

**LBEL PARIS RENOVANCE JOUR- octinoxate, octocrylene, and oxybenzone cream**  
**Ventura International 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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**L'BEL**  
**RENOVÂNC E JOUR**

***Drug Facts***

**Active Ingredients**

Octinoxate (7.5 %), Octocrylene (5 %), Oxybenzone (3 %)

**Purpose**

Sunscreen

**Uses**

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

**Warnings**

- **For external use only.**

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash and irritation develops and lasts.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply smoothly every morning before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.

**Other information**

- Moderate sun protection product.
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.

**Inactive ingredients**

Aqua (water), cyclohexasiloxane, soy protein phthalate, glycerin, pisum sativum (pea) extract, c12-15 alkyl benzoate, caprylic / capric triglyceride, cyclopentasiloxane, cetyl alcohol, cetearyl alcohol, isopropyl myristate, isononyl isononanoate, sorbitan stearate, mannitol, glyceryl stearate, potassium

cetyl phosphate, dimethicone / vinyl dimethicone crosspolymer, dimethicone crosspolymer, triethanolamine, acrylates / c10-30 alkyl acrylate crosspolymer, cetareth-20, propylparaben, panthenol, sodium pca, steareth-20, ceteth-20, parfum (fragrance), ci 77891 (titanium dioxide), chlorphenesin, dimethiconol, teprenone, ppg-26-buteth-26, polysorbate 80, peg-40 hydrogenated castor oil, tetrasodium edta, cyclodextrin, butylene glycol, hydrolyzed algin, hederia helix (ivy) leaf / stem extract, faex extract (yeast extract), magnesium pca, chlorella vulgaris extract, maris aqua (sea water), algin, tocopheryl acetate, zinc pca, retinyl palmitate, saccharomyces / magnesium ferment, ascorbyl palmitate, serine, urea, acacia, senegal gum, bioflavonoids, allantoin, disodium succinate, saccharomyces /iron ferment, manganese pca, saccharomyces /copper ferment, saccharomyces /calcium ferment, saccharomyces /silicon ferment, saccharomyces /zinc ferment.

