

**EXUVIANCE ESSENTIAL DAILY DEFENSE SPF 30- octinoxate and titanium dioxide cream**  
**NeoStrata Company Inc.**

*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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**Exuviance® Essential Daily Defense Crème SPF 30**

***Drug Facts***

**Active ingredients**

Ethylhexyl Methoxycinnamate (Octinoxate) 6.0%  
Titanium Dioxide 4.0%

**Purpose**

Sunscreen

**Uses**

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

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

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

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

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

**Directions**

- Apply liberally to face and neck daily, 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. - 2 p.m.
  - Wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

**Inactive ingredients**

Aqua (Water), Glycolic Acid, C12-15 Alkyl Benzoate, Isocetyl Stearate, Glycerin, Glyceryl Stearate, Octyldodecyl Neopentanoate, Hydrogenated Polydecene, PEG-100 Stearate, Ammonium Hydroxide, Citric Acid, Dimethicone, Propylene Glycol, Lactobionic Acid, Cetearyl Alcohol, Methicone,

Tocopheryl (Vitamin E) Acetate, Rosa Centifolia Flower Extract, Sambucus Nigra Flower Extract, Vitis Vinifera (Grape) Seed Extract, Chamomilla Recutita (Matricaria) Flower Extract, Aloe Barbadensis Leaf Extract, Caprylyl Glycol, Arginine, Calendula Officinalis Flower Extract, Palmitic Acid, Stearic Acid, Myristic Acid, Hydroxyethylcellulose, Disodium EDTA, Xanthan Gum, Alumina, Polyhydroxystearic Acid, Polysorbate 20, Phenoxyethanol, Chlorphenesin

**Other information**

- Store at 15°C-30°C (59°F-86°F)
- Protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free 1-800-225-9411 (9am-5pm ET)

**PRINCIPAL DISPLAY PANEL - 50 g Bottle Carton**

DERMATOLOGIST DEVELOPED

**Exuviance®**

Essential Daily  
Defense Creme

**normal / combination**

**with Sunscreen**

**Broad Spectrum SPF 20**

**Antiaging complex reduces lines,  
stimulates cell renewal**

**AHA/Bionic blend plus antioxidants  
for added defense**

Net Wt 50 g / 1.75 oz

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**the science of skin transformation™**

EXUVIANCE is a dermatologist developed line created by Drs. Van Scott and Yu, widely recognized around the world as leaders in the field of cosmetic dermatology. They are the creators and original patent holders of the first "lunchtime" glycolic peel and discovered the rejuvenating powers of Alpha Hydroxy and Polyhydroxy Acids. Exuviance contains clinically proven ingredients to transform skin and deliver visible results backed by evidence from numerous clinical studies, patents and articles in major medical journals of dermatology.

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GLUE

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#### Drug Facts (continued)

Caprylyl Glycol, Arginine, Calendula Officinalis Flower Extract, Palmitic Acid, Stearic Acid, Myristic Acid, Hydroxyethylcellulose, Disodium EDTA, Xanthan Gum, Alumina, Polyhydroxystearic Acid, Polysorbate 20, Phenoxyethanol, Chlorphenesin

