

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15- octinoxate 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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Hydrated Face Makeup Foundation SPF 15

Drug Facts

Active Ingredients

Octinoxate (6%)

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 to the forehead, nose, chin and both cheeks. Blend with circular motion and spread softly.
- 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

Aqua (water), coco-caprylate/caprates, ethylhexyl palmitate, glycerin, octyldodecanol, polymethyl methacrylate, cyclopentasiloxane, cetyl ppg-10/1 dimethicone, polyglyceryl-4 isostearate, sodium chloride, talc, dimethicone, hexyl laurate, dimethicone/vinyl dimethicone crosspolymer,

cyclomethicone, disteardimonium hectorite, cyclohexasiloxane, glycine soja protein (glycine soja (soybean) protein), microcrystalline wax, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, propylparaben, tocopheryl acetate, petrolatum, dimethiconol, phospholipids, cholesterol, silica, bha, bht, candelilla cera (euphorbia cerifera (candelilla) wax), beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, triethoxycaprylylsilane, ci 77891 (titanium dioxide), ci 77492 (iron oxides), ci 77491(iron oxides), ci 77499 (iron oxides).

PRINCIPAL DISPLAY PANEL - 30 g Carton

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Hydrated Face Makeup Foundation SPF 15

30 g e (1 oz.)

Inactive ingredients
Aqua (water), ethylhexyl methoxycinnamate, coco-caprylate/caprate, ethylhexyl palmitate, glycerin, octyldodecanol, polymethyl methacrylate, cyclopentasiloxane, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, sodium chloride, talc, dimethicone, hexyl laurate, dimethicone/vinyl dimethicone crosspolymer, cyclomethicone, disteardimonium hectorite, cyclohexasiloxane, glycine soja protein (glycine soja (soybean) protein), microcrystalline cera (microcrystalline wax), diazolidinyl urea, cetearyl dimethicone

Drug Facts (continued)
reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Other information
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may

Directions
Apply smoothly every morning before sun exposure and as needed. Apply to the forehead, nose, chin and both cheeks. Blend with circular motion and spread softly. Moderate sun protection product.

Drug Facts (continued)
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Hydrated Face Makeup Foundation SPF 15

30g e (1 oz.)

Drug Facts (continued)

crosspolymer, methylparaben, propylparaben, tocopheryl acetate, petrolatum, dimethiconol, phospholipids.

triethoxycaprylylsilane, cholesterol, silica, bha, bht, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May Contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491(iron oxides), CI 77499 (iron oxides).

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia.

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.

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

Drug Facts
Active Ingredients
 Octinoxate (6%)
Purpose
 Sunscreen

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-317
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC 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:13537-317-02	1 in 1 BOX		
1	NDC:13537-317-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-318
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

CETEARYL GLUCO SIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (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:13537-318-02	1 in 1 BOX		
1	NDC:13537-318-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
TALC (UNII: 7SEV7J4R1U)
DIMETHICONE (UNII: 92RU3N3Y1O)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CYCLOMETHICONE (UNII: NMQ347994Z)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
SOYBEAN (UNII: L7HT8F1ZOD)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
PETROLATUM (UNII: 4T6H12BN9U)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
CHOLESTEROL (UNII: 97C5T2UQ7J)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	BROWN (Beige 3)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-319-02	1 in 1 BOX		
1	NDC:13537-319-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15
 octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-320
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-320-02	1 in 1 BOX		
1	NDC:13537-320-01	30 g in 1 JAR		

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15
 octinoxate powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-321
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A218C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics			
Color	BROWN (Beige 5)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-321-02	1 in 1 BOX		
1	NDC:13537-321-01	30 g in 1 JAR		

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15
octinoxate powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-322
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (Beige 6)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-322-02	1 in 1 BOX		
1	NDC:13537-322-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-323
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)

CARNAUBA WAX (UNII: R12CBM0EIZ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

FERRIC OXIDE RED (UNII: 1K09F3G675)

FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	RED (Rosa 1)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-323-02	1 in 1 BOX		
1	NDC:13537-323-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-324
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	

POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TALC (UNII: 7SEV7J4R1U)
DIMETHICONE (UNII: 92RU3N3Y1O)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CYCLOMETHICONE (UNII: NMQ347994Z)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
SOYBEAN (UNII: L7HT8F1ZOD)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
PETROLATUM (UNII: 4T6H12BN9U)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHOLESTEROL (UNII: 97C5T2UQ7J)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC 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:13537-324-02	1 in 1 BOX		
1	NDC:13537-324-01	30 g in 1 JAR		

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-325
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	RED (Rosa 3)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-325-02	1 in 1 BOX		
1	NDC:13537-325-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-326
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
PETROLATUM (UNII: 4T6H12BN9U)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHOLESTEROL (UNII: 97C5T2UQ7J)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	RED (Rosa 4)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-326-02	1 in 1 BOX		
1	NDC:13537-326-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-327
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	RED (Rosa 5)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13537-327-02	1 in 1 BOX		
1	NDC:13537-327-01	30 g in 1 JAR		

Marketing Information

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

ESIKA HYDRATED FACE MAKEUP FOUNDATION SPF 15

octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-328
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	RED (Rosa 6)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-328-02	1 in 1 BOX		
1	NDC:13537-328-01	30 g in 1 JAR		

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