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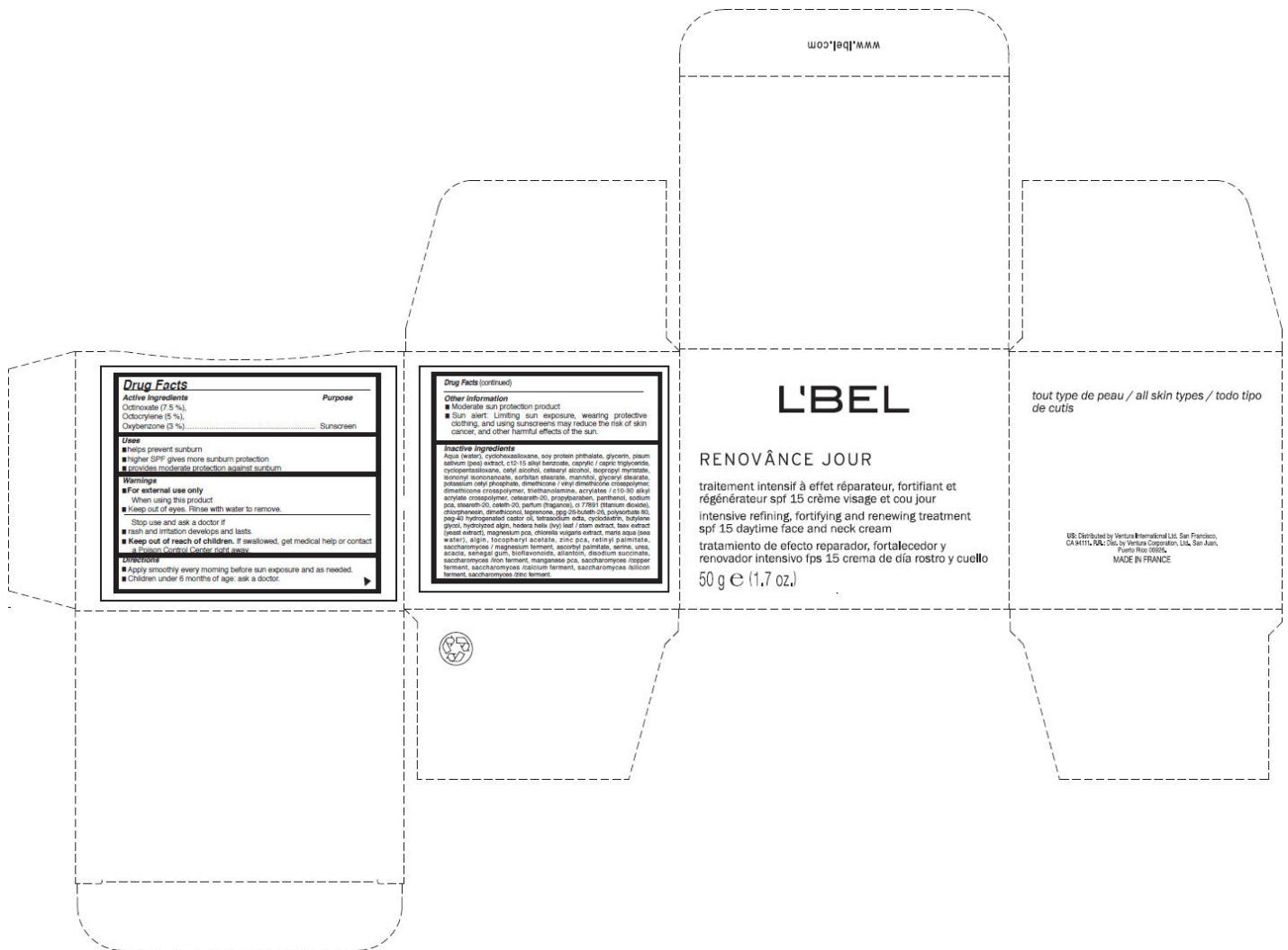
## PRINCIPAL DISPLAY PANEL - 50 g Jar Carton

L'BEL

RENOVÂNCE JOUR

intensive refining, fortifying and renewing treatment  
spf 15 daytime face and neck cream

50 g e (1.7 oz.)



### Drug Facts

#### Active Ingredients

Octinoxate (7.5%)

Octocrylene (5%)

Oxybenzone (3%)

#### Purpose

Sunscreen

#### Use

Helps prevent sunburn

Higher SPF gives more sunburn protection

Provides moderate protection against sunburn

#### Warnings

##### For external use only

When using this product

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash and irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center or your doctor.

#### Directions

Apply smoothly every morning before sun exposure and as needed.

Children under 6 months of age, ask a doctor.

### Drug Facts (continued)

#### Other Information

Moderate sun protection product

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.

#### Inactive Ingredients

Aqua (water), cyclohexasiloxane, xy protein phosphate, glycerin, pisin sodium (sea) extract, c10-15 alkyl succinate, cetylol / capryl triglyceride, cyclopentasiloxane, cetyl alcohol, cetylal alcohol, isopropyl myristate, lauryl alcohol, sorbitol, sorbitol sesquacetate, menthyl glycerol stearate, octadecyl myristyl ether, dimethylsiloxane / vinyl dimethicone crosspolymer, octadecyl myristyl ether, dimethylsiloxane / vinyl dimethicone crosspolymer, acrylates / c10-30 alkyl acrylate crosspolymer, dimethylsiloxane, propylparaben, panthenol, sodium pca, steareth-20, ceteth-20, parfum (fragrance), ci 77891 (titanium dioxide), chlorphenesin, benzophenone, teprenone, ppg-26-buteth-26, polyethylene glycol, hydrolyzed algin, hederia helix (ivy) leaf / stem extract, faex extract (yeast extract), magnesium pca, chlorella vulgaris extract, maris aqua (sea water), algin, tocopheryl acetate, zinc pca, retinyl palmitate, saccharomyces / magnesium ferment, ascorbyl palmitate, serine, urea, acacia, senegal gum, bioflavonoids, allantoin, disodium succinate, saccharomyces /iron ferment, manganese pca, saccharomyces /copper ferment, saccharomyces /calcium ferment, saccharomyces /silicon ferment, saccharomyces /zinc ferment.

