

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

<i>Active ingredients</i>	<i>Purpose</i>
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

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

Other information

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

Inactive ingredients

alumina, beeswax, blue 1 lake¹, 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, red 30 lake¹, saccharin, silica, tetrahexyldecyl ascorbate, titanium dioxide, tocopheryl acetate, yellow 10¹

¹ May contain one or more of these ingredients.

PRINCIPAL DISPLAY PANEL - Kit Blister Pack

NDC 10157-8014-1

SPF 15

Blis tex®

LIP PROTECTANT/SUNSCREEN

Fruit

Smoothies®

*4 Creamy Blends With Delicious
Fruit Flavors And Vitamins C&E*

FREE

Orange

Cream

LIMITED EDITION

STICK

4 Sticks Net Wt. 0.10 oz. (2.83 g) Ea.



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Other information

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Inactive ingredients
alumina, beeswax, blue 1 lake*, diethylhexyl adipate, ethylhexyl

Blistex
Fruit Smoothies

Fruit Smoothies protect and hydrate lips with great-tasting creamy blends and vitamins ... they indulge your lips like no other lip balm.

Super Smooth Lips
Packed with moisturizers and vitamins C & E, Fruit Smoothies are both creamy and juicy.

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

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SATISFACTION GUARANTEED

♻️ Card is 100% Recyclable.

Blistex

Drug Facts (continued)

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, red 30 lake*, saccharin, silica, tetrahexyldecyl ascorbate, titanium dioxide, tocopheryl acetate, yellow 10*

*May contain one or more of these ingredients.

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FRUIT SMOOTHIES

dimethicone, octinoxate, and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-80 14
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-80 14-1	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 4	1 CYLINDER	2.83 g

Part 1 of 4

FRUIT SMOOTHIES ORANGE CREAM

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	1 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)	
yellow wax (UNII: 2ZA36H0S2V)	
diethylhexyl adipate (UNII: MBY1SL921L)	
glyceryl monostearate (UNII: 230OU9XXE4)	
ethylhexyl palmitate (UNII: 2865993309)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
hydrogenated coconut oil (UNII: JY810XM1OM)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
isopropyl stearate (UNII: 43253ZW1MZ)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
high density polyethylene (UNII: UG00KM4WR7)	
saccharin (UNII: FST467XS7D)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Product Characteristics

Color	WHITE	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; 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	07/01/2014	

Part 2 of 4

FRUIT SMOOTHIES TRIPLE TROPICAL

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	1 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)	
yellow wax (UNII: 2ZA36H0S2V)	
diethylhexyl adipate (UNII: MBY1SL921L)	
glyceryl monostearate (UNII: 230OU9XXE4)	
ethylhexyl palmitate (UNII: 2865993309)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
hydrogenated coconut oil (UNII: JY81OXM1OM)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
isopropyl stearate (UNII: 43253ZW1MZ)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
high density polyethylene (UNII: UG00KM4WR7)	

D&C red no. 30 (UNII: 2S42T2808B)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
saccharin (UNII: FST467XS7D)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Product Characteristics

Color	ORANGE	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; 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	07/01/2014	

Part 3 of 4

FRUIT SMOOTHIES MELON MEDLEY

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	1 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)	
yellow wax (UNII: 2ZA36H0S2V)	
diethylhexyl adipate (UNII: MBY1SL921L)	
glyceryl monostearate (UNII: 230OU9XXE4)	
ethylhexyl palmitate (UNII: 2865993309)	

isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
hydrogenated coconut oil (UNII: JY81OXM1OM)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
isopropyl stearate (UNII: 43253ZW1MZ)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
high density polyethylene (UNII: UG00KM4WR7)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
saccharin (UNII: FST467XS7D)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

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; 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	07/01/2014	

Part 4 of 4

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	1 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)	
yellow wax (UNII: 2ZA36H0S2V)	
diethylhexyl adipate (UNII: MBY1SL921L)	
glyceryl monostearate (UNII: 230OU9XXE4)	
ethylhexyl palmitate (UNII: 2865993309)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
microcrystalline wax (UNII: XOF597Q3KY)	
myristyl myristate (UNII: 4042ZC00DY)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
hydrogenated coconut oil (UNII: JY81OXM1OM)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
isopropyl stearate (UNII: 43253ZW1MZ)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
titanium dioxide (UNII: 15FIX9V2JP)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
high density polyethylene (UNII: UG00KM4WR7)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
D&C red no. 30 (UNII: 2S42T2808B)	
saccharin (UNII: FST467XS7D)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

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; 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	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/01/2014	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-8014)

Revised: 6/2014

Blistex Inc.