

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 1) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 2) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 3) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 4) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 5) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 6) - BROWN- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 1) - PINK- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 2) - PINK- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 3) - PINK- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 4) - PINK- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 5) - PINK- octinoxate and oxybenzone emulsion

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 6) - PINK- octinoxate and oxybenzone emulsion

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 PRO HYDRO-NUTRITIVE FOUNDATION SPF 15

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE: 5.00%	Sunscreen
OXYBENZONE: 2.00%	Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (**see Directions**) decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor if** rash occurs.

- **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.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months of age: Ask a doctor
- Reapply at least every 2 hours.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses.

Other information

- Protect this product in this container from excessive heat and direct sun. Keep away from heat sources and direct sunlight. Store well and under 50°C (112°F).

Inactive ingredients

WATER, CYCLOMETHICONE, CYCLOPENTASILOXANE, TALC, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, PISUM SATIVUM (PEA) EXTRACT, PEG-12 DIMETHICONE CROSSPOLYMER, HEXYL LAURATE, ISOSTEARYL NEOPENTANOATE, DISTEARDIMONIUM HECTORITE, CYCLOHEXASILOXANE, HYDROXYACETOPHENONE, ROSA CENTIFOLIA FLOWER WATER, SODIUM CHLORIDE, PHENOXYETHANOL, MANNITOL, DIMETHICONE, PROPYLENE CARBONATE, PROPYLENE GLYCOL, OCTYLDODECANOL, BUTYLENE GLYCOL, DIMETHICONOL, CAPRYLYL GLYCOL, CETEARYL DIMETHICONE CROSSPOLYMER, TOCOPHERYL ACETATE, CHLORPHENESIN, MICROCRYSTALLINE WAX, POLYMETHYLSILSESQUIOXANE, PETROLATUM, PHOSPHOLIPIDS, CYCLODEXTRIN, CHOLESTEROL, YEAST EXTRACT, EUPHORBIA CERIFERA (CANDELILLA) WAX, BEESWAX, CETEARYL ALCOHOL, CETEARYL GLUCOSIDE, COPERNICIA CERIFERA (CARNAUBA) WAX, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, GLYCOSPHINGOLIPIDS, DISODIUM SUCCINATE.

MAY CONTAIN:

TITANIUM DIOXIDE, METHICONE, IRON OXIDES.

Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 1) - Brown

**ésika
PRO**

**Hydro-Nutritive
Foundation
SPF 15**

30 ml e (1 fl.oz.)

Make up foundation for an immediate natural youthful effect. With its innovative ingredients that nourish, hydrate and re-vitalize the skin to make it look renewed and radiant.

Drug Facts

Active Ingredients Purpose
Octinoxate 5.00% Sunscreen
Oxybenzone 2.00% 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.

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Directions

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Drug Facts (continued)

Other information

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Inactive ingredients: water, cyclo methicone, cyclopentasiloxane, talc, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, pisum sativum (pea) extract, peg-12 dimethicone crosspolymer, hexyl laurate, isostearyl neopentanoate, disteardimonium hectorite, cyclohexasiloxane, hydroxyacetophenone, rosa centifolia flower water, sodium chloride, phenoxyethanol, mannitol, dimethicone, propylene carbonate, propylene glycol, octyldodecanol, butylene glycol, dimethiconol, caprylyl glycol, cetearyl dimethicone crosspolymer, tocopheryl acetate, chlorphenesin, microcrystalline wax, polymethylsilsesquioxane, petrolatum, phospholipids, cyclodextrin, cholesterol, yeast extract, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, disodium succinate. **May contain:** titanium dioxide, iron oxides, methicone.

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

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 2) - Brown

ésika

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Hydro-Nutritive

Foundation

SPF 15

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Drug Facts (continued)

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 3) - Brown

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PRO

Hydro-Nutritive

Foundation

SPF 15

30 ml e (1 fl.oz.)

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Drug Facts (continued)

Other information

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 4) - Brown

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PRO

Hydro-Nutritive

Foundation

SPF 15

30 ml e (1 fl.oz.)

