

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED- octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) - PINK- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN- octinoxate and oxybenzone lipstick**  
**ESIKA HYDRACOLOR 2 IN 1 SPF 25- octinoxate and oxybenzone**  
**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.*

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**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING LIPSTICK SPF 25**

***Drug Facts***

| <b><i>Active Ingredients</i></b> | <b><i>Purpose</i></b> |
|----------------------------------|-----------------------|
| Octinoxate 6.64 %                | Sunscreen             |
| Oxybenzone 1.51 %                | 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.

Contains Oxybenzone

### **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

### **Other information**

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

### **Inactive ingredients**

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, OZOKERITE, WATER, POLYETHYLENE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, FRAGRANCE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SODIUM STARCH OCTENYLSUCCINATE, TOCOPHERYL ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONIUM GERBERI EXTRACT, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT. **MAY CONTAIN** : MICA, TITANIUM DIOXIDE, RED 30 LAKE, IRON OXIDES, YELLOW 5 LAKE, RED 21 LAKE, RED 27 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE, PEG-8 METHYL ETHER TRIETHOXYSILANE, CARMINE.

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

### **PRINCIPAL DISPLAY PANEL - 4 g Tube Box – All Shades**

HYDRACOLOR 2 IN 1

Highly Moisturizing and Coloring

**Lipstick** SPF 25

Net Weight 0.14 oz. e (4 g)

**ésika**



**Drug Facts (continued)**  
 if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

**Inactive Ingredients**  
 Dipentaerythryl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate, ▶

**Drug Facts (continued)**  
 Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride, ▼

**Drug Facts (continued)**  
 Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. **May Contain:** Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake, ▶

**Drug Facts (continued)**  
 Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-6 Methyl Ether Triethoxysilane, Carmine.

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. [www.esika.biz](http://www.esika.biz)

HYDRACOLOR 2 IN 1  
 Highly Moisturizing and Coloring  
 Lipstick SPF 25  
 Net Weight 0.14 oz. e (4 g)

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**Drug Facts**  
**Active Ingredients** .....**Purpose**  
 OCTINOXATE 6.64% .....Sunscreen  
 OXYBENZONE 1.51% .....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 ▶

**Drug Facts (continued)**  
 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. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen. ▲

**PRINCIPAL DISPLAY PANEL - Kit Carton**

HYDRACOLOR 2 IN 1  
 Highly Moisturizing and Coloring  
**Lipstick** SPF 25

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Net Wt. 0.28 oz. e (8 g)



www.esika.biz

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

**Drug Facts**

**Active Ingredients** ..... Sunscreen  
 Octinoxate 6.64% ..... Sunscreen  
 Oxybenzone 1.51% ..... 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.

**Drug Facts (continued)**

- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

**Other Information**

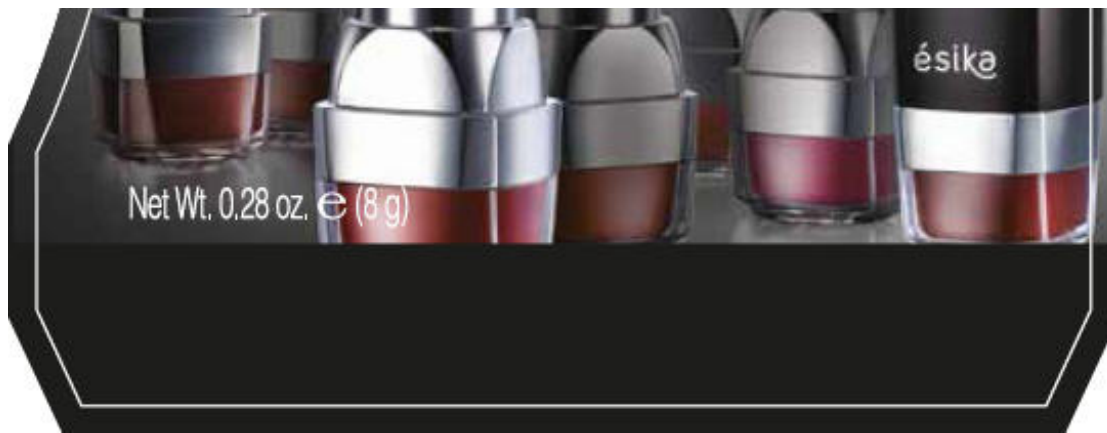
- Protect this product in this container from excessive heat and direct sun.

