

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 1) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 2) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 3) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 4) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 5) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 6) - ROSE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 1) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 2) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 3) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 4) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 5) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 6) - BEIGE- octinoxate, oxybenzone, and titanium dioxide cream

Ventura Corporation LTD

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.

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20

Drug Facts

Active Ingredients

OCTINOXATE 7.0 %, OXYBENZONE 2.0%, TITANIUM DIOXIDE 2.0%

Purpose

Sunscreen

Uses

- 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 damage 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.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

Other information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

ISOSTEARYL NEOPENTANOATE, C12-15 ALKYL BENZOATE, POLYMETHYL METHACRYLATE, ZEA MAYS STARCH (ZEA MAYS (CORN) STARCH), SILICA, MICA, ETHYLHEXYL METHOXYCINNAMATE, ETHYLHEXYL PALMITATE, OZOKERITE, COPERNICIA CERIFERA CERA (COPERNICIA CERIFERA (CARNAUBA) WAX), BENZOPHENONE-3, TITANIUM DIOXIDE, PHENOXYETHANOL, OCTYLDODECANOL, TRIMETHYLSILOXYSILICATE, DIMETHICONE, METHYLPARABEN, TOCOPHERYL ACETATE, MICROCRISTALLINA CERA (MICROCRYSTALLINE WAX), PROPYLPARABEN, PETROLATUM, PHOSPHOLIPIDS, BHT, C9-13 FLUOROALCOHOL, BUTYLPARABEN, ETHYLPARABEN, PHOSPHORIC ACID, CHOLESTEROL, ISOBUTYLPARABEN, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, CANDELILLA CERA (EUPHORBIA CERIFERA (CANDELILLA) WAX), CERA ALBA (BEESWAX), CETEARYL GLUCOSIDE, CETEARYL ALCOHOL, GLYCOSPHINGOLIPIDS. **May contain:** CI 77491 (IRON OXIDES), CI 77492 (IRON OXIDES), CI 77499 (IRON OXIDES), CI 77891 (TITANIUM DIOXIDE), CHITOSAN.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - (ROSE 1) - ROSE

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Base de Maquillaje para Rostro
3-en-1 Pro FPS 20

6 g e (.21 oz.)



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Titanium dioxide 2.0 %.....

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■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

isostearyl neopentanoate, C12-15 alkyl benzoate, polymethyl methacrylate, zea mays starch (zea mays (corn) starch), silica, mica, ethylhexyl methoxycinnamate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), benzophenone-3, titanium dioxide, phenoxyethanol, octyldodecanol, trimethylsiloxysilicate, dimethicone, methylparaben, tocopheryl acetate, microcristallina cera (microcrystalline wax), propylparaben, petrolatum, phospholipids, bht, C9-13 fluoroalcohol, butylparaben, ethylparaben, phosphoric acid, cholesterol, isobutylparaben, polyglyceryl-2 dipolyhydroxystearate, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl glucoside, cetearyl alcohol, glycosphingolipids. **May contain:** CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77891 (titanium dioxide), chitosan.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

ésika

3-in-1 Pro Make Up
Foundation SPF 20

Base de Maquillaje para Rostro
3-en-1 Pro FPS 20

6 g e (.21 oz.)



ésika

3-in-1 Pro Make Up
Foundation SPF 20

Base de Maquillaje para Rostro
3-en-1 Pro FPS 20

6 g e (.21 oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0%, Oxybenzone 2.0 %,
Titanium dioxide 2.0 %.....

Purpose

Sunscreen

Uses: ■ Help prevents 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 damage 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. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Children under 6 months of age: Ask a doctor. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating.

Other information:

■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

isostearyl neopentanoate, C12-15 alkyl benzoate, polymethyl methacrylate, zea mays starch (zea mays (corn) starch), silica, mica, ethylhexyl methoxycinnamate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), benzophenone-3, titanium dioxide, phenoxyethanol, octyldodecanol, trimethylsiloxysilicate, dimethicone, methylparaben, tocopheryl acetate, microcristallina cera (microcrystalline wax), propylparaben, petrolatum, phospholipids, bht, C9-13 fluoroalcohol, butylparaben, ethylparaben, phosphoric acid, cholesterol, isobutylparaben, polyglyceryl-2 dipolyhydroxystearate, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl glucoside, cetearyl alcohol, glycosphingolipids. **May contain:** CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77891 (titanium dioxide), chitosan.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

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3-in-1 Pro Make Up
Foundation SPF 20

Base de Maquillaje para Rostro
3-en-1 Pro FPS 20

6 g e (.21 oz.)



