SOFTLIPS PEARL- octinoxate, octisalate 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

Octinoxate 7.5%

Octisalate 5%

Purpose

Octinoxate - Sunscreen

Octisalate - Sunscreen

Uses

- helps prevent sunburn

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

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

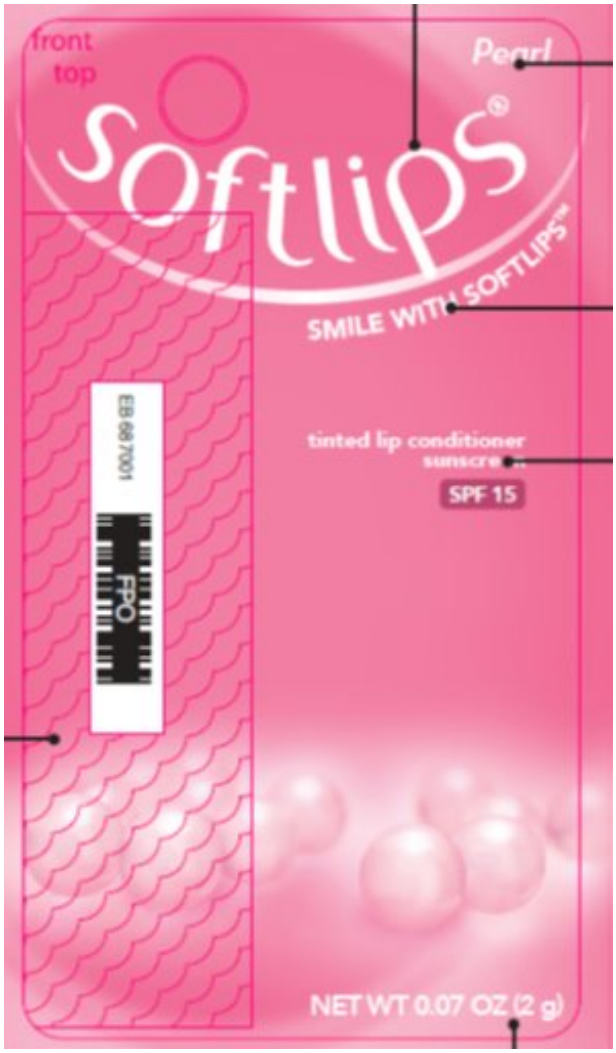
Inactive ingredients

lanolin oil, hydrogenated polyisobutene, ozokerite, limnanthes alba (meadowfoam) seed oil, VP/hexadecene copolymer, mineral oil, bis-diglyceryl 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

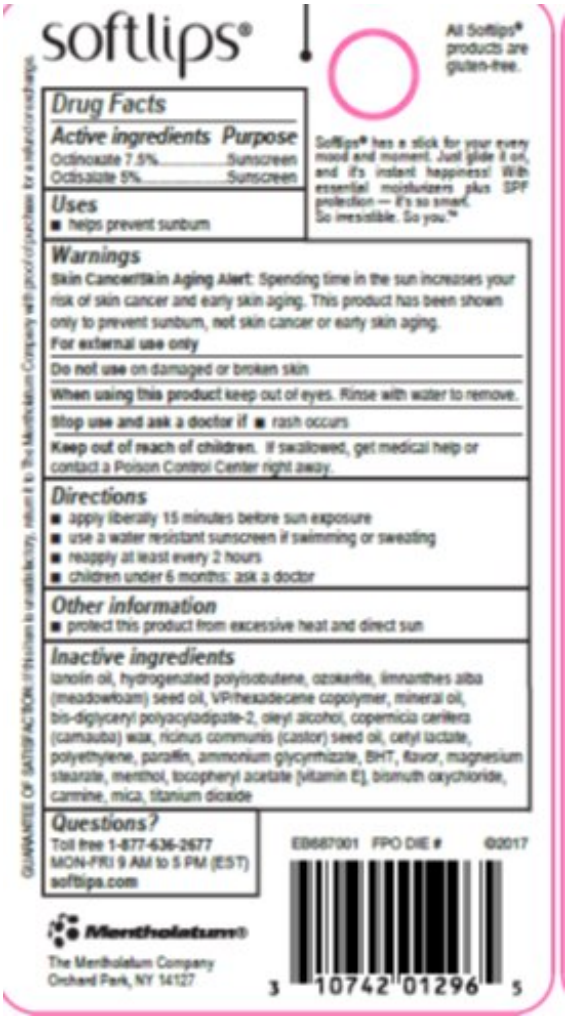
Questions?

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

Principal Display Panel



Principal Display Panel



SOFTLIPS PEARL

octinoxate, octisalate stick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8573
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	NDC:10742-8573-1	1 in 1 BLISTER PACK	02/01/2010	
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	part352	02/01/2010	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8573)

Revised: 2/2023 The Mentholatum Company