

**SOFTLIPS VANILLA- 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 ingredient**

Dimethicone 2%

**Purpose**

Dimethicone - Skin protectant

**Uses**

- temporarily protects and helps relieve chapped or cracked lips
- helps 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

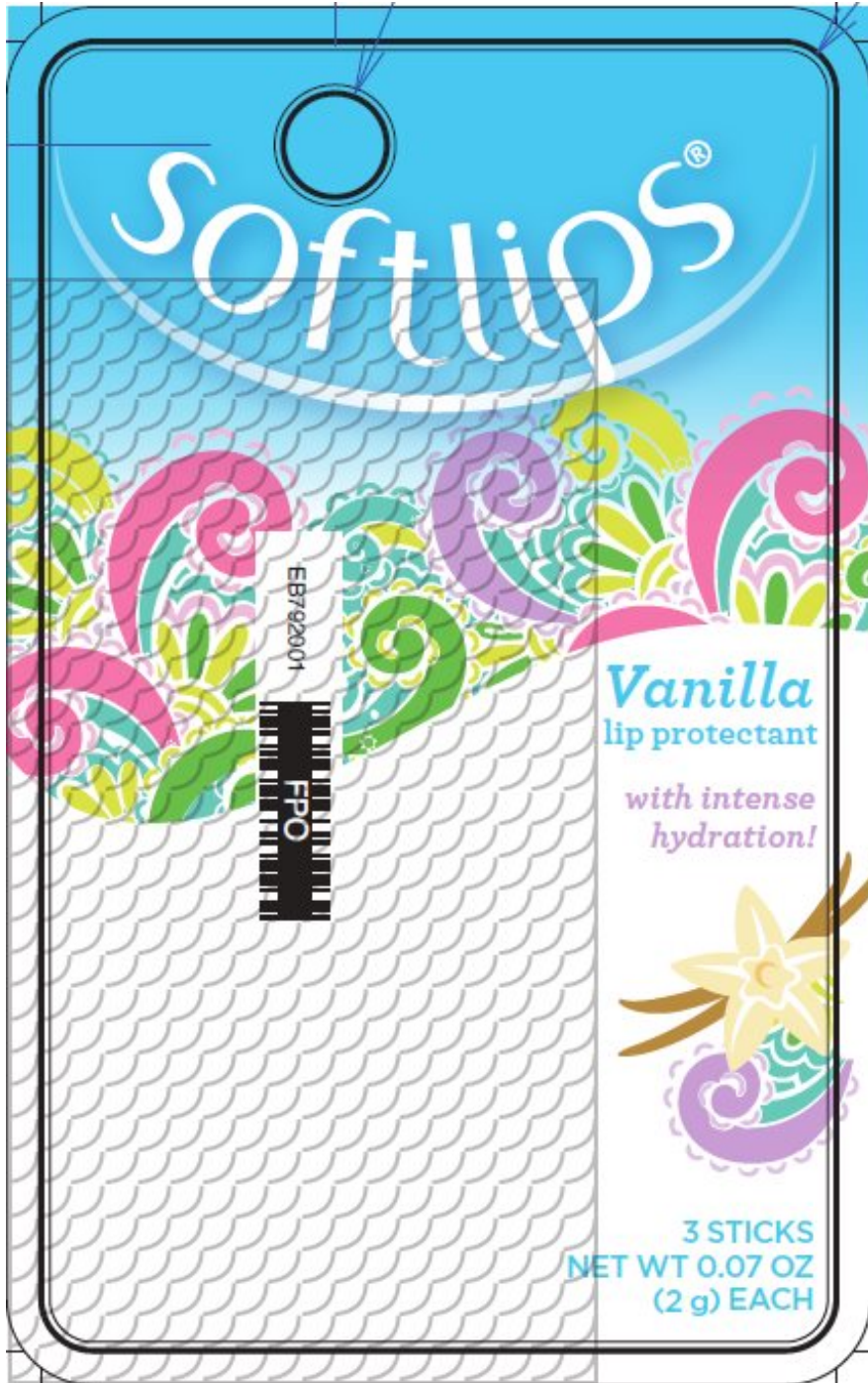
**Inactive ingredients**

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

**Questions?**

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

**Package/Label Principal Display Panel**



**Package/Label Principal Display Panel**

Treat your lips to the sweetness of Softlips® Vanilla. A warm and smooth glide of lip-nourishing ingredients to leave your lips soft and hydrated.



100%  
Recyclable  
Card



PRODUCT NOT  
TESTED ON ANIMALS



GLUTEN  
FREE\*



PARABEN  
FREE



PHthalate  
FREE

Made in the USA with global materials.

### Drug Facts

Active ingredient	Purpose
Dimethicone 2%	Skin protectant

**Uses**

- temporarily protects and helps relieve chapped or cracked lips
- helps 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, octyldodecanol, squalane, myristyl myristate, ricinus communis (castor) seed oil, myristyl lactate, cetyl alcohol, myristyl laurate, myristyl alcohol, BHT, flavor, menthol, tocopheryl acetate [vitamin E]

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

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



The Mentholatum Company  
Orchard Park, NY 14127  
EB792001 ©2021

softlips.com



Retain card for complete information.

## SOFTLIPS VANILLA

dimethicone stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8508
<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
---	-------------	--------------

### Inactive Ingredients

Ingredient Name	Strength
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<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</b> (UNII: H4N855PNZ1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8508-1	2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/03/2016	
2	NDC:10742-8508-2	3 in 1 BLISTER PACK	07/26/2021	
2		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	10/03/2016	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8508)