**Inactive Ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXADECAPRYLATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMATE, OZOKERITE, WATER, POLYETHYLENE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, COPERNICIA CERIFERA (CARNUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRYLATE, FRAGRANCE, CAPRYLIC/CAPRIC ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONUM GERBERI EXTRACT, BUTYROSPERMIUM PAKI (SHEA) BUTTER, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, MAY CONTAIN: MICA, TITANIUM DIOXIDE, RED 30 LAKE, IRON OXIDES, YELLOW 5 LAKE, RED 21 LAKE, RED 27 LAKE, RED 7 LAKE, TAUC, BLUE 1 LAKE, PEG-8 METHYL ETHER TRIETHOXYSLANE, CARMINE.

HYDRACOLOR 2 IN 1  
Highly Moisturizing and Coloring  
Lipstick SPF 25

ésika





## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-590 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |

|                                       |
|---------------------------------------|
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-590-02 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-590-01 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-591 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0K00R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                             |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-591-04 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-591-03 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |



# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED

octinoxate and oxybenzone lipstick

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-592 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98H0)                           |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |

|                                      |  |
|--------------------------------------|--|
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         | NDC:13537-592-06 | 1 in 1 BOX                                       |                      |                    |
| 1         | NDC:13537-592-05 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED

octinoxate and oxybenzone lipstick

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-593 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                              |                   |                 |
|--|-------------------|-----------------|
| Ingredient Name  | Basis of Strength | Strength        |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |

|   |
|---|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)             |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)            |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-593-08 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-593-07 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-594 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0K00R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HE492ZZ3T)                               |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                         |                 |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-594-10 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-594-09 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-595 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |

|                                       |
|---------------------------------------|
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-595-12 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-595-11 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-596 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0KO0R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         | NDC:13537-596-14 | 1 in 1 BOX                                       |                      |                    |
| 1         | NDC:13537-596-13 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and oxybenzone lipstick

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-597 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |



|                                      |  |
|--------------------------------------|--|
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-597-16 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-597-15 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-598 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |

|   |
|---|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)             |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)            |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-598-18 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-598-17 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-599 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-599-20 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-599-19 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE**

octinoxate and oxybenzone lipstick

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-609 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |

|                                       |
|---------------------------------------|
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-609-22 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-609-21 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-610 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0KO0R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W471Q8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         | NDC:13537-610-24 | 1 in 1 BOX                                       |                      |                    |
| 1         | NDC:13537-610-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK

octinoxate and oxybenzone lipstick

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-611 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |

|                                      |  |
|--------------------------------------|--|
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-611-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-611-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-612 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |



|   |
|---|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)             |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)            |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-612-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-612-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-613 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-613-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-613-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN**

octinoxate and oxybenzone lipstick

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-614 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |

|                                       |
|---------------------------------------|
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-614-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-614-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-615 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0KO0R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-615-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-615-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED

octinoxate and oxybenzone lipstick

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-616 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HE492ZZ3T)                               |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |

|                                      |  |
|--------------------------------------|--|
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-616-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-616-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-617 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |

|   |
|---|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)             |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)            |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-617-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-617-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE

octinoxate and oxybenzone lipstick

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-618 |
|--------------|----------------|--------------------|---------------|



**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                         |                 |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-618-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-618-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-619 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |

|                                       |
|---------------------------------------|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-619-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-619-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-620 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)               |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-620-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-620-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-621 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |

|                                      |  |
|--------------------------------------|--|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-621-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-621-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-622 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |

|   |
|---|
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                        |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-622-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-622-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-623 |
|--------------|----------------|--------------------|---------------|

