SOFTLIPS WATERMELON, 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

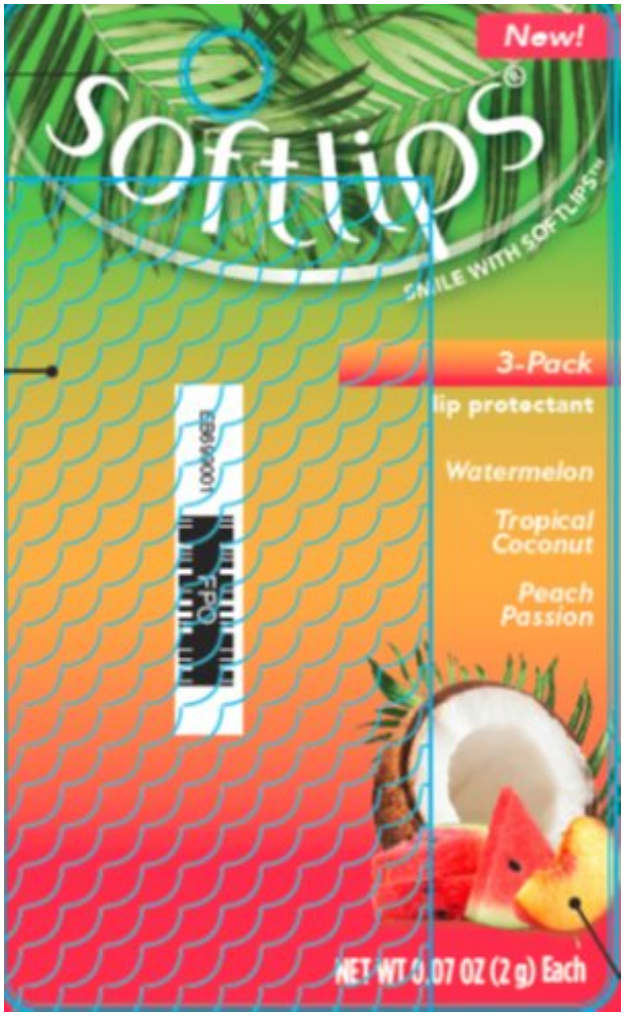
ozokerite, petrolatum, ethylhexyl palmitate, squalane, octyldodecanol, myristyl myristate, ricinus communis (castor) seed oil, myristyl lactate, flavor, cetyl alcohol, myristyl laurate,

myristyl alcohol, BHT, menthol, tocopheryl acetatate [vitamin E]

Questions?

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

Package/Label Principal Display Panel



Package/Label Principal Display Panel

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dimethicone stick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-7003
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)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-7003-3	3 in 1 BLISTER PACK	10/15/2018	
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	10/15/2018	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-7003)

Revised: 2/2023 The Mentholatum Company