SOFTLIPS OASIS WATERMELON BLACKBERRY- 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.

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

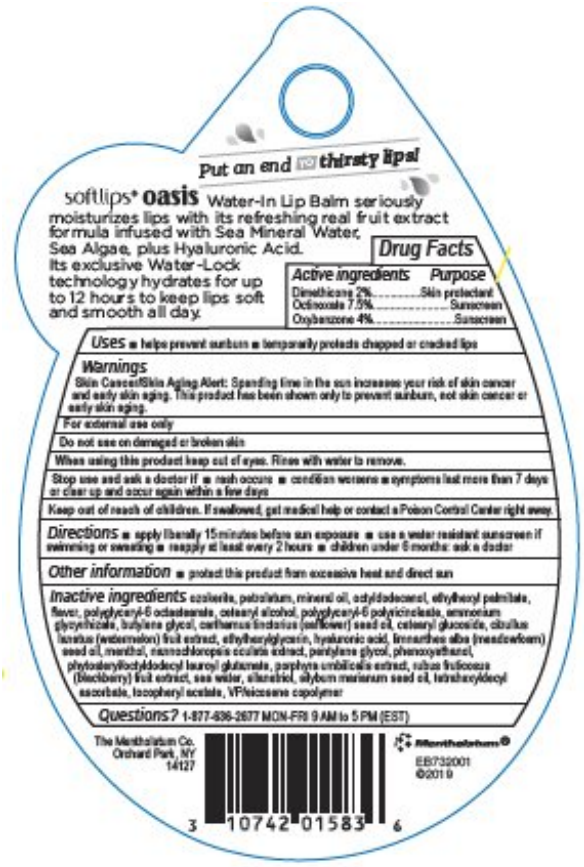
- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor

Inactive ingredients

ozokerite, petrolatum, mineral oil, octyldodecanol, ethylhexyl palmitate, flavor, polyglyceryl-6 octastearate, cetearyl alcohol, polyglyceryl-6 polyricinoleate, ammonium glycyrrhizate, butylene glycol, carthamus tinctorius (safflower) seed oil, cetearyl glucoside, citrullus lanatus (watermelon) fruit extract, ethylhexylglycerin, hyaluronic acid, limnanthes alba (meadowfoam) seed oil, menthol, nannochloropsis oculata extract, pentylene glycol, phenoxyethanol, phytosteryl/octyldodecyl lauroyl glutamate, porphyra umbilicalis extract, rubus fruticosus (blackberry) fruit extract, sea water, silanetriol, silybum marianum seed oil, tetrahexyldecyl ascorbate, tocopheryl acetate, VP/eicosene copolymer

Package/Label Principal Display Panel

Principal Display Panel



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8747
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
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
POLYGLYCERYL-6 DISTEARATE (UNII: Z35I17EQOP)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
WATERMELON (UNII: 231473QB6R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYALURONIC ACID (UNII: S270N0TRQY)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
BLACKBERRY (UNII: 8A6OMU3I8L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILANETRIOL (UNII: E52D0J3TS5)	
SILYBUM MARIANUM SEED OIL (UNII: NYY23HEN06)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8747-1	1 in 1 BLISTER PACK	05/01/2019	
1		4.5 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	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(10742-8747)