

## **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.*

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### **Fruit Smoothies®**

#### **Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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 lake<sup>1</sup>, 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 lake<sup>1</sup>, saccharin, silica, tetrahexyldecyl ascorbate, titanium dioxide, tocopheryl acetate, yellow 10<sup>1</sup>

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<sup>1</sup> May contain one or more of these ingredients.

**PRINCIPAL DISPLAY PANEL - Kit Blister Pack**

NDC 10157-8010-1

**SPF 15**

**Blis tex<sup>®</sup>**

**LIP PROTECTANT/SUNSCREEN**

*Fruit*

*Smoothies<sup>®</sup>*

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

**FREE**

*Summer*

*Sweet Fruit*

**LIMITED EDITION**

**STICK**

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

NDC 10157-8010-1

SPF 15

# Blistex

LIP PROTECTANT/SUNSCREEN

## Fruit Smoothies

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

### FREE

### Summer Sweet Fruit



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#### Drug Facts

##### Active ingredients

Dimethicone 1.0% (w/w)

Octinoxate 7.5% (w/w)

Oxybenzone 2.5% (w/w)

##### Purpose

Lip protectant

Sunscreen

Sunscreen

## Blistex

### Fruit Smoothies

Fruit Smoothies protect and hydrate lips with great-tasting creamy blends

### Uses

- 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

### Other information

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

### Inactive ingredients

alumina, beeswax, blue 1 lake\*, diethylhexyl adipate,

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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Oak Brook, IL 60522-5392 #42622

SATISFACTION  
GUARANTEED

**Blistex**

♻️ Card is 100% Recyclable.

### Drug Facts (continued)

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

\*May contain one or more of these ingredients.



## FRUIT SMOOTHIES

dimethicone, octinoxate, and oxybenzone kit

### Product Information

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-80 10-1	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 1 of 4****FRUIT SMOOTHIES STRAWBERRY BANANA**

dimethicone, octinoxate, and oxybenzone stick

**Product Information**

<b>Route of Administration</b>	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>aluminum oxide</b> (UNII: LMI26O6933)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>diethylhexyl adipate</b> (UNII: MBY1SL921L)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>myristyl myristate</b> (UNII: 4042ZC00DY)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>ethylhexyl stearate</b> (UNII: EG3PA2K3K5)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>hydrogenated coconut oil</b> (UNII: JY810XM10M)	
<b>isopropyl palmitate</b> (UNII: 8CRQ2TH63M)	
<b>isopropyl stearate</b> (UNII: 43253ZW1MZ)	
<b>tetrahexyldecyl ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>phenyl trimethicone</b> (UNII: DR0K5NOJ4R)	
<b>high density polyethylene</b> (UNII: UG00KM4WR7)	
<b>saccharin</b> (UNII: FST467XS7D)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	

**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	09/01/2013	

**Part 2 of 4****FRUIT SMOOTHIES TRIPLE TROPICAL**

dimethicone, octinoxate, and oxybenzone stick

**Product Information**

<b>Route of Administration</b>	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>aluminum oxide</b> (UNII: LMI26O6933)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>diethylhexyl adipate</b> (UNII: MBY1SL921L)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>myristyl myristate</b> (UNII: 4042ZC00DY)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>ethylhexyl stearate</b> (UNII: EG3PA2K3K5)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>hydrogenated coconut oil</b> (UNII: JY810XM1OM)	
<b>isopropyl palmitate</b> (UNII: 8CRQ2TH63M)	
<b>isopropyl stearate</b> (UNII: 43253ZW1MZ)	
<b>tetrahexyldecyl ascorbate</b> (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		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	09/01/2013	

### Part 3 of 4

### FRUIT SMOOTHIES SUMMER SWEET FRUIT

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: LM26O6933)	
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: JY810XM10M)	
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		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	09/01/2013	

### 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
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>diethylhexyl adipate</b> (UNII: MBY1SL921L)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>myristyl myristate</b> (UNII: 4042ZC00DY)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>ethylhexyl stearate</b> (UNII: EG3PA2K3K5)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>hydrogenated coconut oil</b> (UNII: JY810XMIOM)	
<b>isopropyl palmitate</b> (UNII: 8CRQ2TH63M)	
<b>isopropyl stearate</b> (UNII: 43253ZW1MZ)	
<b>tetrahexyldecyl ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>phenyl trimethicone</b> (UNII: DR0K5NOJ4R)	
<b>high density polyethylene</b> (UNII: UG00KM4WR7)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C red no. 30</b> (UNII: 2S42T2808B)	
<b>saccharin</b> (UNII: FST467XS7D)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	

## Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## 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
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OTC MONOGRAPH FINAL	part347	09/01/2013	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part347	09/01/2013	

**Labeler** - Blistex Inc. (005126354)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Blistex Inc.		005126354	MANUFACTURE(10157-8010)

Revised: 8/2013

Blistex Inc.