

BLISTEX SOFT AND LUSH- dimethicone, octinoxate, and oxybenzone stick
Blis tex Inc.

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.

Blis tex® Soft and Lush®

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 6.6% (w/w)	Sunscreen
Oxybenzone 3.0% (w/w)	Sunscreen

Uses

- temporarily protects and helps relieve chapped or cracked lips
- 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 help 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
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacyladipate-2, bis-stearyl dimethicone, ceramide NG, ceresin, cetyl dimethicone, cetyl palmitate, flavors, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate, microcrystalline wax, paraffin, PEG-8, PEG-60 hydrogenated castor oil, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polyhydroxystearic acid, saccharin, silica, titanium dioxide

PRINCIPAL DISPLAY PANEL - 3.69 g Cylinder Blister Pack

NDC 10157-1100-1

Blistex®

LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES®

Soft &

Lush®

New!

Creamy Smooth Texture
For Supple, Kissable Lips

Ceramide-Enhanced Formula
Softens & Conditions

SPF 15

Net Wt. 0.13 oz. (3.69 g)



BLISTEX SOFT AND LUSH

dimethicone, octinoxate, and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-1100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.6 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PETROLATUM (UNII: 4T6H12BN9U)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
CERAMIDE 2 (UNII: C04977SRJ5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SACCHARIN (UNII: FST467XS7D)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
STEARYL DIMETHICONE (400 MPA.S AT 50 C) (UNII: R327X197HY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-1100-1	1 in 1 BLISTER PACK		
1		3.69 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	part347	07/01/2015	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-1100)

Revised: 3/2015

Blistex Inc.