

FRUIT SMOOTHIES- dimethicone, octinoxate, and oxybenzone
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.

Fruit Smoothies®

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

PACKAGE WARNING

CHOKING HAZARD. Has removable cap. Not for children under 3 years.

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, bis-PEG-12 dimethicone beeswax, butylparaben, C20-40 pareth-3, ethylparaben, flavors, fruit extracts, glycerin, glyceryl stearate, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate, lecithin, methylparaben, microcrystalline wax, myristyl myristate, ozokerite, panthenol, pantothenic acid polypeptide, polybutene, polyhydroxystearic acid, propylparaben, purified water, silica, sodium saccharin, squalane, sucralose, tetrahexyldecyl ascorbate, titanium dioxide, tridecyl

neopentanoate, triisononanoic acid May contain: blue 1 lake, red 30 lake, yellow 10.

Other information

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

PRINCIPAL DISPLAY PANEL - Kit Blister Pack

NDC 10157-9883-3

SPF 15

Blis tex®

LIP PROTECTANT/SUNSCREEN

Fruit

Smoothies®

*3 Creamy Blends with Natural
Fruit Extracts, Flavors & Vitamins*

3 STICKS NET WT. .10 oz (2.83g) EACH

NDC 10157-9883-3

SPF 15

Blistex®

LIP PROTECTANT/SUNSCREEN

Fruit Smoothies®

3 Creamy Blends with Natural Fruit Extracts, Flavors & Vitamins



3 STICKS NET WT. .10 oz (2.83g) EACH

Drug Facts

Active ingredients

Dimethicone 2.0% (w/w)
Octinoxate 7.5% (w/w)
Oxybenzone 2.5% (w/w)

Purpose

Lip protectant
Sunscreen
Sunscreen

Uses

temporarily protects and helps relieve

Blistex®

Fruit Smoothies®

Fruit Smoothies protect and hydrate lips with natural fruit extracts and vitamins. Their unique flavors in creamy blends

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

Warnings

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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, bis-PEG-12 dimethicone, beeswax, butylparaben, C20-40 pareth-3, ethylparaben, flavors, fruit extracts, glycerin, glyceryl stearate, hydrogenated castor oil, hydrogenated polyisobutene, ▶

moisturize your lips like no other lip balm.

Super-Smooth Lips:

Packed with moisturizers and fortified with natural fruit extracts plus vitamins, Fruit Smoothies are both creamy and juicy.

Fantastic Flavors:

Fruit Smoothies explode with fresh tasting fruit flavors. The three carefully balanced combinations let you choose which flavor experience you want when you want it.

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Oak Brook, IL 60522-5392 #42698

SATISFACTION
GUARANTEED

♻️ Card is 100% Recyclable.

Blistex

Drug Facts (continued)

isopropyl myristate, lecithin, methylparaben, microcrystalline wax, myristyl myristate, ozokerite, panthenol, pantothenic acid polypeptide, polybutene, polyhydroxystearic acid, propylparaben, purified water, silica, sodium saccharin, squalane, sucralose, tetrahexyldecyl ascorbate, titanium dioxide, tridecyl neopentanoate, trisononanol. May contain: blue 1 lake, red 30 lake, yellow 10.

Other information

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



FRUIT SMOOTHIES

dimethicone, octinoxate, and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-9883
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9883-3	1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CYLINDER	2.83 g
Part 2	1 CYLINDER	2.83 g
Part 3	1 CYLINDER	2.83 g

Part 1 of 3

FRUIT SMOOTHIES MELON MEDLEY

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	7.5 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
aluminum oxide (UNII: LM26O6933)	
C20-40 pareth-3 (UNII: 68103A23TQ)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
hydrogenated castor oil (UNII: ZF94AP8MEY)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
panthenol (UNII: WV9CM0O67Z)	
TRIISONONANOIN (UNII: XF4K22WN6T)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
saccharin sodium (UNII: SB8ZUX40TY)	
squalane (UNII: GW89575KF9)	
sucralose (UNII: 96K6UQ3ZD4)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
tridecyl neopentanoate (UNII: 3Z8H1DA7J5)	
water (UNII: 059QF0K00R)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
ceresin (UNII: Q1LS2UJO3A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYLPARABEN (UNII: A2I8C7H9T)	

Product Characteristics

Color GREEN **Score**

Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.83 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/14/2013	

Part 2 of 3

FRUIT SMOOTHIES TRIPLE TROPICAL
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
aluminum oxide (UNII: LM26O6933)	
C20-40 pareth-3 (UNII: 68103A23TQ)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
hydrogenated castor oil (UNII: ZF94AP8MEY)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
panthenol (UNII: WV9CM0O67Z)	
TRIISONONANOIN (UNII: XF4K22WN6T)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
saccharin sodium (UNII: SB8ZUX40TY)	
squalane (UNII: GW89575KF9)	

sucralose (UNII: 96K6UQ3ZD4)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
tridecyl neopentanoate (UNII: 3Z8H1DA7J5)	
water (UNII: 059QF0KO0R)	
D&C red no. 30 (UNII: 2S42T2808B)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
ceresin (UNII: Q1LS2UJO3A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.83 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/14/2013	

Part 3 of 3

FRUIT SMOOTHIES BERRY EXPLOSION

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
aluminum oxide (UNII: LMI26O6933)	
C20-40 pareth-3 (UNII: 68103A23TQ)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
hydrogenated castor oil (UNII: ZF94AP8MEY)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
panthenol (UNII: WV9CM0O67Z)	
TRIISONONANOIN (UNII: XF4K22WN6T)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
saccharin sodium (UNII: SB8ZUX40TY)	
squalane (UNII: GW89575KF9)	
sucralose (UNII: 96K6UQ3ZD4)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
tridecyl neopentanoate (UNII: 3Z8H1DA7J5)	
water (UNII: 059QF0K00R)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
D&C red no. 30 (UNII: 2S42T2808B)	
ceresin (UNII: Q1LS2UJO3A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.83 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/14/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/14/2013	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-9883)

Revised: 6/2013

Blistex Inc.