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0K00R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |



## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-623-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-623-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-624 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |

|   |
|---|
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)           |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)           |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)            |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)    |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98110)    |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)       |
| <b>SODIUM CHLORIDE</b> (UNII: 451W471Q8X)       |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)            |
| <b>MICA</b> (UNII: V8A1AW0880)                  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)      |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)    |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)         |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)      |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)    |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)    |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)     |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)   |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-624-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-624-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-664 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)               |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-664-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-664-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-665 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |

|                                      |  |
|--------------------------------------|--|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-665-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-665-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-666 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |

|   |
|---|
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                        |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-666-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-666-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-667 |
|--------------|----------------|--------------------|---------------|

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0K00R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-667-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-667-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-668 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |



|   |
|---|
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)           |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)           |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)            |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)    |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98110)    |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)       |
| <b>SODIUM CHLORIDE</b> (UNII: 451W471Q8X)       |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)            |
| <b>MICA</b> (UNII: V8A1AW0880)                  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)      |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)    |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)         |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)      |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)    |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)    |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)     |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)   |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-668-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-668-23 | 4 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-691 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-691-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-691-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-692 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |

|                                      |  |
|--------------------------------------|--|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-692-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-692-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-693 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |

|   |
|---|
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                        |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-693-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-693-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-694 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |          |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |          |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |          |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |          |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |          |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |          |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |          |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |          |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |          |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |          |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |          |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)                          |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |          |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |          |
| <b>MICA</b> (UNII: V8A1AW0880)  |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |          |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |          |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |          |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |          |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |          |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |          |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |          |

**Packaging**

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-694-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-694-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) - PINK**

octinoxate and oxybenzone lipstick

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-695 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |

|                                       |
|---------------------------------------|
| CHLORPHENESIN (UNII: I670DAL4SZ)      |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-695-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-695-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-696 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |



## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                             |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-696-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-696-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-697 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |

|                                      |  |
|--------------------------------------|--|
| MICA (UNII: V8A1AW0880)              |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-697-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-697-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-698 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |

|   |
|---|
| CARNAUBA WAX (UNII: R12CBM0EIZ)                           |
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                        |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-698-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-698-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED**  
 octinoxate and oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:13537-699 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |          |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |          |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |          |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |          |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |          |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |          |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |          |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |          |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |          |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |          |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |          |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H0)                           |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |          |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |          |
| <b>MICA</b> (UNII: V8A1AW0880)  |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |          |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |          |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |          |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |          |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |          |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |          |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |          |

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-699-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-699-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-700 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |

|                                       |
|---------------------------------------|
| CHLORPHENESIN (UNII: I670DAL4SZ)      |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-700-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-700-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-701 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13537-701-24 | 1 in 1 BOX                                       |                      |                    |
| 1 | NDC:13537-701-23 | 4 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## ESIKA HYDRACOLOR 2 IN 1 SPF 25

octinoxate and oxybenzone kit

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-669 |
|--------------|----------------|--------------------|---------------|

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-669-28 | 2 in 1 BOX          |                      |                    |
| 1 | NDC:13537-669-27 | 1 in 1 TUBE         |                      |                    |

### Quantity of Parts

| Part #  | Package Quantity | Total Product Quantity |
|---------|------------------|------------------------|
| Part 1  | 1 TUBE           | 8 g                    |
| Part 2  | 1 TUBE           | 8 g                    |
| Part 3  | 1 TUBE           | 8 g                    |
| Part 4  | 1 TUBE           | 8 g                    |
| Part 5  | 1 TUBE           | 8 g                    |
| Part 6  | 1 TUBE           | 8 g                    |
| Part 7  | 1 TUBE           | 8 g                    |
| Part 8  | 1 TUBE           | 8 g                    |
| Part 9  | 1 TUBE           | 8 g                    |
| Part 10 | 1 TUBE           | 8 g                    |
| Part 11 | 1 TUBE           | 8 g                    |
| Part 12 | 1 TUBE           | 8 g                    |
| Part 13 | 1 TUBE           | 8 g                    |
| Part 14 | 1 TUBE           | 8 g                    |
| Part 15 | 1 TUBE           | 8 g                    |
| Part 16 | 1 TUBE           | 8 g                    |
| Part 17 | 1 TUBE           | 8 g                    |
| Part 18 | 1 TUBE           | 8 g                    |
| Part 19 | 1 TUBE           | 8 g                    |
| Part 20 | 1 TUBE           | 8 g                    |
| Part    |                  |                        |

