldodecanol, ethylhexyl palmitate, polyglyceryl-6 octastearate, cetearyl alcohol, flavor, polyglyceryl-6 polyricinoleate, sea water, VP/eicosene copolymer, ammonium glycyrrhizate, butylene glycol, carthamus tinctorius (safflower) seed oil, cetearyl glucoside, ethylhexylglycerin, hyaluronic acid, limnanthes alba (meadowfoam) seed oil, mangifera indica (mango) fruit extract, menthol, nannochloropsis oculata extract, pentylene glycol, phenoxyethanol, phytosteryl/octyldodecyl lauroyl glutamate, porphyra umbilicalis extract, prunus persica (peach) fruit extract, silanetriol, silybum marianum seed oil, tetrahexyldecyl ascorbate [Vitamin C], tocopheryl acetate [Vitamin E]

Package/Label Principal Display Panel



Principal Display Panel

Put an end to **thirsty lips!**

softlips® oasis Water-In Lip Balm seriously moisturizes lips with its refreshing real fruit extract formula infused with Sea Mineral Water, Sea Algae, plus Hyaluronic Acid.

Its exclusive Water-Lock technology hydrates for up to 12 hours to keep lips soft and smooth all day.

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Questions? 1-877-636-2677 MON-FRI 9 AM to 5 PM (EST)

Manufactured By:
The Mentholatum Co.
Orchard Park, NY
14127



Mentholatum®
EB718001
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SOFTLIPS OASIS PEACH MANGO

dimethicone, oxybenzone, octinoxate stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10742-8743 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 20 mg in 1 g |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 40 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CERESIN (UNII: Q1LS2UJO3A) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| POLYGLYCERYL-6 DISTEARATE (UNII: Z35I17EQOP) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3) | |
| AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| SAFFLOWER OIL (UNII: 65UEH262IS) | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y) | |
| MANGO (UNII: I629I3NR86) | |
| RACEMENTHOL (UNII: YS08XHA860) | |
| PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q) | |
| PORPHYRA UMBILICALIS (UNII: 14AN0J70WO) | |
| PEACH (UNII: 3OKE88I3QG) | |
| SILANETRIOL (UNII: E52D0J3TS5) | |
| SILYBUM MARIANUM SEED OIL (UNII: NYY23HEN06) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10742-8743-1 | 1 in 1 BLISTER PACK | 05/01/2019 | |
| 1 | | 4.5 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:10742-8743-2 | 4.5 g in 1 TUBE; Type 0: Not a Combination Product | 07/15/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 05/01/2019 | |

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| The Mentholatum Company | | 002105757 | manufacture(10742-8743) |

Revised: 2/2023

The Mentholatum Company