ésika

3-in-1 Pro Make Up
Foundation SPF 20

Base de Maquillaje para Rostro
3-en-1 Pro FPS 20

6 g e (.21 oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0%, Oxybenzone 2.0 %,
Titanium dioxide 2.0 %.....

Purpose

Sunscreen

Uses: ■ Help prevents 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 damage 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. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Children under 6 months of age: Ask a doctor. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating.

Other information:

■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

isostearyl neopentanoate, C12-15 alkyl benzoate, polymethyl methacrylate, zea mays starch (zea mays (corn) starch), silica, mica, ethylhexyl methoxycinnamate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), benzophenone-3, titanium dioxide, phenoxyethanol, octyldodecanol, trimethylsiloxysilicate, dimethicone, methylparaben, tocopheryl acetate, microcristallina cera (microcrystalline wax), propylparaben, petrolatum, phospholipids, bht, C9-13 fluoroalcohol, butylparaben, ethylparaben, phosphoric acid, cholesterol, isobutylparaben, polyglyceryl-2 dipolyhydroxystearate, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl glucoside, cetearyl alcohol, glycosphingolipids. **May contain:** CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77891 (titanium dioxide), chitosan.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 1) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-198
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYL PARABEN (UNII: 3QP1I1U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-198-02	1 in 1 BOX		
1	NDC:13537-198-01	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 2) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-197
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7H9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	

PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-197-04	1 in 1 BOX		
1	NDC:13537-197-03	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 3) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-196
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	

ETHYLHEXYL PALMITATE (UNII: 2865993309)
CARNAUBA WAX (UNII: R12CBM0EIZ)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
OCTYLDODECANOL (UNII: 461N1O614Y)
DIMETHICONE (UNII: 92RU3N3Y1O)
METHYLPARABEN (UNII: A2I8C7H9T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLPARABEN (UNII: 3QP1I03FV8)
ETHYLPARABEN (UNII: 14255EXE39)
PHOSPHORIC ACID (UNII: E4GA8884NN)
CHOLESTEROL (UNII: 97C5T2UQ7J)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-196-06	1 in 1 BOX		
1	NDC:13537-196-05	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 4) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-195
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A218C7H9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYL PARABEN (UNII: 3QPI1U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-195-08	1 in 1 BOX		
1	NDC:13537-195-07	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 5) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-194
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OC TYLDO DECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYL PARABEN (UNII: 3QPI1U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-194-10	1 in 1 BOX		
1	NDC:13537-194-09	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (ROSE 6) - ROSE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-193
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (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)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-193-12	1 in 1 BOX		
1	NDC:13537-193-11	6 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 1) - BEIGE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-192
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-192-14	1 in 1 BOX		
1	NDC:13537-192-13	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 2) - BEIGE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-191
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYL PARABEN (UNII: 3QPIU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-19-16	1 in 1 BOX		
1	NDC:13537-19-15	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 3) - BEIGE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-190
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLPARABEN (UNII: 3QP1I1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-190-18	1 in 1 BOX		
1	NDC:13537-190-17	6 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 4) - BEIGE
 octinoxate, oxybenzone, and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-189
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 1g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.02 g in 1g

Inactive Ingredients	
Ingredient Name	Strength
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLPARABEN (UNII: 3QP11U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
PHOSPHORIC ACID (UNII: E4GA8884NN)
CHOLESTEROL (UNII: 97C5T2UQ7J)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-189-20	1 in 1 BOX		
1	NDC:13537-189-19	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 5) - BEIGE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-188
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-188-22	1 in 1 BOX		
1	NDC:13537-188-21	6 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/06/2014	

ESIKA 3-IN-1 PRO MAKE UP FOUNDATION SPF 20 BASE DE MAQUILLAJE PARA ROSTRO 3-EN-1 PRO FPS 20 (BEIGE 6) - BEIGE

octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-187
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
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYL PARABEN (UNII: 3QPIIU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-187-24	1 in 1 BOX		

1	NDC:13537-187-23	6 g in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352		03/06/2014	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-198, 13537-197, 13537-196, 13537-195, 13537-194, 13537-193, 13537-192, 13537-191, 13537-190, 13537-189, 13537-188, 13537-187)

Revised: 3/2014

Ventura Corporation LTD