

SOFTLIPS TROPICAL COCONUT PEACH PASSION- dimethicone 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 ingredients

Dimethicone 2%

Purpose

Dimethicone - Skin protectant

Uses

- helps prevent and temporarily protects chapped or cracked lips
- helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- 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 as needed

Inactive ingredients

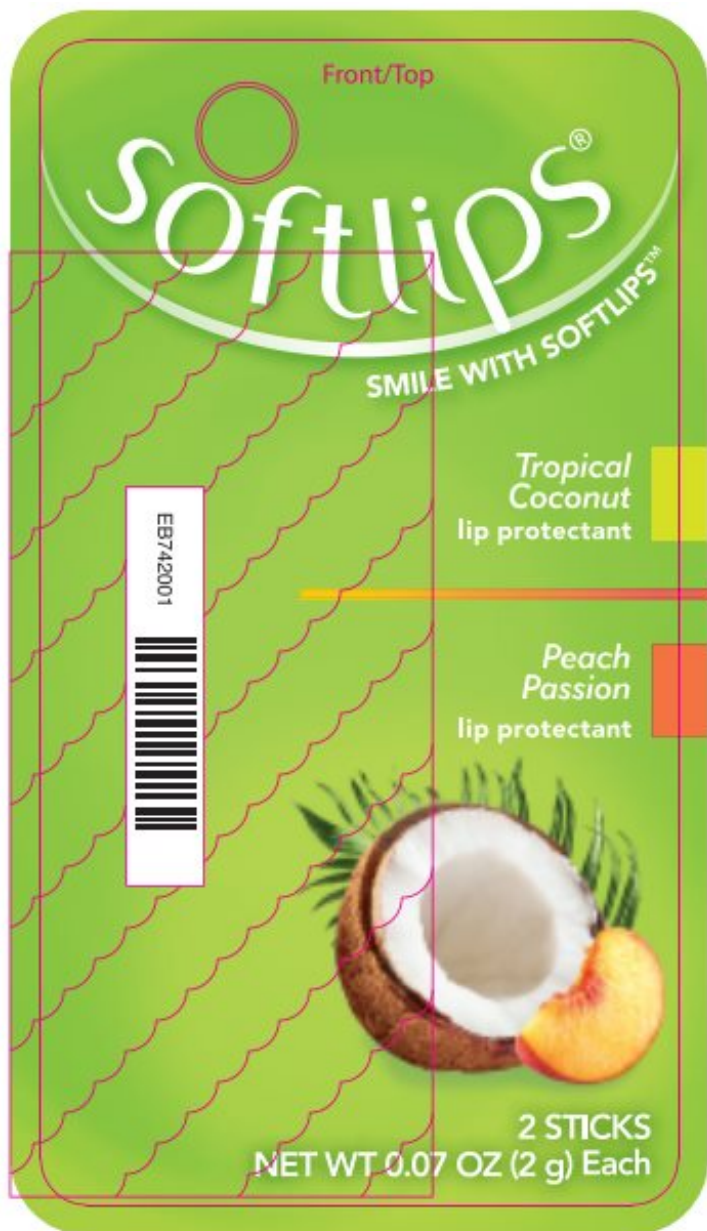
ozokerite, petrolatum, ethylhexyl palmitate, squalane, octyldodecanol, myristyl myristate, ricinus communis (castor) seed oil, myristyl lactate, cetyl alcohol, flavor, myristyl laurate, myristyl alcohol, ammonium glycyrrhizate, BHT, menthol, tocopheryl acetate [vitamin E]

Questions?

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

softlips.com

Package/Label Principal Display Panel



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softlips®



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

Softlips® has a lip balm for your every mood and moment. Just glide it on, and it's instant happiness! With lip-nourishing moisturizers and fun flavors, it's so smart. So irresistible. So you.™

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GUARANTEE OF SATISFACTION: If this item is unsatisfactory, return it to The Mentholatum Company with proof of purchase for a refund or exchange.



EB742001

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Manufactured By:
The Mentholatum Company
Orchard Park, NY 14127

Retain this package for complete information.



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SOFTLIPS TROPICAL COCONUT PEACH PASSION

dimethicone stick

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10742-7005 |
|-------------------------|----------------|--------------------|----------------|
| 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 | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| CERESIN (UNII: Q1LS2UJO3A) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | | | | |
| SQUALANE (UNII: GW89575KF9) | | | | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | | | | |
| MYRISTYL MYRISTATE (UNII: 4042ZC00DY) | | | | |
| CASTOR OIL (UNII: D5340Y2I9G) | | | | |
| MYRISTYL LACTATE (UNII: 1D822OC34X) | | | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | | | |
| MYRISTYL LAURATE (UNII: 58U0NZN2BT) | | | | |
| MYRISTYL ALCOHOL (UNII: V42034O9PU) | | | | |
| AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C) | | | | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | | | | |
| LEVOMENTHOL (UNII: BZ1R15MTK7) | | | | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:10742-7005-1 | 2 in 1 BLISTER PACK | 05/01/2020 | |
| 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 | part347 | 05/01/2020 | | |

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| The Mentholatum Company | | 002105757 | manufacture(10742-7005) |