SILK AND SHINE- dimethicone, octinoxate, and oxybenzone stick Blistex 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.

Silk & Shine

Drug Facts

Active ingredients	Purpose
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 7.5% (w/w)	Sunscreen
Oxybenzone 2.5% (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

Inactive ingredients

arachidyl alcohol, arachidyl glucoside, behenyl alcohol, bis-diglyceryl polyacyladipate-2, flavors, hydrogenated polyisobutene, isostearoyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polybutene, PPG-5-Ceteth-20, saccharin, titanium dioxide, tocopheryl acetate

Other information

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

PRINCIPAL DISPLAY PANEL - 3.69g Cylinder Blister Pack

NDC 10157-9882-1

 $Blistex_{\hbox{$\mathbb{R}$}}$

LIP PROTECTANT/SUNSCREEN

SILK &

 $\text{SHINE}_{\text{\tiny \i\!R}}$

Now!

More Silk

More Shine

Satiny Smooth Lips

Plus A Light Glossy Shine

SPF 15

Infused With Real Silk Extracts

NET WT. .13 oz (3.69g)



Drug Facts

Active ingredients
Dimethicone 2.0% (w/w)
Octinoxate 7.5% (w/w)

Oxybenzone 2.5% (w/w)

Purpose Lip protectant Sunscreen Sunscreen

Blistex SILK & SHINE

Silk & Shine's unique silk and vitamin

Uses

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Directions

- · apply liberally 15 minutes before sun exposure
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- children under 6 months of age: Ask a doctor

Inactive ingredients

petrolatum, phenoxyethanol, phenyl

arachidyl alcohol, arachidyl glucoside, behenyl alcohol, bis-diglyceryl polyacyladipate-2, flavors, hydrogenated polyisobutene, isostearoyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate,

formula makes lips feel satiny smooth and enhances their natural appearance with a light glossy shine...for lips that look and feel ultra healthy and ultra lush."

Super-Silky Lips:

Silk & Shine feels exquisitely soft going on and leaves your lips feeling that way. Silk extracts, special moisturizers and vitamins B5 & E help create a satiny texture that makes lip surfaces smooth and supple... like a lush kiss* for your lips!

A Touch of Shine:

Silk & Shine imparts a touch of sheer gloss to the lips for a healthy, finished appearance. Your lips will look as good as they feel.

#34294 @2012 Blistex Inc. P.O. Box 5392 Oak Brook, IL 60522-5392

Oak Brook, IL 60522-5392
Card is 100% Recyclable.

GUARANTEED Blistex

Drug Facts (continued)

trimethicone, polybutene, PPG-5-Ceteth-20, saccharin, titanium dioxide, tocopheryl acetate

Other information

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



SILK AND SHINE

dimethicone, octinoxate, and oxybenzone stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10157-9882

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	7.5 g in 100 g
Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y)	Oxybenzone	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
arachidyl alcohol (UNII: 1QR1QRA9BU)	
arachidyl glucoside (UNII: 6JVW35JOOJ)	
docosanol (UNII: 9G10E216XY)	
mica (UNII: V8A1AW0880)	
microcrystalline wax (UNII: XOF597Q3KY)	
mineral oil (UNII: T5L8T28FGP)	
panthenyl ethyl ether (UNII: F4WMF8NX3B)	
paraffin (UNII: 19 O 0 E 3 H 2 Z E)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
petrolatum (UNII: 4T6H12BN9U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
PPG-5-Ceteth-20 (UNII: 4AAN25P8P4)	
saccharin (UNII: FST467XS7D)	
titanium dioxide (UNII: 15FIX9V2JP)	
isopropyl behenate (UNII: 1BWO0L9BHI)	
Ceresin (UNII: Q1LS2UJO3A)	
Polybutene (1400 MW) (UNII: 1NA5AO9GH7)	
Silk, Acid Hydrolyzed (1000 MW) (UNII: 8549W658QV)	
.alphatocopherol acetate (UNII: 9E8X80D2L0)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10157-9882-1	1 in 1 BLISTER PACK		
1	3.69 g in 1 CYLINDER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	11/0 1/20 12	

Labeler - Blistex Inc (005126354)

Establishment			
Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-9882)

Revised: 10/2012 Blistex Inc