

**SOFTLIPS OASIS PINEAPPLE COCONUT- dimethicone, oxybenzone, octinoxate 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 ingredient**

Dimethicone 2%

Octinoxate 7.5%

Oxybenzone 4%

**Purpose**

Dimethicone - Skin protectant

Octinoxate - 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, petrolatum, mineral oil, octyldodecanol, ethylhexyl palmitate, polyglyceryl-6 octastearate, cetearyl alcohol, flavor, polyglyceryl-6 polyricinoleate, sea water, VP/eicosene copolymer, ammonium glycyrrhizate, ananas sativus (pineapple) fruit extract, butylene glycol, carthamus tinctorius (safflower) seed oil, cetearyl glucoside, cocos nucifera (coconut) extract, ethylhexylglycerin, hyaluronic acid, limnanthes alba (meadowfoam) seed oil, menthol, nannochloropsis oculata extract, pentylene glycol, phenoxyethanol, phytosteryl/octyldodecyl lauroyl glutamate, porphyra umbilicalis extract, silanetriol, silybum marianum seed oil, tetrahexyldecyl ascorbate [vitamin C], tocopheryl acetate [vitamin E]

## **Package/Label Principal Display Panel**



Principal Display Panel

Put an end **to** thirsty lips!

softlips® **oasis** Water-In Lip Balm seriously moisturizes lips with its refreshing real fruit extract formula infused with Sea Mineral Water, Sea Algae, plus Hyaluronic Acid.

Its exclusive Water-Lock technology hydrates for up to 12 hours to keep lips soft and smooth all day.

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

Manufactured By:  
The Mentholatum Co.  
Orchard Park, NY  
14127



**Mentholatum®**  
EB722001  
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**SOFTLIPS OASIS PINEAPPLE COCONUT**

dimethicone, oxybenzone, octinoxate stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8745
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>POLYGLYCERYL-6 DISTEARATE</b> (UNII: Z35I17EQOP)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POLYGLYCERYL-3 RICINOLEATE</b> (UNII: MZQ63P0N0W)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>PINEAPPLE</b> (UNII: 2A88ZO081O)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>COCONUT</b> (UNII: 3RT3536DHY)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	
<b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)	
<b>RACEMENTHOL</b> (UNII: YS08XHA860)	
<b>PHYMATOLITHON CALCAREUM</b> (UNII: 6J1M3WA0ZK)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)	
<b>PORPHYRA UMBILICALIS</b> (UNII: 14AN0J70WO)	
<b>SILANETRIOL</b> (UNII: E52D0J3TS5)	
<b>SILYBUM MARIANUM SEED OIL</b> (UNII: NYY23HEN06)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8745-1	1 in 1 BLISTER PACK	05/01/2019	
1		4.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-8745-2	4.5 g in 1 TUBE; Type 0: Not a Combination Product	07/15/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/01/2019	

**Labeler** - The Mentholatum Company (002105757)

**Registrant** - The Mentholatum Company (002105757)

## Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8745)

Revised: 2/2023

The Mentholatum Company