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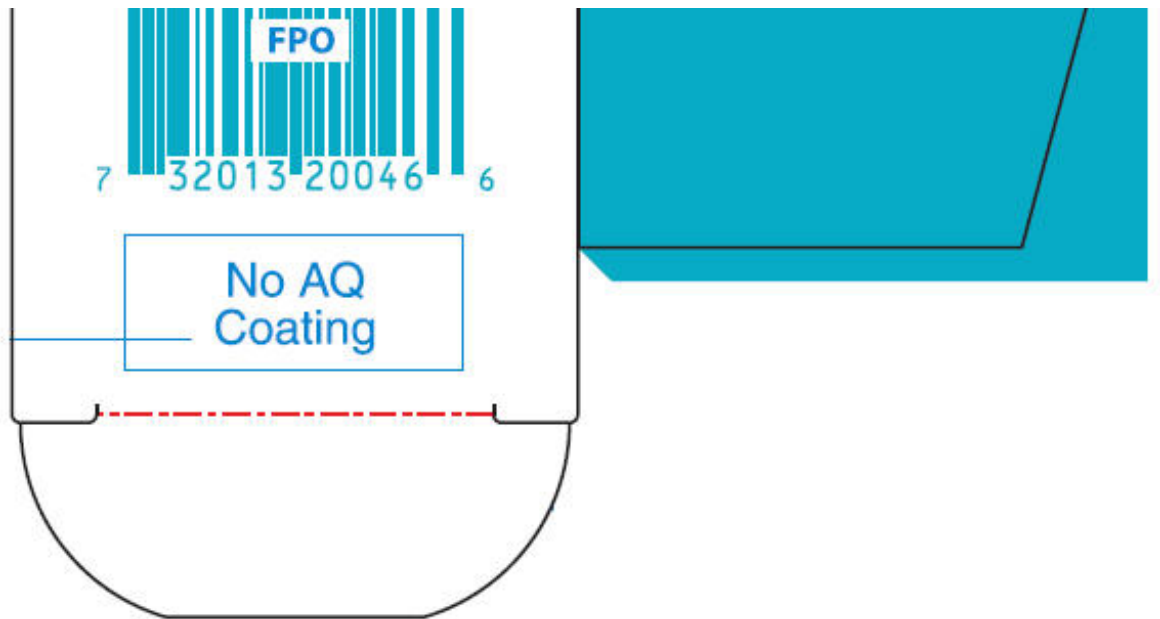
Call toll free: 1-800-225-9411 (9am-5pm ET)

**This hydrating daily antiaging cream is formulated to brighten skin tone, help visibly reduce the appearance of fine lines and wrinkles, and refine skin texture. Contains a unique combination of Alpha Hydroxy and Bionic Acids, botanicals, multi-antioxidants, including grape seed extract and Pro-Vitamin E, along with broad spectrum sunscreen (SPF 20) to provide protection against daily environmental exposure. Dermatologist and allergy tested.**

Reveal the Beauty of Great Skin®

U.S. Patents 6,335,023; 6,740,327  
Mfd. for NeoStrata Co., Inc. Princeton, NJ 08540 USA  
Made in USA NOT TESTED ON ANIMALS  
[www.environme.com](http://www.environme.com)





## EXUVIANCE ESSENTIAL DAILY DEFENSE SPF 30

octinoxate and titanium dioxide cream

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58414-2046 |
| <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        | 60 mg in 1 g |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 40 mg in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                            |          |
| <b>GLYCOLIC ACID</b> (UNII: 0WT12SX38S)                    |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)          |          |
| <b>ISOCETYL STEARATE</b> (UNII: 3RJ7186O9W)                |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                         |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)            |          |
| <b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)       |          |
| <b>HYDROGENATED POLYDECENE (550 MW)</b> (UNII: U333RI6EB7) |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)                 |          |
| <b>AMMONIA</b> (UNII: 5138Q19F1X)                          |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)          |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                      |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                 |          |
| <b>LACTOBIONIC ACID</b> (UNII: 65R938S4DV)                 |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)              |          |

|  |
|--|
| METHICONE (20 CST) (UNII: 6777U11MKT)                      |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)              |
| ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)                  |
| SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)                   |
| VITIS VINIFERA SEED (UNII: C34U15ICXA)                     |
| CHAMOMILE (UNII: FGL3685T2X)                               |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                         |
| ARGININE (UNII: 94ZLA3W45F)                                |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)            |
| PALMITIC ACID (UNII: 2V16EO95HI)                           |
| STEARIC ACID (UNII: 4ELV7Z65AP)                            |
| MYRISTIC ACID (UNII: 0IBV7S25AW)                           |
| HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP) |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                        |
| XANTHAN GUM (UNII: TTV12P4NEE)                             |
| ALUMINUM OXIDE (UNII: LM26O6933)                           |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)       |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)                          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                           |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58414-2046-1 | 1 in 1 CARTON   | 07/10/2013           | 01/31/2021         |
| 1 |                  | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part352                                  | 07/10/2013           | 01/31/2021         |

**Labeler** - NeoStrata Company Inc. (605754829)

### Establishment

| Name                   | Address | ID/FEI    | Business Operations     |
|------------------------|---------|-----------|-------------------------|
| Cosmetic Essence, LLC. |         | 825646862 | MANUFACTURE(58414-2046) |