SOFTLIPS VANILLA- dimethicone, octinoxate, octisalate, oxybenzone ointment
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%

Octinoxate 7.5%

Octisalate 3%

Oxybenzone 3%

Purpose

Dimethicone - Skin protectant

Octinoxate - Sunscreen

Octisalate - Sunscreen

Oxybenzone - Sunscreen

Uses

- helps prevent sunburn
- temporarily protects chapped or cracked lips

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash occurs
- 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 liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor

Other information

- protect this product from excessive heat and direct sun

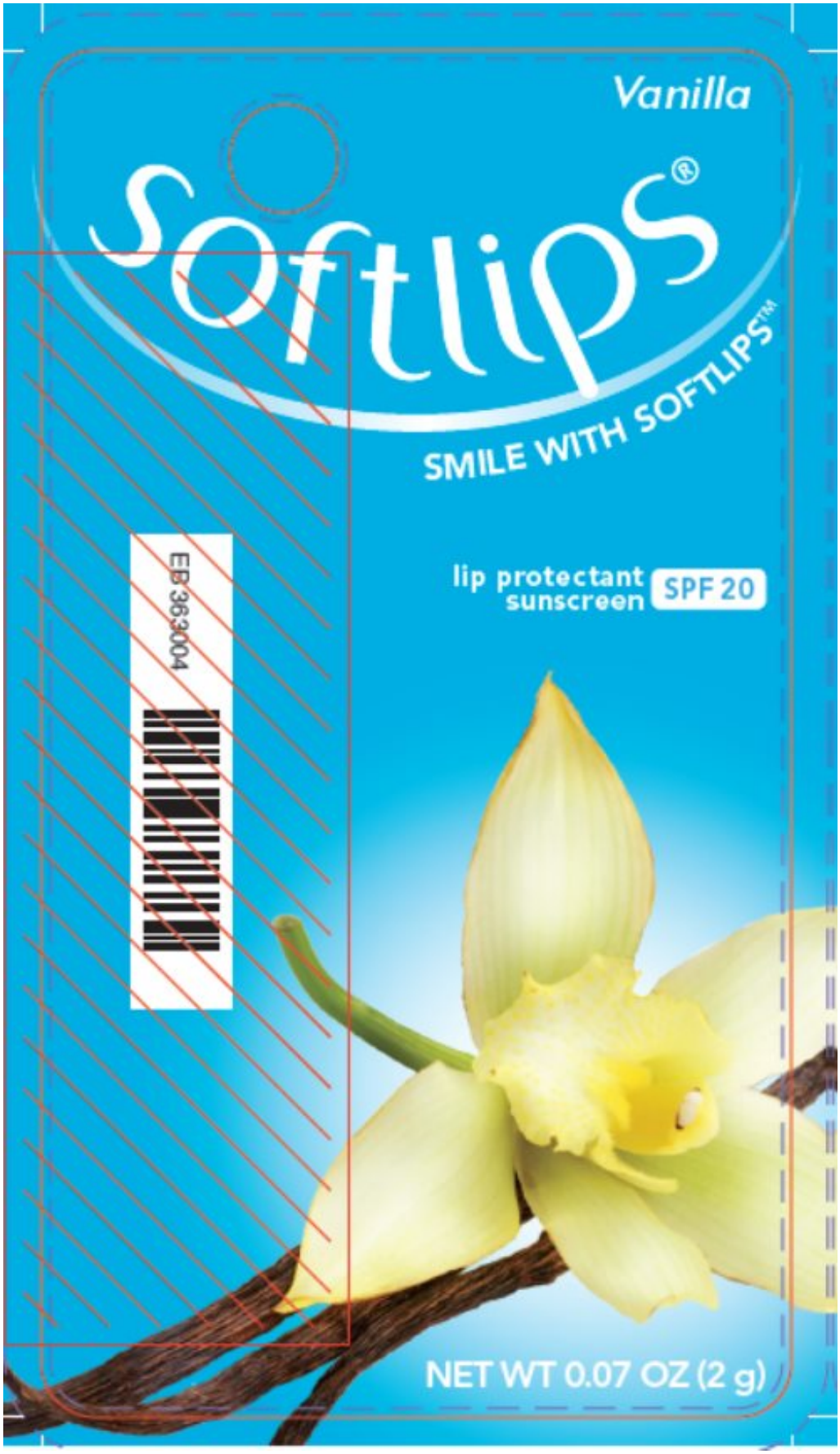
Inactive ingredients

ozokerite, squalane, ethylhexyl palmitate, petrolatum, myristyl myristate, myristyl lactate, cetyl alcohol, myristyl laurate, myristyl alcohol, BHT, flavor, menthol, tocopheryl acetatate [vitamin E]

Questions?

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

Principal Display Panel



Principal Display Panel

softlips®

All Softlips® products are gluten-free.

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Octinoxate 7.5%	Sunscreen
Octisalate 3%	Sunscreen
Oxybenzone 3%	Sunscreen

Softlips® has a lip balm for your every mood and moment. Just glide it on, and it's instant happiness! With essential moisturizers plus SPF protection— it's so smart. So irresistable. So you.™

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Mentholatum®

The Mentholatum Company
Orchard Park, NY 14127

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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.

SOFTLIPS VANILLA

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-3051
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
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
SQUALANE (UNII: GW89575KF9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PETROLATUM (UNII: 4T6H12BN9U)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
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:10742-3051-1	1 in 1 BLISTER PACK	11/19/1997	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-3051-9	2 in 1 BLISTER PACK	11/19/1997	
2		2 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:10742-3051-2	2 g in 1 TUBE; Type 0: Not a Combination Product	11/19/1997	
4	NDC:10742-3051-3	3 in 1 BLISTER PACK	03/02/2020	
4		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 not final	part352	11/19/1997	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-3051)

Revised: 2/2023 The Mentholatum Company