|                |        |     |
|----------------|--------|-----|
| <b>Part 21</b> | 1 TUBE | 8 g |
| <b>Part 22</b> | 1 TUBE | 8 g |
| <b>Part 23</b> | 1 TUBE | 8 g |
| <b>Part 24</b> | 1 TUBE | 8 g |
| <b>Part 25</b> | 1 TUBE | 8 g |
| <b>Part 26</b> | 1 TUBE | 8 g |
| <b>Part 27</b> | 1 TUBE | 8 g |
| <b>Part 28</b> | 1 TUBE | 8 g |
| <b>Part 29</b> | 1 TUBE | 8 g |
| <b>Part 30</b> | 1 TUBE | 8 g |
| <b>Part 31</b> | 1 TUBE | 8 g |
| <b>Part 32</b> | 1 TUBE | 8 g |
| <b>Part 33</b> | 1 TUBE | 8 g |
| <b>Part 34</b> | 1 TUBE | 8 g |
| <b>Part 35</b> | 1 TUBE | 8 g |
| <b>Part 36</b> | 1 TUBE | 8 g |
| <b>Part 37</b> | 1 TUBE | 8 g |
| <b>Part 38</b> | 1 TUBE | 8 g |
| <b>Part 39</b> | 1 TUBE | 8 g |
| <b>Part 40</b> | 1 TUBE | 8 g |
| <b>Part 41</b> | 1 TUBE | 8 g |
| <b>Part 42</b> | 1 TUBE | 8 g |

## Part 1 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN

octinoxate and oxybenzone lipstick

#### Product Information

Route of Administration

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H0)                           |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 2 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |

|                                       |
|---------------------------------------|
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 3 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0KO0R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)               |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 4 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED

octinoxate and oxybenzone lipstick

#### Product Information

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

#### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HE492ZZ3T)                               |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |

|                                      |  |
|--------------------------------------|--|
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 5 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |



|   |
|---|
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                        |

| <b>Packaging</b> |           |  |                      |                    |
|------------------|-----------|--|----------------------|--------------------|
| #                | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1                |           | 8 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL          | part352                                  | 11/23/2015           |                    |

**Part 6 of 42**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK**  
 octinoxate and oxybenzone lipstick

**Product Information****Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

## Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 7 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |

|                                       |
|---------------------------------------|
| CERAMIDE 3 (UNII: 4370DF050B)         |
| CHLORPHENESIN (UNII: I670DAL4SZ)      |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 8 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)

OXYBENZONE

0.0151 g in 1 g

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                             |          |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 9 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and oxybenzone lipstick

## Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |

|   |
|---|
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)       |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)       |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)            |
| <b>MICA</b> (UNII: V8A1AW0880)                  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)      |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)    |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)         |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)      |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)    |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)    |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)     |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)   |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 10 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |          |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |          |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |          |

|   |
|---|
| WATER (UNII: 059QF0KO0R)                                  |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)              |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                      |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                           |
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98II0)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                        |

| Packaging |           |  |                      |                    |
|-----------|-----------|--|----------------------|--------------------|
| #         | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |



# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98II0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |

|                                      |  |
|--------------------------------------|--|
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 12 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |

|   |
|---|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HE492ZZ3T)              |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)            |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 13 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0K00R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

**Part 14 of 42****ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN**

octinoxate and oxybenzone lipstick

**Product Information****Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HE492ZZ3T)                               |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |

|                                       |
|---------------------------------------|
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 15 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

