SOFTLIPS PEARL PLUS VANILLA- dimethicone, octinoxate, octisalate, oxybenzone
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.

SOFTLIPS PEARL PLUS VANILLA

Softlips Pearl

Drug Facts

Active ingredient

Octinoxate 7.5%

Octisalate 5%

Purpose

Octinoxate – Sunscreen

Octisalate - Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Agent 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.

Dosage and Administration

- 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

lanolin oil, hydrogenated polyisobutene, ozokerite, limnanthes alba (meadowfoam) seed oil, VP/hexadecane copolymer, mineral oil, bis-diglycerl polyacyladipate-2, oleyl alcohol, copernicia cerifera (carnauba) wax, ricinus communis (castor) seed oil, cetyl lactate, polyethylene, paraffin, ammonium glycyrrhizate, BHT, flavor, magnesium stearate, menthol, tocopheryl acetate [vitamin E], bismuth oxychloride, carmine, mica, titanium dioxide

Questions or comments?

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

Softlips.com

Softlips Vanilla

Drug Facts

Active Ingredient

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 Agent 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.

Dosage and Administration

- 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 acetate [vitamin E]

Questions or comments?

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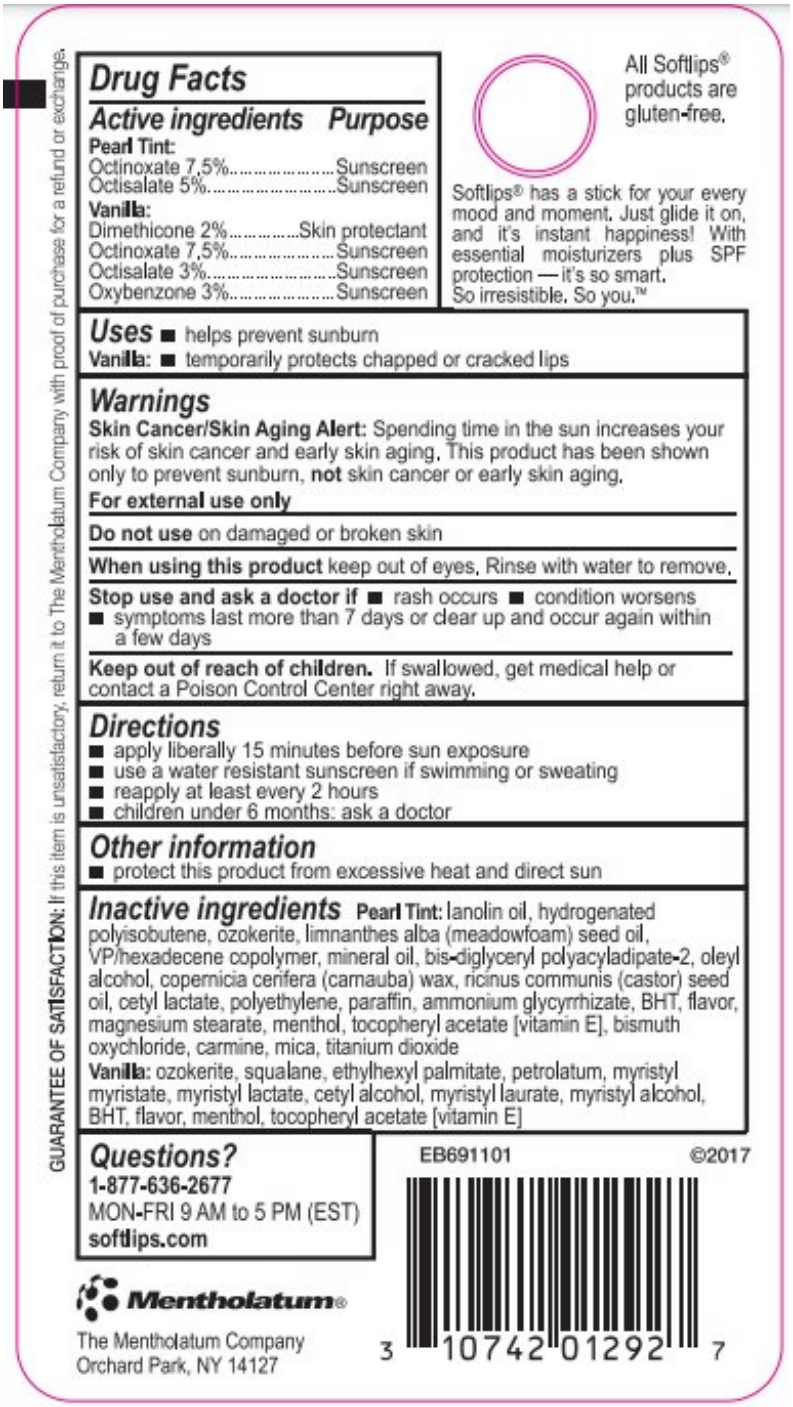
Softlips.com

Principal Display Panel

Principal Display Panel



SOFTLIPS PEARL PLUS VANILLA

dimethicone, octinoxate, octisalate, oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-7011

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-	1 in 1 PACKAGE; Type 0: Not a Combination	01/02/2017	

1	7011-1	Product	01/02/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 CYLINDER	1 g
Part 2	1 CYLINDER	1 g

Part 1 of 2

SOFTLIPS PEARL

octinoxate, octisalate stick

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
LANOLIN OIL (UNII: OVV5IIJ58F)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
CERESIN (UNII: Q1LS2UJO3A)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
MINERAL OIL (UNII: T5L8T28FGP)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CASTOR OIL (UNII: D5340Y2I9G)	
CETYL LACTATE (UNII: A7EVH2RK4O)	
PARAFFIN (UNII: I9O0E3H2ZE)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CARMINIC ACID (UNII: CID8Z8N95N)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2010	

Part 2 of 2

SOFTLIPS VANILLA

dimethicone, octinoxate, octisalate, oxybenzone stick

Product Information

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		2 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/19/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/02/2017	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-7011)

Revised: 2/2023 The Mentholatum Company