

SOFTLIPS TROPICAL COCONUT- 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

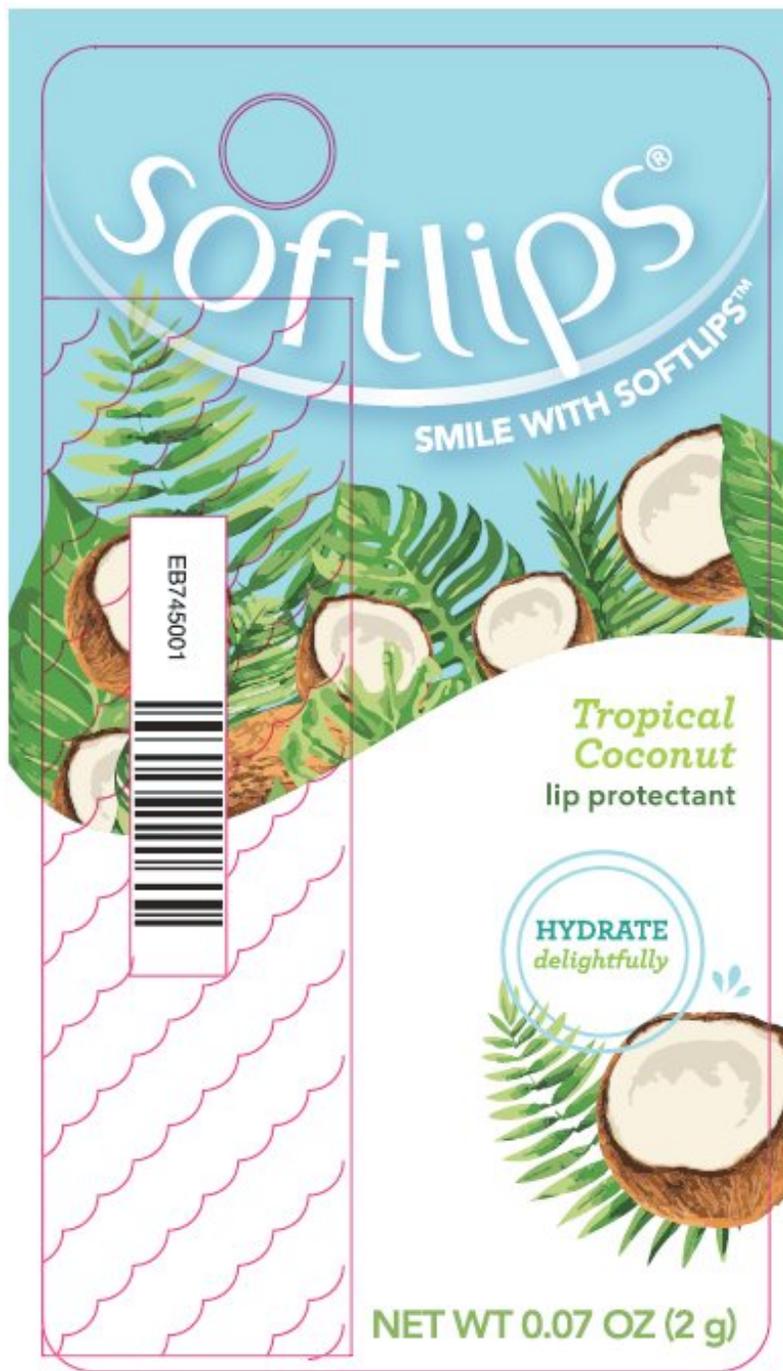
Inactive ingredients

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 9AM to 5PM (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.



EB745001 ©2019

Manufactured By:
The Mentholatum Company
Orchard Park, NY 14127



Retain this package for complete information.

SOFTLIPS TROPICAL COCONUT

dimethicone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-7007
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:10742-7007-1	1 in 1 BLISTER PACK	09/30/2019	
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	09/30/2019	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-7007)