L'BEL

RENOVÂNCE JOUR

traitement intensif à effet réparateur, fortifiant et régénérateur spf 15 crème visage et cou jour  
intensive refining, fortifying and renewing treatment spf 15 daytime face and neck cream  
tratamiento de efecto reparador, fortalecedor y renovador intensivo fps 15 crema de día rostro y cuello  
50 g e (1.7 oz.)

tout type de peau / all skin types / todo tipo de cutis

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MADE IN FRANCE

# LBEL PARIS RENOVANCE JOUR

octinoxate, octocrylene, and oxybenzone cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:14783-038 |
| <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               | 3.75 g in 50 g  |
| <b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | Octocrylene              | 2.5 g in 50 g   |
| <b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)   | Oxybenzone               | 1.5 g in 50 g   |

## Inactive Ingredients

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>water</b> (UNII: 059QF0K00R)                               |                 |
| <b>cyclomethicone 6</b> (UNII: XHK3U310BA)                    |                 |
| <b>glycerin</b> (UNII: PDC6A3C0OX)                            |                 |
| <b>snow pea</b> (UNII: 84SKC33B1I)                            |                 |
| <b>c12-15 alkyl benzoate</b> (UNII: A9EJ3J61HQ)               |                 |
| <b>medium-chain triglycerides</b> (UNII: C9H2L21V7U)          |                 |
| <b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)                    |                 |
| <b>cetyl alcohol</b> (UNII: 936JST6JCN)                       |                 |
| <b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)                 |                 |
| <b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)                 |                 |
| <b>isononyl isononanoate</b> (UNII: S4V5BS6GCCX)              |                 |
| <b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)               |                 |
| <b>mannitol</b> (UNII: 3OWL53L36A)                            |                 |
| <b>glyceryl monostearate</b> (UNII: 230OU9XXE4)               |                 |
| <b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)           |                 |
| <b>trolamine</b> (UNII: 9O3K93S3TK)                           |                 |
| <b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)       |                 |
| <b>propylparaben</b> (UNII: Z8IX2SC1OH)                       |                 |
| <b>panthenol</b> (UNII: WV9CM0O67Z)                           |                 |
| <b>sodium pyrrolidone carboxylate</b> (UNII: 469OTG57A2)      |                 |
| <b>steareth-20</b> (UNII: L0Q8IK9E08)                         |                 |
| <b>ceteth-20</b> (UNII: I835H2IHHX)                           |                 |
| <b>chlorphenesin</b> (UNII: I670DAL4SZ)                       |                 |
| <b>titanium dioxide</b> (UNII: 15FIX9V2JP)                    |                 |
| <b>teprenone</b> (UNII: S8S8451A4O)                           |                 |
| <b>polysorbate 80</b> (UNII: 6OZP39ZG8H)                      |                 |
| <b>polyoxyl 40 hydrogenated castor oil</b> (UNII: 7YC686GQ8F) |                 |
| <b>edetate sodium</b> (UNII: MP1J8420LU)                      |                 |
| <b>butylene glycol</b> (UNII: 3XUS85K0RA)                     |                 |
| <b>kalmia latifolia leaf</b> (UNII: 79N6542N18)               |                 |
| <b>yeast</b> (UNII: 3NY3SM6B8U)                               |                 |

