BLISTEX RASPBERRY LEMONADE BLAST- 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.

Blis tex_®

Raspberry Lemonade Blast®

Drug Facts

Active ingredients	Purpose
Dimethicone 1.0% (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

alumina, beeswax, diethylhexyl adipate, ethylhexyl palmitate, ethylhexyl stearate, flavors, glyceryl stearate, hydrogenated coconut oil, isopropyl myristate, isopropyl palmitate, isopropyl stearate, jojoba esters, microcrystalline wax, myristyl myristate, phenoxyethanol, phenyl trimethicone, polyethylene, polyhydroxystearic acid, saccharin, silica, tetrahexyldecyl ascorbate, titanium dioxide, tocopheryl acetate

Other information

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

PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Label

Blis tex_®

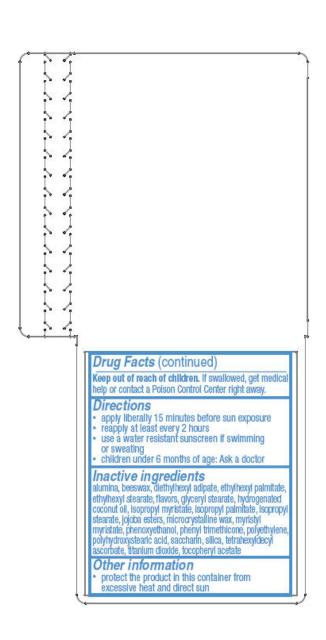
SPF 15

RaSPBeRRY

LemonaDe BLaST®

NET WT. .15 oz (4.25g)





BLISTEX RASPBERRY LEMONADE BLAST

dimethicone, octinoxate, and oxybenzone stick

P	ro	od	110	ct	Inf	fo.	rm	เล	tio	n

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10157-9800

Route of Administration

TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1 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
aluminum oxide (UNII: LMI26O6933)	
yellow wax (UNII: 2ZA36H0S2V)	
diethylhexyl adipate (UNII: MBY1SL921L)	
ethylhexyl palmitate (UNII: 2865993309)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
glyceryl monostearate (UNII: 230 O U9 XXE4)	
hydrogenated coconut oil (UNII: JY81OXM1OM)	
isopropyl myristate (UNII: 0 RE8 K4LNJS)	
isopropyl palmitate (UNII: 8 CRQ2TH6 3M)	
isopropyl stearate (UNII: 43253ZW1MZ)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
phenoxyethanol (UNII: HIE492ZZ3T)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
high density polyethylene (UNII: UG00KM4WR7)	
saccharin (UNII: FST467XS7D)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9 V2JP)	
.alphatocopherol acetate (UNII: 9E8X80D2L0)	

Product Characteristics				
Color	WHITE	Score		
Shape	BULLET	Size		
Flavor	RASPBERRY (lemonade)	Imprint Code		
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10157-9800-1	4.25 g in 1 CYLINDER		

Marketing I	Information
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OTC MONOGRAPH FINAL	part352	11/0 1/20 10	

Labeler - Blistex Inc (005126354)

Establishment			
Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-9800)

Revised: 3/2013 Blistex Inc