

## **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.*

-----

### **Blis tex (Fruit Smoothies)**

#### ***Drug Facts***

| <b><i>Active ingredients</i></b> | <b><i>Purpose</i></b> |
|----------------------------------|-----------------------|
| Dimethicone 2.0%<br>(w/w)        | Lip protectant        |
| Octinoxate 7.5% (w/w)            | Sunscreen             |
| Oxybenzone 2.5%<br>(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<sup>1</sup>, bis-PEG-12 dimethicone beeswax, blue 1 lake<sup>1</sup>, butylparaben, C20-40 pareth-3, ethylparaben, flavors, fruit extracts, glycerin, glyceryl stearate, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate<sup>1</sup>, lecithin, methylparaben, microcrystalline wax, myristyl myristate, ozokerite,

panthenol, pantothenic acid polypeptide, polybutene, polyhydroxystearic acid<sup>1</sup>, propylparaben, purified water, red 30 lake<sup>1</sup>, silica<sup>1</sup>, sodium saccharin, squalane, sucralose, tetrahexyldecyl ascorbate, titanium dioxide<sup>1</sup>, tridecyl neopentanoate, triisononoin, yellow 10<sup>1</sup>

---

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

**Other information**

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

**PRINCIPAL DISPLAY PANEL - 4 Stick Blister Pack**

NDC 10157-9883-6

**SPF 15**

**Blis tex®**

**LIP PROTECTANT/SUNSCREEN**

*Fruit*

*Smoothies®*

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

**FREE**

*Orange*

*Cream*

**LIMITED EDITION**

**STICK**

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

NDC 10157-9883-6

SPF 15

# Blistex

LIP PROTECTANT/SUNSCREEN

## Fruit Smoothies

4 Creamy Blends with Natural Fruit Extracts, Flavors & Vitamins

### FREE

Orange Cream 

LIMITED EDITION STICK



4 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

## 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

**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, blue 1 lake\*, butylparaben, C20-40 pareth-3, ethylparaben, flavors, fruit extracts, glycerin, glyceryl stearate, hydrogenated castor oil, hydrogenated

**Indulge 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 four carefully balanced combinations let you choose which flavor experience you want when you want it.

©2012 Blistex Inc., P.O. Box 5392  
Oak Brook, IL 60522-5392 #42735

SATISFACTION  
GUARANTEED

**Blistex**

♻️ Card is 100% Recyclable.

### Drug Facts (continued)

polyisobutene, isopropyl myristate\*, lecithin, methylparaben, microcrystalline wax, myristyl myristate, ozokerite, panthenol, pantothenic acid polypeptide, polybutene, polyhydroxystearic acid\*, propylparaben, purified water, red 30 lake\*, silica\*, sodium saccharin, squalane, sucralose, tetrahexyldecyl ascorbate, titanium dioxide\*, tridecyl neopentanoate, trilononanol, yellow 10\*

\* May contain one or more of these ingredients.

### Other information

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



## FRUIT SMOOTHIES

dimethicone, octinoxate, and oxybenzone kit

### Product Information

|                     |                |                           |                |
|---------------------|----------------|---------------------------|----------------|
| <b>Product Type</b> | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10157-9883 |
|---------------------|----------------|---------------------------|----------------|

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:10157-9883-6 | 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 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: 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)                 |          |
| triisnonanol (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)                     |          |
| FD&C blue no. 1 (UNII: H3R47K3TBD)           |          |
| D&C yellow no. 10 (UNII: 35SW5USQ3G)         |          |
| ceresin (UNII: Q1LS2UJO3A)                   |          |
| propylparaben (UNII: Z8IX2SC1OH)             |          |
| butylparaben (UNII: 3QPIU3FV8)               |          |
| ethylparaben (UNII: 14255EXE39)              |          |
| methylparaben (UNII: A218C7HI9T)             |          |

## 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                                  | 06/01/2012           |                    |

## 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       | 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)               |          |
| triisnonanoin (UNII: XF4K22WN6T)           |          |
| silicon dioxide (UNII: ETJ7Z6XBU4)         |          |

|                                                     |
|-----------------------------------------------------|
| <b>saccharin sodium</b> (UNII: SB8ZUX40TY)          |
| <b>squalane</b> (UNII: GW89575KF9)                  |
| <b>sucralose</b> (UNII: 96K6UQ3ZD4)                 |
| <b>tetrahexyldecyl ascorbate</b> (UNII: 9LBV3F07AZ) |
| <b>titanium dioxide</b> (UNII: 15FIX9V2JP)          |
| <b>tridecyl neopentanoate</b> (UNII: 3Z8H1DA7J5)    |
| <b>water</b> (UNII: 059QF0KO0R)                     |
| <b>D&amp;C red no. 30</b> (UNII: 2S42T2808B)        |
| <b>D&amp;C yellow no. 10</b> (UNII: 35SW5USQ3G)     |
| <b>ceresin</b> (UNII: Q1LS2UJO3A)                   |
| <b>propylparaben</b> (UNII: Z8IX2SC1OH)             |
| <b>butylparaben</b> (UNII: 3QPIU3FV8)               |
| <b>ethylparaben</b> (UNII: 14255EXE39)              |
| <b>methylparaben</b> (UNII: A218C7HI9T)             |

### Product Characteristics

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Color</b>    | YELLOW | <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 |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part347                                  | 06/01/2012           |                    |

### Part 3 of 4

### FRUIT SMOOTHIES BERRY EXPLOSION

dimethicone, octinoxate, and oxybenzone stick

### Product Information

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name                                                       | Basis of Strength | Strength       |
|-----------------------------------------------------------------------|-------------------|----------------|
| <b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O) | Dimethicone       | 2 g in 100 g   |
| <b>Octinoxate</b> (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)                 |          |
| triisononanol (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: 3QPHU3FV8)               |          |
| ethylparaben (UNII: 14255EXE39)              |          |
| methylparaben (UNII: A2B8C7H9T)              |          |

### 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                                  | 06/01/2012           |                    |



## Part 4 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       | 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 |
|----------------------------------------------|----------|
| C20-40 pareth-3 (UNII: 68103A23TQ)           |          |
| glycerin (UNII: PDC6A3C0OX)                  |          |
| glyceryl monostearate (UNII: 230OU9XXE4)     |          |
| hydrogenated castor oil (UNII: ZF94AP8MEY)   |          |
| microcrystalline wax (UNII: XOF597Q3KY)      |          |
| myristyl myristate (UNII: 4042ZC00DY)        |          |
| panthenol (UNII: WV9CM0O67Z)                 |          |
| triisononanol (UNII: XF4K22WN6T)             |          |
| saccharin sodium (UNII: SB8ZUX40TY)          |          |
| squalane (UNII: GW89575KF9)                  |          |
| sucralose (UNII: 96K6UQ3ZD4)                 |          |
| tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ) |          |
| tridecyl neopentanoate (UNII: 3Z8H1DA7J5)    |          |
| water (UNII: 059QF0K00R)                     |          |
| ceresin (UNII: Q1LS2UJO3A)                   |          |
| propylparaben (UNII: Z8IX2SC1OH)             |          |
| butylparaben (UNII: 3QPI1U3FV8)              |          |
| ethylparaben (UNII: 14255EXE39)              |          |
| methylparaben (UNII: A218C7HI9T)             |          |

#### 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                                  | 06/01/2012           |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part347                                  | 06/01/2012           |                    |

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

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

Revised: 8/2013

Blistex Inc.