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Drug Facts

Active Ingredients Purpose
Octinoxate 5.00% Sunscreen
Oxybenzone 2.00% Sunscreen

Uses

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Drug Facts (continued)

Other information

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 5) - Brown

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PRO

Hydro-Nutritive

Foundation

SPF 15

30 mL e (1 fl.oz.)

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Drug Facts

Active Ingredients Purpose
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Oxybenzone 2.00% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Drug Facts (continued)

Other information

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Beige 6) - Brown

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Hydro-Nutritive

Foundation

SPF 15

30 mL e (1 fl.oz.)

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Drug Facts

Active Ingredients Purpose
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Oxybenzone 2.00% Sunscreen

Uses

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Drug Facts (continued)

Other information

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 1) - Pink

ésika

PRO

Hydro-Nutritive

Foundation

SPF 15

30 ml e (1 fl.oz.)

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Drug Facts (continued)

Other information

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 2) - Pink

ésika

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Hydro-Nutritive

Foundation

SPF 15

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Drug Facts (continued)

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 3) - Pink

ésika

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Hydro-Nutritive

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Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 4) - Pink

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■ **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.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other information

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

Inactive ingredients: water, cyclo methicone, cyclopentasiloxane, talc, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, pisum sativum (pea) extract, peg-12 dimethicone crosspolymer, hexyl laurate, isostearyl neopentanoate, disteardimonium hectorite, cyclohexasiloxane, hydroxyacetophenone, rosa centifolia flower water, sodium chloride, phenoxyethanol, mannitol, dimethicone, propylene carbonate, propylene glycol, octyldodecanol, butylene glycol, dimethiconol, caprylyl glycol, cetearyl dimethicone crosspolymer, tocopheryl acetate, chlorphenesin, microcrystalline wax, polymethylsilsesquioxane, petrolatum, phospholipids, cyclodextrin, cholesterol, yeast extract, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, disodium succinate. **May contain:** titanium dioxide, iron oxides, methicone.

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

ésika
PRO

Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 5) - Pink

ésika

PRO

Hydro-Nutritive

Foundation

SPF 15

30 ml e (1 fl.oz.)

Make up foundation for an immediate natural youthful effect. With its innovative ingredients that nourish, hydrate and re-vitalize the skin to make it look renewed and radiant.

Drug Facts

Active Ingredients Purpose
Octinoxate 5.00% Sunscreen
Oxybenzone 2.00% 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 damaged or broken skin.

■ **When using this product** keep out of eyes. Rinse with water to remove.

■ **Stop use and ask a doctor** if rash occurs.

■ **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.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other information

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

Inactive ingredients: water, cyclomethicone, cyclopentasiloxane, talc, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, pisum sativum (pea) extract, peg-12 dimethicone crosspolymer, hexyl laurate, isostearyl neopentanoate, disteardimonium hectorite, cyclohexasiloxane, hydroxyacetophenone, rosa centifolia flower water, sodium chloride, phenoxyethanol, mannitol, dimethicone, propylene carbonate, propylene glycol, octyldodecanol, butylene glycol, dimethiconol, caprylyl glycol, cetearyl dimethicone crosspolymer, tocopheryl acetate, chlorphenesin, microcrystalline wax, polymethylsilsesquioxane, petrolatum, phospholipids, cyclodextrin, cholesterol, yeast extract, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, disodium succinate. **May contain:** titanium dioxide, iron oxides, methicone.

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

ésika
PRO

Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - (Rosa 6) - Pink

ésika

PRO

Hydro-Nutritive

Foundation

SPF 15

30 ml e (1 fl.oz.)

Make up foundation for an immediate natural youthful effect. With its innovative ingredients that nourish, hydrate and re-vitalize the skin to make it look renewed and radiant.

Drug Facts

Active Ingredients Purpose
Octinoxate 5.00% Sunscreen
Oxybenzone 2.00% 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 damaged or broken skin.