Route of Administration: TOPICAL

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

**Part 16 of 42****ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN**

octinoxate and oxybenzone lipstick

**Product Information****Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |          |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |          |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |          |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |          |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |          |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |          |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |          |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |          |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |          |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |          |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |          |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)                          |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |          |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |          |



|                                      |  |
|--------------------------------------|--|
| MICA (UNII: V8A1AW0880)              |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 17 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |

|   |
|---|
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)           |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                           |
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                        |

| Packaging |           |  |                      |                    |
|-----------|-----------|--|----------------------|--------------------|
| #         | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

**Part 18 of 42**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED**  
 octinoxate and oxybenzone lipstick

## Product Information

### Route of Administration

TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |

D&C RED NO. 7 (UNII: ECW0LZ41X8)

TALC (UNII: 7SEV7J4R1U)

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

## Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 19 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |

|   |  |
|---|--|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)        |  |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)       |  |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)            |  |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)         |  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |  |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)           |  |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)           |  |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)            |  |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)    |  |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H0)     |  |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)       |  |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)       |  |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)            |  |
| <b>MICA</b> (UNII: V8A1AW0880)                  |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)      |  |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)    |  |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)         |  |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)      |  |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |  |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)    |  |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)    |  |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)     |  |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                  |  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 20 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE

octinoxate and oxybenzone lipstick

### Product Information

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H0)                           |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 21 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |

|                                       |
|---------------------------------------|
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 22 of 42

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK**  
 octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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



|  |
|--|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |
| WATER (UNII: 059QF0KO0R)                                       |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)               |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |
| WINE GRAPE (UNII: 3GOV20705G)                                  |
| MICA (UNII: V8A1AW0880)  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |
| TALC (UNII: 7SEV7J4R1U)  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 23 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED

octinoxate and oxybenzone lipstick

#### Product Information

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

#### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HE492ZZ3T)                               |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |

|                                      |  |
|--------------------------------------|--|
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 24 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |

|   |
|---|
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                        |

| <b>Packaging</b> |           |  |                      |                    |
|------------------|-----------|--|----------------------|--------------------|
| #                | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1                |           | 8 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL          | part352                                  | 11/23/2015           |                    |

**Part 25 of 42**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK**  
 octinoxate and oxybenzone lipstick

**Product Information****Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

## Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 26 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |

|                                       |
|---------------------------------------|
| CERAMIDE 3 (UNII: 4370DF050B)         |
| CHLORPHENESIN (UNII: I670DAL4SZ)      |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 27 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)

OXYBENZONE

0.0151 g in 1 g

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                             |          |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

## Part 28 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

## Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |

|                                      |
|--------------------------------------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)   |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)   |
| WINE GRAPE (UNII: 3GOV20705G)        |
| MICA (UNII: V8A1AW0880)              |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |
| ALUMINUM OXIDE (UNII: LM26O6933)     |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |
| TALC (UNII: 7SEV7J4R1U)              |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 29 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |

|   |
|---|
| WATER (UNII: 059QF0KO0R)                                  |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)              |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                      |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)           |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                           |
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                        |

| Packaging |           |  |                      |                    |
|-----------|-----------|--|----------------------|--------------------|
| #         | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1         |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

# ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN

octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98II0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |

|                                      |  |
|--------------------------------------|--|
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 31 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |

|   |
|---|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PHENOXYETHANOL (UNII: HE492ZZ3T)              |
| COCONUT OIL (UNII: Q9L0O73W7L)                |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)             |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)            |
| CERAMIDE 3 (UNII: 4370DF050B)                 |
| CHLORPHENESIN (UNII: I670DAL4SZ)              |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)           |
| SHEA BUTTER (UNII: K49155WL9Y)                |
| SOYBEAN OIL (UNII: 241ATL177A)                |
| TOCOPHEROL (UNII: R0ZB2556P8)                 |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)         |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)         |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)            |
| WINE GRAPE (UNII: 3GOV20705G)                 |
| MICA (UNII: V8A1AW0880)                       |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |
| D&C RED NO. 30 (UNII: 2S42T2808B)             |
| ALUMINUM OXIDE (UNII: LM26O6933)              |
| FERRIC OXIDE RED (UNII: 1K09F3G675)           |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)             |
| D&C RED NO. 27 (UNII: 2LRS185U6K)             |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)              |
| TALC (UNII: 7SEV7J4R1U)                       |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)            |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 11/23/2015           |                    |

