

BLISTEX ULTRA RICH HYDRATION- octinoxate, oxybenzone, and dimethicone 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®
Ultra-Rich Hydration™

Drug Facts

Active ingredients	Purpose
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 6.8% (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 from excessive heat and direct sun

Inactive ingredients

aloe barbadensis leaf extract, alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacyladipate-2, blue 1 lake, butyrospermum parkii (shea butter), ceresin, cetyl dimethicone, cetyl palmitate, chamomilla recutita (matricaria) flower extract, flavors, helianthus annuus (sunflower) seed oil, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate,

isostearoyl hydrolyzed silk, jojoba esters, microcrystalline wax, olea europaea (olive) fruit oil, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polyhydroxystearic acid, saccharin, silica, theobroma cacao (cocoa) seed butter, titanium dioxide, tocopheryl acetate, triticum vulgare (wheat) germ oil

PRINCIPAL DISPLAY PANEL - 3.69 g Cylinder Blister Pack

NDC 10157-8015-1

Blistex®

LIP PROTECTANT/SUNSCREEN

**ULTRA-RICH
HYDRATION™**

NEW!

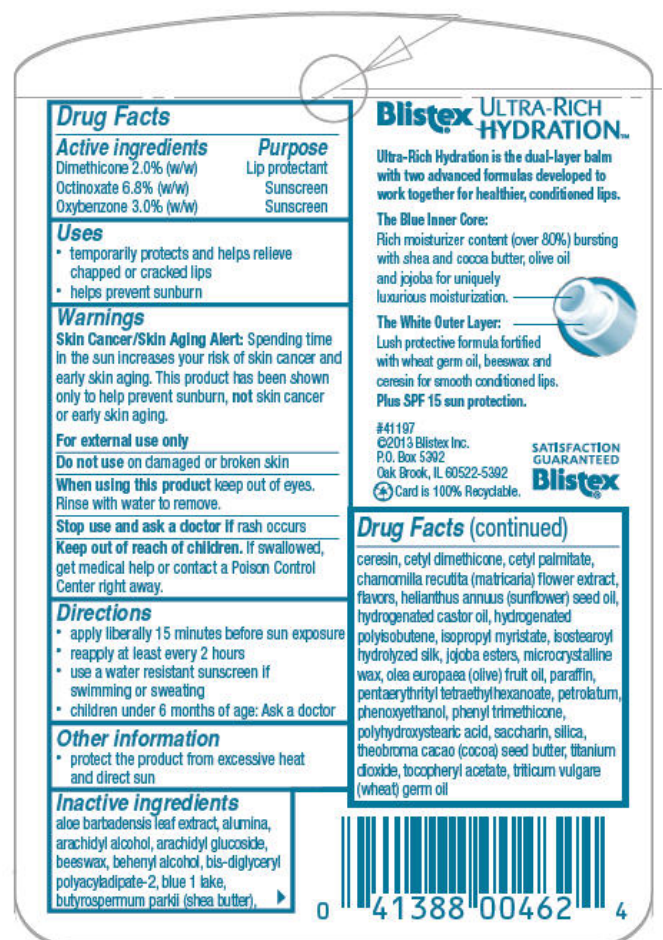
Dual-Layer Balm

**INNER: Deeply Hydrates With
80% Moisturizers**

**OUTER: Smoothes & Seals
With Lush Protectants**

SPF 15

NET WT. .13 oz (3.69g)



BLISTEX ULTRA RICH HYDRATION

octinoxate, oxybenzone, and dimethicone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-80 15
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.8 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3 g in 100 g
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
yellow wax (UNII: 2ZA36H0S2V)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
microcrystalline wax (UNII: XOF597Q3KY)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHEAT GERM OIL (UNII: 14C97E680P)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
CHAMOMILE (UNII: FGL3685T2X)	
ceresin (UNII: Q1LS2UJO3A)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SACCHARIN (UNII: FST467XS7D)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-80 15-1	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	part347	05/30/2014	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10 157-80 15)

Revised: 4/2014

Blistex Inc.