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| <b>vitamin a palmitate</b> (UNII: 1D1K0N0VVC)        |
| <b>ascorbyl palmitate</b> (UNII: QN83US2B0N)         |
| <b>serine</b> (UNII: 452VLY9402)                     |
| <b>urea</b> (UNII: 8W8T17847W)                       |
| <b>acacia</b> (UNII: 5C5403N26O)                     |
| <b>allantoin</b> (UNII: 344S277G0Z)                  |
| <b>sodium succinate anhydrous</b> (UNII: V8ZGC8ISR3) |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:14783-038-61 | 1 in 1 BOX          |                      |                    |
| 1 | NDC:14783-038-62 | 50 g in 1 JAR       |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part352                                  | 08/15/2010           |                    |

## LBEL PARIS RENOVANCE JOUR

octinoxate, octocrylene, and oxybenzone cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:14783-028 |
| <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        | 0.375 g in 5 g |
| <b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | Octocrylene       | 0.25 g in 5 g  |
| <b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)   | Oxybenzone        | 0.15 g in 5 g  |

### Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| <b>water</b> (UNII: 059QF0KO0R)                      |          |
| <b>cyclomethicone 6</b> (UNII: XHK3U310BA)           |          |
| <b>glycerin</b> (UNII: PDC6A3C0OX)                   |          |
| <b>snow pea</b> (UNII: 84SKC33B1I)                   |          |
| <b>c12-15 alkyl benzoate</b> (UNII: A9EJ3J61HQ)      |          |
| <b>medium-chain triglycerides</b> (UNII: C9H2L21V7U) |          |
| <b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)           |          |
| <b>cetyl alcohol</b> (UNII: 936JST6JCN)              |          |
| <b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)        |          |
| <b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)        |          |

|   |
|---|
| <b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)               |
| <b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)               |
| <b>mannitol</b> (UNII: 3OWL53L36A)                            |
| <b>glyceryl monostearate</b> (UNII: 230OU9XXE4)               |
| <b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)           |
| <b>trolamine</b> (UNII: 9O3K93S3TK)                           |
| <b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)       |
| <b>propylparaben</b> (UNII: Z8IX2SC1OH)                       |
| <b>panthenol</b> (UNII: WV9CM0O67Z)                           |
| <b>sodium pyrrolidone carboxylate</b> (UNII: 469OTG57A2)      |
| <b>steareth-20</b> (UNII: L0Q8IK9E08)                         |
| <b>ceteth-20</b> (UNII: I835H2IHHX)                           |
| <b>chlorphenesin</b> (UNII: I670DAL4SZ)                       |
| <b>titanium dioxide</b> (UNII: 15FIX9V2JP)                    |
| <b>teprenone</b> (UNII: S8S8451A4O)                           |
| <b>polysorbate 80</b> (UNII: 6OZP39ZG8H)                      |
| <b>polyoxyl 40 hydrogenated castor oil</b> (UNII: 7YC686GQ8F) |
| <b>edetate sodium</b> (UNII: MP1J8420LU)                      |
| <b>butylene glycol</b> (UNII: 3XUS85K0RA)                     |
| <b>kalmia latifolia leaf</b> (UNII: 79N6542N18)               |
| <b>yeast</b> (UNII: 3NY3SM6B8U)                               |
| <b>vitamin a palmitate</b> (UNII: 1D1K0N0VVC)                 |
| <b>ascorbyl palmitate</b> (UNII: QN83US2B0N)                  |
| <b>serine</b> (UNII: 452VLY9402)                              |
| <b>urea</b> (UNII: 8W8T17847W)                                |
| <b>acacia</b> (UNII: 5C5403N26O)                              |
| <b>allantoin</b> (UNII: 344S277G0Z)                           |
| <b>sodium succinate anhydrous</b> (UNII: V8ZGC8ISR3)          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:14783-028-51 | 1 in 1 BOX          |                      |                    |
| 1 | NDC:14783-028-52 | 5 g in 1 JAR        |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part352                                  | 08/15/2010           |                    |