### Part 32 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0K00R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

**Part 33 of 42****ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE**

octinoxate and oxybenzone lipstick

**Product Information****Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |



|                                       |
|---------------------------------------|
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

### Part 34 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)               |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98110)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                              |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                               |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                             |          |

## Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

**Part 35 of 42****ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN**

octinoxate and oxybenzone lipstick

**Product Information****Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |

|                                      |
|--------------------------------------|
| WINE GRAPE (UNII: 3GOV20705G)        |
| MICA (UNII: V8A1AW0880)              |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  |
| D&C RED NO. 30 (UNII: 2S42T2808B)    |
| ALUMINUM OXIDE (UNII: LM26O6933)     |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |
| TALC (UNII: 7SEV7J4R1U)              |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)   |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

### Part 36 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |

|   |
|---|
| TRIDECYL STEARATE (UNII: A8OE252M6L)                      |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)           |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                           |
| GLYCERIN (UNII: PDC6A3C0OX)                               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)             |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)             |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |
| COCONUT OIL (UNII: Q9L0O73W7L)                            |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |
| CERAMIDE 3 (UNII: 4370DF050B)                             |
| CHLORPHENESIN (UNII: I670DAL4SZ)                          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |
| SHEA BUTTER (UNII: K49155WL9Y)                            |
| SOYBEAN OIL (UNII: 241ATL177A)                            |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                     |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |
| WINE GRAPE (UNII: 3GOV20705G)                             |
| MICA (UNII: V8A1AW0880)                                   |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                       |
| D&C RED NO. 30 (UNII: 2S42T2808B)                         |
| ALUMINUM OXIDE (UNII: LM26O6933)                          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                         |
| D&C RED NO. 27 (UNII: 2LRS185U6K)                         |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                          |
| TALC (UNII: 7SEV7J4R1U)                                   |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                        |

| <b>Packaging</b> |           |  |                      |                    |
|------------------|-----------|--|----------------------|--------------------|
| #                | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
| 1                |           | 8 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL          | part352                                  | 12/18/2015           |                    |

**Part 37 of 42**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK**  
 octinoxate and oxybenzone lipstick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ981I0)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |
| D&C RED NO. 30 (UNII: 2S42T2808B)                              |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                            |          |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                           |          |
| D&C RED NO. 21 (UNII: 08744Z6JNY)                              |          |

|                                    |  |
|------------------------------------|--|
| D&C RED NO. 27 (UNII: 2LRS185U6K)  |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)   |  |
| TALC (UNII: 7SEV7J4R1U)            |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) |  |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

### Part 38 of 42

## ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK

octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |

|                                       |
|---------------------------------------|
| COCONUT OIL (UNII: Q9L0O73W7L)        |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)     |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)    |
| CERAMIDE 3 (UNII: 4370DF050B)         |
| CHLORPHENESIN (UNII: I670DAL4SZ)      |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |
| SHEA BUTTER (UNII: K49155WL9Y)        |
| SOYBEAN OIL (UNII: 241ATL177A)        |
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

### Part 39 of 42

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN**  
 octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|



