

**SOFTLIPS WATERMELON- 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.*

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**Drug Facts**

**Active ingredients**

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, 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)

## Package/Label Principal Display Panel



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Let the refreshing and delicious Softlips® Watermelon perk up your lips. Smooth and soothing glide with nourishing ingredients for soft and hydrated lips!



100%  
Recyclable  
Card



PRODUCT NOT TESTED ON ANIMALS



GLUTEN FREE\*



PARABEN FREE



PHTHALATE FREE

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

Made in the USA  
with global materials.



softlips.com

The Mentholatum Company  
Orchard Park, NY 14127  
EB793001 ©2021

Retain card for complete information.



## SOFTLIPS WATERMELON

dimethicone stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-7008
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:10742-7008-1	1 in 1 BLISTER PACK	09/30/2019	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-7008-2	2 in 1 BLISTER PACK	10/15/2021	
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	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(10742-7008)