■ **When using this product** keep out of eyes. Rinse with water to remove.

■ **Stop use and ask a doctor** if rash occurs.

■ **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.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other information

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

Inactive ingredients: water, cyclomethicone, cyclopentasiloxane, talc, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, pisum sativum (pea) extract, peg-12 dimethicone crosspolymer, hexyl laurate, isostearyl neopentanoate, disteardimonium hectorite, cyclohexasiloxane, hydroxyacetophenone, rosa centifolia flower water, sodium chloride, phenoxyethanol, mannitol, dimethicone, propylene carbonate, propylene glycol, octyldodecanol, butylene glycol, dimethiconol, caprylyl glycol, cetearyl dimethicone crosspolymer, tocopheryl acetate, chlorphenesin, microcrystalline wax, polymethylsilsesquioxane, petrolatum, phospholipids, cyclodextrin, cholesterol, yeast extract, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, disodium succinate. **May contain:** titanium dioxide, iron oxides, methicone.

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

ésika
PRO

Hydro-Nutritive
Foundation
SPF 15

30 ml e (1 fl.oz.)

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 1) - BROWN

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-625
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N10614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-625-02	1 in 1 BOX	03/06/2015	
1	NDC:13537-625-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 2) - BROWN

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-626
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	

DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
OCTYLDODECANOL (UNII: 461N1O614Y)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-626-04	1 in 1 BOX	03/06/2015	
1	NDC:13537-626-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 3) - BROWN

octinoxate and oxybenzone emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-627
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-627-06	1 in 1 BOX	03/06/2015	
1	NDC:13537-627-05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 4) - BROWN

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-628
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N10614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	

YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-628-08	1 in 1 BOX	03/06/2015	
1	NDC:13537-628-07	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 5) - BROWN

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-629
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MANNITOL (UNII: 3OWL53L36A)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
OCTYLDODECANOL (UNII: 461N1O614Y)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-629-10	1 in 1 BOX	03/06/2015	
1	NDC:13537-629-09	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (BEIGE 6) - BROWN

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-630
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-630-12	1 in 1 BOX	03/06/2015	

1	NDC:13537-630-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	03/06/2015		

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 1) - PINK
 octinoxate and oxybenzone emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-631
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-631-14	1 in 1 BOX	03/06/2015	
1	NDC:13537-631-13	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 2) - PINK
 octinoxate and oxybenzone emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-632
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	

PEA (UNII: W4X7H8GYFM)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MANNITOL (UNII: 3OWL53L36A)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
OCTYLDODECANOL (UNII: 461N1O614Y)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-632-16	1 in 1 BOX	03/06/2015	
1	NDC:13537-632-15	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 3) - PINK

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-633
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-633-18	1 in 1 BOX	03/06/2015	
1	NDC:13537-633-17	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 4) - PINK

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-634
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-634-20	1 in 1 BOX	03/06/2015	
1	NDC:13537-634-19	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 5) - PINK

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-635
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

CYCLOMETHICONE (UNII: NMQ347994Z)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
TALC (UNII: 7SEV7J4R1U)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
PEA (UNII: W4X7H8GYFM)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MANNITOL (UNII: 3OWL53L36A)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
OCTYLDODECANOL (UNII: 461N1O614Y)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-635-22	1 in 1 BOX	03/06/2015	
1	NDC:13537-635-21	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

ESIKA PRO HYDRO-NUTRITIVE FOUNDATION SPF 15 (ROSA 6) - PINK

octinoxate and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-636
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
TALC (UNII: 7SEV7J4R1U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEA (UNII: W4X7H8GYFM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECANOL (UNII: 461N10614Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229 XJ4V12)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-636-24	1 in 1 BOX	03/06/2015	
1	NDC:13537-636-23	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/06/2015	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-625, 13537-626, 13537-627, 13537-628, 13537-629, 13537-630, 13537-631, 13537-632, 13537-633, 13537-634, 13537-635, 13537-636)

Revised: 11/2017

Ventura Corporation LTD