## LBEL PARIS RENOVANCE JOUR

octinoxate, octocrylene, and oxybenzone cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:14783-018 |
| <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               | 0.075 g in 1 g  |
| <b>Octocrylene</b> (UNII: 5A68 WGF6 WM) (Octocrylene - UNII:5A68 WGF6 WM) | Octocrylene              | 0.05 g in 1 g   |
| <b>Oxybenzone</b> (UNII: 95OOS7VE0 Y) (Oxybenzone - UNII:95OOS7VE0 Y)     | Oxybenzone               | 0.03 g in 1 g   |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>water</b> (UNII: 059QF0KO0R)                               |                 |
| <b>cyclomethicone 6</b> (UNII: XHK3U310BA)                    |                 |
| <b>glycerin</b> (UNII: PDC6A3C0OX)                            |                 |
| <b>snow pea</b> (UNII: 84SKC33B1I)                            |                 |
| <b>c12-15 alkyl benzoate</b> (UNII: A9EJ3J61HQ)               |                 |
| <b>medium-chain triglycerides</b> (UNII: C9H2L21V7U)          |                 |
| <b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)                    |                 |
| <b>cetyl alcohol</b> (UNII: 936JST6JCN)                       |                 |
| <b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)                 |                 |
| <b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)                 |                 |
| <b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)               |                 |
| <b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)               |                 |
| <b>mannitol</b> (UNII: 3OWL53L36A)                            |                 |
| <b>glyceryl monostearate</b> (UNII: 230OU9XXE4)               |                 |
| <b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)           |                 |
| <b>trolamine</b> (UNII: 9O3K93S3TK)                           |                 |
| <b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)       |                 |
| <b>propylparaben</b> (UNII: Z8IX2SC1OH)                       |                 |
| <b>panthenol</b> (UNII: WV9CM0O67Z)                           |                 |
| <b>sodium pyrrolidone carboxylate</b> (UNII: 469OTG57A2)      |                 |
| <b>steareth-20</b> (UNII: L0Q8IK9E08)                         |                 |
| <b>ceteth-20</b> (UNII: I835H2IHHX)                           |                 |
| <b>chlorphenesin</b> (UNII: I670DAL4SZ)                       |                 |
| <b>titanium dioxide</b> (UNII: 15FIX9V2JP)                    |                 |
| <b>teprenone</b> (UNII: S8S8451A4O)                           |                 |
| <b>polysorbate 80</b> (UNII: 6OZP39ZG8H)                      |                 |
| <b>polyoxyl 40 hydrogenated castor oil</b> (UNII: 7YC686GQ8F) |                 |
| <b>edetate sodium</b> (UNII: MPLJ8420LU)                      |                 |
| <b>butylene glycol</b> (UNII: 3XUS85K0RA)                     |                 |
| <b>kalmia latifolia leaf</b> (UNII: 79N6542N18)               |                 |
| <b>yeast</b> (UNII: 3NY3SM6B8U)                               |                 |
| <b>vitamin a palmitate</b> (UNII: 1D1K0N0VVC)                 |                 |
| <b>ascorbyl palmitate</b> (UNII: QN83US2B0N)                  |                 |
| <b>serine</b> (UNII: 452VLY9402)                              |                 |
| <b>urea</b> (UNII: 8W8T17847W)                                |                 |
| <b>acacia</b> (UNII: 5C5403N26O)                              |                 |
| <b>allantoin</b> (UNII: 344S277G0Z)                           |                 |
| <b>sodium succinate anhydrous</b> (UNII: V8ZGC8ISR3)          |                 |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:14783-018-41 | 1 in 1 BOX          |                      |                    |
| 1 | NDC:14783-018-42 | 1 g in 1 JAR        |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part352                                  | 08/15/2010           |                    |

**Labeler** - Ventura International LTD (603192787)

Revised: 8/2010

Ventura International LTD