**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 0.0664 g in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE               | 0.0151 g in 1 g |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |                 |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |                 |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |                 |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |                 |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |                 |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                |                 |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |                 |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |                 |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |                 |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |                 |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |                 |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H0)                           |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |                 |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |                 |
| <b>MICA</b> (UNII: V8A1AW0880)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |                 |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |                 |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |                 |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |                 |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)                         |                 |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## Part 40 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED

octinoxate and oxybenzone lipstick

## Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0KO0R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                              |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |

|                                       |
|---------------------------------------|
| TOCOPHEROL (UNII: R0ZB2556P8)         |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)    |
| WINE GRAPE (UNII: 3GOV20705G)         |
| MICA (UNII: V8A1AW0880)               |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |
| D&C RED NO. 30 (UNII: 2S42T2808B)     |
| ALUMINUM OXIDE (UNII: LM26O6933)      |
| FERRIC OXIDE RED (UNII: 1K09F3G675)   |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)     |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)      |
| TALC (UNII: 7SEV7J4R1U)               |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)    |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

### Part 41 of 42

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE**  
 octinoxate and oxybenzone lipstick

### Product Information

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

### Inactive Ingredients

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

|   |
|---|
| <b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW) |
| <b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)                       |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                        |
| <b>WATER</b> (UNII: 059QF0KO0R)                                       |
| <b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)                   |
| <b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)                           |
| <b>POLYGLYCERYL-3 DIISO STEARATE</b> (UNII: 46P231IQV8)               |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                                |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                    |
| <b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)      |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                  |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                  |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                              |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                              |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                             |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)                                  |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                               |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                            |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                                 |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)                                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                  |
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)                          |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ981I0)                          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                             |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                             |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)                                  |
| <b>MICA</b> (UNII: V8A1AW0880)  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                            |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                          |
| <b>ALUMINUM OXIDE</b> (UNII: LM26O6933)                               |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                            |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)                       |
| <b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)                          |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)                          |
| <b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)                           |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                         |

### Packaging

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

## Part 42 of 42

### ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

#### Product Information

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 0.0664 g in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 0.0151 g in 1 g |

#### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW) |          |
| TRIDECYL TRIMELLITATE (UNII: FY36J270ES)                       |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                        |          |
| WATER (UNII: 059QF0K00R)                                       |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                   |          |
| TRIDECYL STEARATE (UNII: A8OE252M6L)                           |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                    |          |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)      |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                  |          |
| PHENOXYETHANOL (UNII: HE492ZZ3T)                               |          |
| COCONUT OIL (UNII: Q9L0O73W7L)                                 |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                              |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                             |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                  |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                               |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                            |          |
| SHEA BUTTER (UNII: K49155WL9Y)                                 |          |
| SOYBEAN OIL (UNII: 241ATL177A)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                  |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                          |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                             |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                             |          |
| WINE GRAPE (UNII: 3GOV20705G)                                  |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                            |          |

|                                      |  |
|--------------------------------------|--|
| D&C RED NO. 30 (UNII: 2S42T2808B)    |  |
| ALUMINUM OXIDE (UNII: LM26O6933)     |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |  |
| D&C RED NO. 21 (UNII: 08744Z6JNY)    |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)    |  |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)     |  |
| TALC (UNII: 7SEV7J4R1U)              |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |  |

**Packaging**

| # | Item Code | Package Description                              | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 8 g in 1 TUBE; 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                                  | 12/18/2015           |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 08/25/2015           |                    |

**Labeler - Ventura Corporation LTD (602751344)**

**Establishment**

| Name                        | Address | ID/FEI    | Business Operations  |
|-----------------------------|---------|-----------|--|
| Bel Star S.A.<br>(Colombia) |         | 880160197 | MANUFACTURE(13537-590, 13537-591, 13537-592, 13537-593, 13537-594, 13537-595, 13537-596, 13537-597, 13537-598, 13537-599, 13537-609, 13537-610, 13537-611, 13537-612, 13537-613, 13537-614, 13537-615, 13537-616, 13537-617, 13537-618, 13537-619, 13537-620, 13537-621, 13537-622, 13537-623, 13537-624, 13537-664, 13537-665, 13537-666, 13537-667, 13537-668, 13537-669, 13537-691, 13537-692, 13537-693, 13537-694, 13537-695, 13537-696, 13537-697, 13537-698, 13537-699, 13537-700, 13537-701) |