

BLISTEX ENHANCEMENT SERIES (SOFT AND LUSH, DEEP RENEWAL AND ULTRA-RICH HYDRATION)- dimethicone, octinoxate, oxybenzone, avobenzone and octocrylene
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® Enhancement Series® (Soft and Lush®, Deep Renewal® and Ultra-Rich Hydration®)
SOFT & LUSH®

Drug Facts

Active ingredients	Purpose
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

DEEP RENEWAL®

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.0% (w/w)	Sunscreen
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 7.5% (w/w)	Sunscreen
Octocrylene 2.7% (w/w)	Sunscreen
Oxybenzone 2.5% (w/w)	Sunscreen

Uses

- temporarily protects and helps relieve chapped or cracked lips
- helps prevent sunburn

Warnings

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
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long sleeve shirts, pants, hats, and sunglasses
- 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

atelocollagen, beeswax, butylene glycol, dipalmitoyl hydroxyproline, ethylhexyl palmitate, flavor, jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraisostearate, petrolatum, phenoxyethanol, polybutene, polyethylene, PTFE, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahexyldecyl ascorbate, tocopheryl acetate, ubiquinone

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 in this container from excessive heat and direct sun

Inactive ingredients

aloe barbadensis leaf extract (decolorized), 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 - Kit Blister Pack

Blistex®

**LIP PROTECTANT/SUNSCREEN
ENHANCEMENT SERIES®**

soft • youthful • smooth

BUY 2 GET 1 FREE

NEW!

BROAD SPECTRUM

SPF15

SPF15

SPF15

3 Sticks Net Wt. 0.13 oz. (3.69 g) Ea.

Blistex[®]

LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES[®]

soft • youthful • smooth

BUY 2 GET 1 FREE

NEW!

SPF-15

BROAD SPECTRUM
SPF-15

SPF-15

3 Sticks Net Wt. 0.13 oz. (3.69 g) Ea.

SOFT & LUSH. Creamy Smooth Texture For Supple, Kissable Lips Ceramide-Enhanced Formula Softens & Conditions

Drug Facts		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.	Inactive ingredients alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacryladipate-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
Active ingredients Dimethicone 2.0% (w/w) Octinoxate 6.6% (w/w) Oxybenzone 3.0% (w/w)	Purpose Lip protectant Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		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
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			

DEEP RENEWAL. The anti-aging lip treatment with coenzyme Q-10, clinically proven to visibly reduce fine lines and wrinkles in just four weeks.

Drug Facts		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.	Inactive ingredients atelocollagen, beeswax, butylene glycol, dipalmitoyl hydroxyproline, ethylhexyl palmitate, flavor, jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraisostearate, petrolatum, phenoxyethanol, polybutene, polyethylene, PTFE, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahexyldecyl ascorbate, tocopheryl acetate, ubiquinone
Active ingredients Avobenzone 3.0% (w/w) Dimethicone 2.0% (w/w) Octinoxate 7.5% (w/w) Octocrylene 2.7% (w/w) Oxybenzone 2.5% (w/w)	Purpose Sunscreen Lip protectant Sunscreen Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		Directions • apply liberally 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long sleeve shirts, pants, hats, and sunglasses • children under 6 months of age: Ask a doctor	Other information • protect the product in this container from excessive heat and direct sun
Warnings For external use only Do not use on damaged or broken skin When using this product keep out			

ULTRA-RICH HYDRATION. Inner: Deeply Hydrates With 80% Moisturizers Outer: Smoothes & Seals With Lush Protectants

Drug Facts		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.	Inactive ingredients aloe barbadensis leaf extract (decolorized), alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacryladipate-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, isostearyl 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
Active ingredients Dimethicone 2.0% (w/w) Octinoxate 6.8% (w/w) Oxybenzone 3.0% (w/w)	Purpose Lip protectant Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		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
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			

Caution: May cause irritation, not skin cancer or early skin aging.
For external use only
Do not use on damaged or broken skin

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



BLISTEX ENHANCEMENT SERIES (SOFT AND LUSH, DEEP RENEWAL AND ULTRA-RICH HYDRATION)

dimethicone, octinoxate, oxybenzone, avobenzone and octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-9867
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9867-1	1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CYLINDER	3.69 g
Part 2	1 CYLINDER	3.69 g
Part 3	1 CYLINDER	3.69 g

Part 1 of 3

BLISTEX SOFT AND LUSH

dimethicone, octinoxate, and oxybenzone stick

Product Information

Route of Administration	TOPICAL
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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: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 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 MPAS AT 50C) (UNII: R327X197HY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	08/01/2015	

Part 2 of 3

BLISTEX DEEP RENEWAL

dimethicone, octinoxate, oxybenzone, avobenzone, and octocrylene stick

Product Information

Route of Administration	TOPICAL
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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: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	3 g in 100 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	2.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
CASTOR OIL (UNII: D5340Y2I9G)	
SACCHARIN (UNII: FST467XS7D)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SORBIC ACID (UNII: X045WJ989B)	
SQUALANE (UNII: GW89575KF9)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
CHONDROITIN SULFATE SODIUM (SHARK) (UNII: Q75WVO004L)	
UBIDECARENONE (UNII: EJ27X76M46)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	08/01/2015	

BLISTEX ULTRA-RICH HYDRATION

dimethicone, octinoxate, and oxybenzone stick

Product Information

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	6.8 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3 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: 3W1JG795YI)	
CHAMOMILE (UNII: FGL3685T2X)	
CERESIN (UNII: Q1LS2UJO3A)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SACCHARIN (UNII: FST467XS7D)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	08/01/2015	

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(10157-9867)

Revised: 8/2015

Blistex Inc.