

## **ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20- octinoxate, oxybenzone, and titanium dioxide powder**

**Ventura Corporation (San Juan, P.R)**

*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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**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

### ***Drug Facts***

#### **Active Ingredients**

Octinoxate (7%), Oxybenzone (2%), Titanium Dioxide (2%)

#### **Purpose**

Sunscreen

#### **Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides moderate protection against sunburn

#### **Warnings**

- **For external use only.**
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash and irritation develops and lasts.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply smoothly every morning before sun exposure and as needed.
- apply evenly on face and neck using a latex pad. Touch up when necessary.
- moderate sun protection product.

#### **Other information**

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

#### **Inactive ingredients**

Isostearyl neopentanoate, C12-15 alkyl benzoate, polymethyl methacrylate, corn starch, silica, mica, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), phenoxyethanol, octyldodecanol, trimethylsiloxysilicate, dimethicone, methylparaben, tocopheryl

acetate, microcrystalline wax, propylparaben, petrolatum, phospholipids, bht, c9-13 fluoroalcohol, butylparaben, ethylparaben, phosphoric acid, cholesterol, isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, chitosan, ci 77492 (iron oxides), ci 77491 (iron oxides), ci 77499 (iron oxides).

**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 1**

ē sika

**3-in-1 Pro Make Up  
Foundation SPF 20**

6 g e (.21 oz.)



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 2**

ēsika

**3-in-1 Pro Make Up  
Foundation SPF 20**

6 g e (.21 oz.)



**Drug Facts**

Active Ingredients	Purpose
Octinoxate (7%), Oxybenzone (2%), Titanium Dioxide (2%)	Sunscreen

**Uses**

- Helps prevent sunburn. ■ Higher SPF gives more sunburn protection. ■ Provides moderate protection against sunburn.

**Warnings**

- For external use only
- When using this product keep out of eyes, Rinse with water to remove.
- Stop use and ask a doctor if rash and irritation develops and lasts.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply smoothly every morning before sun exposure and as needed. ■ Apply evenly on face and neck using a latex pad. Touch up when necessary. ■ Moderate sun protection product.

**Other information**

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients**

Isostearyl neopentanoate, C12-15 alkyl benzoate, polymethyl methacrylate, zea mays starch( zea mays (corn) starch), silica, mica, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), phenoxyethanol, octyldodecanol, trimethylsiloxysilicate, dimethicone, methylparaben, tocopheryl acetate, microcristalina cera (microcrystalline wax), propylparaben, petrolatum, phospholipids, bht, c9-13 fluoralkohol, butylparaben, ethylparaben, phosphoric acid, cholesterol, isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, chitosan, May contain: CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499 (iron oxides).

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3-in-1 Pro Make Up  
Foundation SPF 20

6 g e (.21 oz.)

**ARTE REFERENCIAL  
NO USAR PARA REPRODUCIR**

**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 3**

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**3-in-1 Pro Make Up  
Foundation SPF 20**

6 g e (.21 oz.)



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 4**

**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 5**

**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Beige 6**

**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 1**

**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 2

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3-in-1 Pro Make Up  
Foundation SPF 20

6 g e (.21 oz.)





PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 3

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3-in-1 Pro Make Up  
Foundation SPF 20

6 g e (.21 oz.)



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 4**

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**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



**PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 5**

**ēsika**

**3-in-1 Pro Make Up  
Foundation SPF 20**

**6 g e (.21 oz.)**



PRINCIPAL DISPLAY PANEL - 6 g Carton - Rosa 6

ēsika

3-in-1 Pro Make Up  
Foundation SPF 20

6 g e (.21 oz.)



## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-329
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1g

## Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A2I8C7HI9T)	
microcrystalline wax (UNII: XOF597Q3KY)	
propylparaben (UNII: Z8IX2SC1OH)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
phosphoric acid (UNII: E4GA8884NN)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	

## Product Characteristics

Color	BROWN (Beige 1)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-329-02	1 in 1 BOX		
1	NDC:13537-329-01	6 g in 1 CASE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

# ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-330
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>ceresin</b> (UNII: Q1LS2UJO3A)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>methylparaben</b> (UNII: A218C7H9T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>butylparaben</b> (UNII: 3QPI1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

## Product Characteristics

Color	BROWN (Beige 2)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-330-02	1 in 1 BOX		
1	NDC:13537-330-01	6 g in 1 CASE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-331
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A2I8C7HI9T)	
microcrystalline wax (UNII: XOF597Q3KY)	



<b>propylparaben</b> (UNII: Z8IX2SC1OH)
<b>petrolatum</b> (UNII: 4T6H12BN9U)
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)
<b>butylparaben</b> (UNII: 3QP1U3FV8)
<b>ethylparaben</b> (UNII: 14255EXE39)
<b>phosphoric acid</b> (UNII: E4GA8884NN)
<b>cholesterol</b> (UNII: 97C5T2UQ7J)
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)
<b>candelilla wax</b> (UNII: WL0328HX19)
<b>yellow wax</b> (UNII: 2ZA36H0S2V)
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)
<b>ferric oxide red</b> (UNII: 1K09F3G675)
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)

