

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13- octinoxate and oxybenzone lotion
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.

ēsika
Hydro-Nutritive
Foundation
SPF 13

Drug Facts

Active Ingredients

Octinoxate (5%), Oxybenzone (2%)

Purpose

Sunscreen

Uses

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

Warnings

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

Directions

- Apply smoothly every morning before sun exposure and as needed.
- Apply 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), 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, rosa centifolia flower water, sodium

chloride, mannitol, dimethicone, propylene carbonate, propylene glycol, phenoxyethanol, octyldodecanol, butylene glycol, dimethiconol, methylparaben, propylparaben, cetearyl dimethicone crosspolymer, tocopheryl acetate, microcristallina cera (microcrystalline wax), methicone, polymethylsilsesquioxane, petrolatum, phospholipids, bha, bht, cyclodextrin, butylparaben, ethylparaben, cholesterol, faex extract (yeast extract), isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, olea europaea oil unsaponifiables (olea europaea (olive) oil unsaponifiables), glycosphingolipids, disodium succinate. **May contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499 (iron oxides).

PRINCIPAL DISPLAY PANEL - 30 ml Carton - Beige 1

ēsika

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Foundation

SPF 13

30 ml e (1 fl.oz.)

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Drug Facts (continued)

cyclohexasiloxane, rosa centifolia flower water, sodium chloride, mannitol, dimethicone, propylene carbonate, propylene glycol, phenoxyethanol, octyldodecanol, butylene glycol, dimethiconol, methylparaben, propylparaben, cetearyl dimethicone crosspolymer, tocopheryl acetate, microcrystalline cera (microcrystalline wax), methicone, polymethylsilsesquioxane, petrolatum, phospholipids, bha, bht, cyclodextrin, butylparaben, ethylparaben, cholesterol, faex extract (yeast extract), isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, olea europaea oil unsaponifiables (olea europaea (olive) oil unsaponifiables), glycosphingolipids, disodium succinate. **May contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499 (iron oxides).

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Beige 2

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Beige 5

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Beige 6

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Rosa 1

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Rosa 2

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PRINCIPAL DISPLAY PANEL - 30 ml Carton - Rosa 3

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■ 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), 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, ▶

Drug Facts (continued)

cyclohexasiloxane, rosa centifolia flower water, sodium chloride, mannitol, dimethicone, propylene carbonate, propylene glycol, phenoxyethanol, octyldodecanol, butylene glycol, dimethiconol, methylparaben, propylparaben, cetearyl dimethicone crosspolymer, tocopheryl acetate, microcrystalline cera (microcrystalline wax), methicone, polymethylsilsesquioxane, petrolatum, phospholipids, bha, bht, cyclodextrin, butylparaben, ethylparaben, cholesterol, faex extract (yeast extract), isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, olea europaea oil unsaponifiables (olea europaea (olive) oil unsaponifiables), glycosphingolipids, disodium succinate. **May contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77493 (iron oxides).

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

ēsika

Hydro-Nutritive
Foundation
SPF 13

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 ml Carton - Rosa 5

ēsika

Hydro-Nutritive

Foundation

SPF 13

30 ml e (1 fl.oz.)

Make up foundation for an immediate natural youthful effect. With its nutritional multi-vitamin ingredients, it nourishes, hydrates and re-energizes the skin to restore vitality and healthy color.

Drug Facts

Active Ingredients Purpose

Octinoxate (5%),
Oxybenzone (2%)..... Sunscreen

Uses

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

Warnings

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

Directions

■ Apply smoothly every morning before sun exposure and as needed.
■ Apply 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), 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, ▶

Drug Facts (continued)

cyclohexasiloxane, rosa centifolia flower water, sodium chloride, mannitol, dimethicone, propylene carbonate, propylene glycol, phenoxyethanol, octyldodecanol, butylene glycol, dimethiconol, methylparaben, propylparaben, cetearyl dimethicone crosspolymer, tocopheryl acetate, microcrystalline cera (microcrystalline wax), methicone, polymethylsilsesquioxane, petrolatum, phospholipids, bha, bht, cyclodextrin, butylparaben, ethylparaben, cholesterol, faex extract (yeast extract), isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, olea europaea oil unsaponifiables (olea europaea (olive) oil unsaponifiables), glycosphingolipids, disodium succinate. **May contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77493 (iron oxides).

