

**EARTH AND VINE BB BROAD SPECTRUM SPF 15 SUNSCREEN- octinoxate and titanium dioxide cream**

**Emilia Personal Care 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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**Earth and Vine™ BB Broad Spectrum SPF 15 Sunscreen**

**Active ingredient**

Octinoxate, 4.0%

Titanium Dioxide, 2.1%

**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 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use water resistant sunscreen if swimming or sweating

- Children under 6 months of age: ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. – 2 p.m.
  - Wear long-sleeved shirts, pants, hats and sunglasses

### Other Information

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

### Inactive ingredients

water, talc, C12-15 Alkyl benzoate, caprylic/capric triglyceride, potassium cetyl phosphate, cyclopentasiloxane, glyceryl myristate, isononyl isononanoate, behenyl alcohol, mineral oil, glycerin, propylene glycol, microcrystalline cellulose, cellulose gum, phenoxyethanol, ethylhexylglycerin, malus domestica fruit cell culture, xanthan gum, lecithin, nylon-12, triethanolamine, ammonium acryloyldimethyltaurate/VP copolymer, iron oxides, fragrance, butylene glycol, allantoin, caffeine, ascorbic acid, disodium EDTA, tocopheryl acetate (vitamin E), chamomilla recutita (matricaria) flower extract, persea gratissima (avocado) oil, cucumis sativus (cucumber) fruit oil, ginkgo biloba leaf extract, butyrospermum parkii (shea butter), simmondsia chinensis (jojoba) seed oil, BHT, camellia sinensis leaf extract, hyaluronic acid.

### Package/Label Principal Display Panel

**Earth & Vine™**

**AGE-DEFYING SKINCARE**

SKIN

ILLUMINATOR

BB CREAM

SPF 15

- Brightens & evens skin tone
- Formulated with powerful antioxidants
- Broad Spectrum SPF15
- Light/Medium skin tone
- Enhanced with Nutriplex™
  - *a skin nutrition complex*

2.5 fl oz

75 mL

Return your skin's appearance to its original radiant self with **Earth & Vine™ Skin Illuminator BB Cream**. This BB Cream combines apple stem cells with broad spectrum SPF15 and additional anti-aging ingredients to awaken skin, even skin tone and brightens for smooth, natural looking skin

### Directions:

Apply liberally 15 minutes before sun exposure. Reapply every 2 hours. Use water resistant sunscreen if swimming or sweating.

Children under 6 months: Ask a doctor

## How Can Apples Deliver Beautiful Skin?

**Earth & Vine™** is a collection of skincare products uniquely formulated with the stem cells of Uttwiler Spätlauber, a rare Swiss apple with origins dating to the mid-18th century. Long known for its ability to be stockpiled without withering or showing “signs of aging.” Today, this exceptional gift of nature is recognized for its ability to maintain the vibrancy and freshness of skin. Treat your skin with “an apple a day” to awaken dormant skin cells, and to combat chronological aging of the skin.

**Earth & Vine™** is a collection of skin care products that are uniquely formulated to harness the power of fruit stem cells – nature’s greatest weapon against the aging process. Apple stem cells which are known for their anthocyanins – **powerful antioxidants** that help protect skin from UV radiation, premature photo-aging, oxidative stress. When blended with other **organic anti-aging ingredients**, skin looks naturally younger by diminishing the appearance of fine lines and wrinkles, evens and brightens skin tone, and clarifies the complexion.

**Nutriplex™**, our exclusive complex of a powerful, proprietary blend of the earth’s greatest nutrients and botanicals form a nutritious defense against the aging process.

- **Rare Apple Stem Cells** – for anti-aging & anti-wrinkles
- **Chamomile** – soothes and revitalizes skin
- **Green Tea** – contains anti-inflammatory properties that slow signs of aging
- **Powerful Moisturizers** including Shea Butter & Jojoba Oil to nourish and hydrate skin

Visit us at

**[www.earthandvineskincare.com](http://www.earthandvineskincare.com)**

Made in Israel

Distributed by:

Emilia Personal Care

5890 Sawmill Road, Suite 230

Dublin, OH 43017

WD418 83 C1

**Earth & Vine**  
AGE-DEFYING SKINCARE

**SKIN ILLUMINATOR BB CREAM SPF 15**

Return your skin's appearance to its original radiant self with **Earth & Vine™ Skin Illuminator BB Cream**. This BB Cream combines apple stem cells with broad spectrum SPF15 and additional anti-aging ingredients to awaken skin, even skin tone and brightens for smooth, natural looking skin

**Directions:**  
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Use water resistant sunscreen if swimming or sweating.  
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- Brightens & evens skin tone  
- Formulated with powerful antioxidants  
- Broad Spectrum SPF15  
- Light/Medium skin tone  
- Enhanced with Nutriplex™  
- a skin nutrition complex

2.5 fl oz / 75 mL

**Drug Facts**

**Active Ingredients**

Octinoxate, 8.0%	Sunscreen
Titanium Dioxide, 2.1%	Sunscreen

**Uses**

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Made in Israel  
Distributed by:  
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5890 Sawmill Road, Suite 230  
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WD418 83 C1

Carton Label

## EARTH AND VINE BB BROAD SPECTRUM SPF 15 SUNSCREEN

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-419
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
TALC (UNII: 7SEV7J4R1U)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
GLYCERYL MYRISTATE (UNII: 6992Y81827)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
DOCOSANOL (UNII: 9G1OE216XY)
MINERAL OIL (UNII: T5L8T28FGP)
GLYCERIN (UNII: PDC6A3C0OX)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
APPLE (UNII: B423VGH5S9)
XANTHAN GUM (UNII: TTV12P4NEE)
NYLON-12 (UNII: 446U8J075B)
TROLAMINE (UNII: 9O3K93S3TK)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
FERRIC OXIDE RED (UNII: 1K09F3G675)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ALLANTOIN (UNII: 344S277G0Z)
CAFFEINE (UNII: 3G6A5W338E)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
EDETATE DISODIUM (UNII: 7FLD91C86K)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHAMOMILE (UNII: FGL3685T2X)
AVOCADO OIL (UNII: 6VNO72PFC1)
CUCUMBER FRUIT OIL (UNII: R81Y52NPCT)
GINKGO (UNII: 19FUJ2C58T)
SHEA BUTTER (UNII: K49155WL9Y)
JOJOBA OIL (UNII: 724GKU717M)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HYALURONIC ACID (UNII: S270N0TRQY)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-419-12	1 in 1 CARTON		
1		75 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 not final	part352	09/01/2014	