### Product Characteristics

<b>Color</b>	BROWN (Beige 3)	<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	NDC:13537-331-02	1 in 1 BOX		
1	NDC:13537-331-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-332
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g

<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g
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### Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A218C7H9T)	
microcrystalline wax (UNII: XOF597Q3KY)	
propylparaben (UNII: Z8IX2SC1OH)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
butylparaben (UNII: 3QP1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
phosphoric acid (UNII: E4GA8884NN)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	

### Product Characteristics

Color	BROWN (Beige 4)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-332-02	1 in 1 BOX		
1	NDC:13537-332-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-333
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A218C7H9T)	
microcrystalline wax (UNII: XOF597Q3KY)	
propylparaben (UNII: Z8IX2SC1OH)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
phosphoric acid (UNII: E4GA8884NN)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	

## Product Characteristics

<b>Color</b>	BROWN (Beige 5)	<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	NDC:13537-333-02	1 in 1 BOX		
1	NDC:13537-333-01	6 g in 1 CASE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-334
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>ceresin</b> (UNII: Q1LS2UJO3A)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	

<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>butylparaben</b> (UNII: 3QPIU3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	BROWN (Beige 6)	<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	NDC:13537-334-02	1 in 1 BOX		
1	NDC:13537-334-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-335
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>ceresin</b> (UNII: Q1LS2UJO3A)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>butylparaben</b> (UNII: 3QPIU3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	RED (Rosa 1)	<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	NDC:13537-335-02	1 in 1 BOX		
1	NDC:13537-335-01	6 g in 1 CASE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-336
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A2I8C7HI9T)	
microcrystalline wax (UNII: XOF597Q3KY)	
propylparaben (UNII: Z8IX2SC1OH)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
butylparaben (UNII: 3QPI1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
phosphoric acid (UNII: E4GA8884NN)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferric oxide red (UNII: 1K09F3G675)	

ferrosoferric oxide (UNII: XM0M87F357)

### Product Characteristics

Color	RED (Rosa 2)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-336-02	1 in 1 BOX		
1	NDC:13537-336-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-337
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	



<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>methylparaben</b> (UNII: A218C7H9T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>butylparaben</b> (UNII: 3QP1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	RED (Rosa 3)	<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	NDC:13537-337-02	1 in 1 BOX		
1	NDC:13537-337-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-338
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>ceresin</b> (UNII: Q1LS2UJO3A)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>methylparaben</b> (UNII: A218C7H9T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>butylparaben</b> (UNII: 3QP1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

**Product Characteristics**

<b>Color</b>	RED (Rosa 4)	<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	NDC:13537-338-02	1 in 1 BOX		
1	NDC:13537-338-01	6 g in 1 CASE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-339
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
starch, corn (UNII: O8232NY3SJ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ethylhexyl palmitate (UNII: 2865993309)	
ceresin (UNII: Q1LS2UJO3A)	
carnauba wax (UNII: R12CBM0EIZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
methylparaben (UNII: A218C7H9T)	
microcrystalline wax (UNII: XOF597Q3KY)	
propylparaben (UNII: Z8IX2SC1OH)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
butylparaben (UNII: 3QP1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
phosphoric acid (UNII: E4GA8884NN)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	

<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	RED (Rosa 5)	<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	NDC:13537-339-02	1 in 1 BOX		
1	NDC:13537-339-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA 3-IN-1 PRO MAKEUP FOUNDATION SPF 20

octinoxate, oxybenzone, and titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-340
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>ceresin</b> (UNII: Q1LS2UJO3A)	

<b>carnauba wax</b> (UNII: R12CBM0EIZ)
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>octyldodecanol</b> (UNII: 461N1O614Y)
<b>dimethicone</b> (UNII: 92RU3N3Y1O)
<b>methylparaben</b> (UNII: A2I8C7HI9T)
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)
<b>propylparaben</b> (UNII: Z8IX2SC1OH)
<b>petrolatum</b> (UNII: 4T6HI2BN9U)
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)
<b>butylparaben</b> (UNII: 3QPII3FV8)
<b>ethylparaben</b> (UNII: 14255EXE39)
<b>phosphoric acid</b> (UNII: E4GA8884NN)
<b>cholesterol</b> (UNII: 97C5T2UQ7J)
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)
<b>candelilla wax</b> (UNII: WL0328HX19)
<b>yellow wax</b> (UNII: 2ZA36H0S2V)
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)
<b>ferric oxide red</b> (UNII: 1K09F3G675)
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)

### Product Characteristics

<b>Color</b>	RED (Rosa 6)	<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	NDC:13537-340-02	1 in 1 BOX		
1	NDC:13537-340-01	6 g in 1 CASE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

**Labeler** - Ventura Corporation (San Juan, P.R) (602751344)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE