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ēsika

Hydro-Nutritive
Foundation
SPF 13

30 ml e (1 fl.oz.)

PRINCIPAL DISPLAY PANEL - 30 ml Carton - Rosa 6

ēsika

Hydro-Nutritive

Foundation

SPF 13

30 ml e (1 fl.oz.)

Make up foundation for an immediate natural youthful effect. With its nutritional multi-vitamin ingredients, it nourishes, hydrates and re-energizes the skin to restore vitality and healthy color.

Drug Facts

Active Ingredients Purpose

Octinoxate (5%),
Oxybenzone (2%)..... Sunscreen

Uses

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

Warnings

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

Directions

- Apply smoothly every morning before sun exposure and as needed.
- Apply 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), cyclomethicone, cyclopentasiloxane, talc, cetyl ppg-10/1 dimethicone, polyglyceryl-4 isostearate, pisum sativum (pea) extract, peg-12 dimethicone crosspolymer, hexyl laurate, isostearyl neopentanoate, disteardimonium hectorite, ▶

Drug Facts (continued)

cyclohexasiloxane, rosa centifolia flower water, sodium chloride, mannitol, dimethicone, propylene carbonate, propylene glycol, phenoxyethanol, octyldodecanol, butylene glycol, dimethiconol, methylparaben, propylparaben, cetearyl dimethicone crosspolymer, tocopheryl acetate, microcrystalline cera (microcrystalline wax), methicone, polymethylsilsesquioxane, petrolatum, phospholipids, bha, bht, cyclodextrin, butylparaben, ethylparaben, cholesterol, faex extract (yeast extract), isobutylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, olea europaea oil unsaponifiables (olea europaea (olive) oil unsaponifiables), glycosphingolipids, disodium succinate. **May contain:** CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77493 (iron oxides).

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ēSIKā

Hydro-Nutritive
Foundation
SPF 13

30 ml e (1 fl.oz.)

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-305 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A218C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPH1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |

| | |
|--|--|
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6 UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric oxide (UNII: XM0M87F357) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-305-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-305-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-306 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |

| |
|--|
| talc (UNII: 7SEV7J4RIU) |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) |
| pea (UNII: W4X7H8GYFM) |
| hexyl laurate (UNII: 4CG9F9W01Q) |
| cyclomethicone 6 (UNII: XHK3U310BA) |
| rosa centifolia flower oil (UNII: H32V31VMWY) |
| sodium chloride (UNII: 451W47IQ8X) |
| mannitol (UNII: 3OWL53L36A) |
| dimethicone (UNII: 92RU3N3Y1O) |
| propylene carbonate (UNII: 8D08K3S51E) |
| propylene glycol (UNII: 6DC9Q167V3) |
| phenoxyethanol (UNII: HIE492ZZ3T) |
| octyldodecanol (UNII: 461N1O614Y) |
| butylene glycol (UNII: 3XUS85K0RA) |
| methylparaben (UNII: A218C7HI9T) |
| propylparaben (UNII: Z8IX2SC1OH) |
| microcrystalline wax (UNII: XOF597Q3KY) |
| petrolatum (UNII: 4T6H12BN9U) |
| butylated hydroxyanisole (UNII: REK4960K2U) |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) |
| butylparaben (UNII: 3QPH1U3FV8) |
| ethylparaben (UNII: 14255EXE39) |
| cholesterol (UNII: 97C5T2UQ7J) |
| yeast (UNII: 3NY3SM6B8U) |
| isobutylparaben (UNII: 0QQJ25X58G) |
| candelilla wax (UNII: WL0328HX19) |
| yellow wax (UNII: 2ZA36H0S2V) |
| cetostearyl alcohol (UNII: 2DMT128M1S) |
| cetearyl glucoside (UNII: 09FUA47KNA) |
| carnauba wax (UNII: R12CBM0EIZ) |
| olive oil (UNII: 6UYK2W1W1E) |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) |
| titanium dioxide (UNII: 15FIX9V2JP) |
| ferric oxide yellow (UNII: EX438O2MRT) |
| ferric oxide red (UNII: 1K09F3G675) |
| ferrosoferric 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:13537-306-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-306-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-307 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A218C7H9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPHU3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |

| | |
|---|--|
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-307-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-307-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-308 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4R1U) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6HI2BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPII1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric oxide (UNII: XM0M87F357) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-308-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-308-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-309 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A218C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |

| | |
|---|--|
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QP11U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-309-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-309-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-310 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPII1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-310-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-310-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-311 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4R1U) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |

| | |
|---|--|
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QP11U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-311-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-311-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13
 octinoxate and oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-312 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC10H) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPH1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |

| | |
|--|--|
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric oxide (UNII: XM0M87F357) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-312-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-312-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-313 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0K00R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |

| | |
|--|--|
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6HI2BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPII1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-313-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-313-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-314 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4R1U) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QP1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |

| | |
|---|--|
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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:13537-314-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-314-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-315 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4RIU) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A218C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) | |
| butylparaben (UNII: 3QPI1U3FV8) | |
| ethylparaben (UNII: 14255EXE39) | |
| cholesterol (UNII: 97C5T2UQ7J) | |
| yeast (UNII: 3NY3SM6B8U) | |
| isobutylparaben (UNII: 0QQJ25X58G) | |
| candelilla wax (UNII: WL0328HX19) | |
| yellow wax (UNII: 2ZA36H0S2V) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetearyl glucoside (UNII: 09FUA47KNA) | |
| carnauba wax (UNII: R12CBM0EIZ) | |
| olive oil (UNII: 6UYK2W1W1E) | |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| ferric oxide yellow (UNII: EX438O2MRT) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ferrosoferric 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 |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-315-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-315-01 | 30 mL in 1 BOTTLE | | |

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

ESIKA HYDRO-NUTRATIVE FOUNDATION SPF 13

octinoxate and oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-316 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| cyclomethicone (UNII: NMQ347994Z) | |
| cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| talc (UNII: 7SEV7J4R1U) | |
| polyglyceryl-4 isostearate (UNII: 820DPX33S7) | |
| pea (UNII: W4X7H8GYFM) | |
| hexyl laurate (UNII: 4CG9F9W01Q) | |
| cyclomethicone 6 (UNII: XHK3U310BA) | |
| rosa centifolia flower oil (UNII: H32V31VMWY) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| mannitol (UNII: 3OWL53L36A) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene carbonate (UNII: 8D08K3S51E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| methylparaben (UNII: A218C7HI9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| petrolatum (UNII: 4T6H12BN9U) | |

| |
|--|
| butylated hydroxyanisole (UNII: REK4960K2U) |
| butylated hydroxytoluene (UNII: 1P9D0Z171K) |
| butylparaben (UNII: 3QPIU3FV8) |
| ethylparaben (UNII: 14255EXE39) |
| cholesterol (UNII: 97C5T2UQ7J) |
| yeast (UNII: 3NY3SM6B8U) |
| isobutylparaben (UNII: 0QQJ25X58G) |
| candelilla wax (UNII: WL0328HX19) |
| yellow wax (UNII: 2ZA36H0S2V) |
| cetostearyl alcohol (UNII: 2DMT128M1S) |
| cetearyl glucoside (UNII: 09FUA47KNA) |
| carnauba wax (UNII: R12CBM0EIZ) |
| olive oil (UNII: 6UYK2W1W1E) |
| sodium succinate anhydrous (UNII: V8ZGC8ISR3) |
| titanium dioxide (UNII: 15FIX9V2JP) |
| ferric oxide yellow (UNII: EX438O2MRT) |
| ferric oxide red (UNII: 1K09F3G675) |
| ferrosoferric 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:13537-316-02 | 1 in 1 BOX | | |
| 1 | NDC:13537-316-01 | 30 mL in 1 BOTTLE | | |

Marketing Information

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

Establishment

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