

**TINTED BB- octinoxate and titanium dioxide cream**  
**Kareway Product, 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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**Drug Facts**

**Active Ingredients**

Octyl Methoxycinnamate 6%

Titanium Dioxide 8.5%

**Purpose**

Sunscreen

Sunscreen

**Use**

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 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 product is swallowed, get medical help or call 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 seating
- children under 6 months: ask a doctor

**Other information**

- protect this product from excessive heat and direct sun

**Inactive Ingredients**

water, proylene glycol, glycerin, cyclo pentasiloxane, cetyl ethylhexanoate, niacinamide, polysorbate 60, stearic acide, cyclohexasiloxane, glyceryl stearate, cetyl alcohol, sorbitan sesquioleate, dimethicone, triethanolamine, dimethiconol, magnesium aluminum silicate, cl 19140, triethoxycaprylylsilane, betaine, cl 77492, methyparaben, cl 77491, xanthan gum, allantoin, propylparaben, disodium EDTA, cl 77499, tocopheryl acetate, adenosine,

**Package label**

BB Cream

AQUA TINTED  
**BB**  
CREAM  
LIGHT BEIGE

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**BB**  
CREAM  
LIGHT BEIGE

AQUA TINTED  
**BB**  
CREAM  
LIGHT BEIGE



**BB** SPF20  
CREAM  
LIGHT BEIGE

All-in-one Beauty Balm formula works to MOISTURIZE, PRIME, SMOOTH, BRIGHTEN, EVENS TONE and PROTECT skin from the sun.



1.33 FL OZ (40mL)

The tinted multi-tasking Epielle™ BB Cream provides a flawless finished look with instant sheer coverage to let your natural glowing skin tone to shine through.

**Drug Facts**

| Active Ingredients             | Purpose   |
|--------------------------------|-----------|
| Octyl Methoxycinnamate 6.0%... | Sunscreen |
| Titanium Dioxide 8.5%.....     | Sunscreen |

**Directions**

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use water resistant sunscreen if swimming or seating
- children under 6 months: ask a doctor

**Other information**

- protect this product from excessive heat and direct sun

**Inactive ingredients**

Water, Propylene Glycol, Glycerin, Cyclo pentasiloxane, Cetyl Ethylhexanoate, Niacinamide, Polysorbate 60, Stearic Acid, Cyclohexasiloxane, Glyceryl Stearate, Cetyl Alcohol, Sorbitan Sesquioleate, Dimethicone, Triethanolamine, Dimethiconol, Magnesium Aluminum Silicate, CI 19140, Triethoxycaprylylsilane, Betaine, CI 77492, Methylparaben, CI 77491, Xanthan Gum, Allantoin, Propylparaben, Disodium EDTA, CI 77499, Tocopheryl Acetate, Adenosine

Exclusively distributed by:



Kareway Product Inc.  
Compton, CA 90220  
Made in Korea



**TINTED BB**

octinoxate and titanium dioxide cream

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:67510-0378 |
| <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               | 6 mg in 100 mg   |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE         | 8.5 mg in 100 mg |

**Inactive Ingredients**

| <b>Ingredient Name</b>                                | <b>Strength</b> |
|---|-----------------|
| <b>WATER</b> (UNII: 059QF0KO0R)                       |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)            |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                    |                 |
| <b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)        |                 |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)                 |                 |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)              |                 |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                |                 |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)               |                 |
| <b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)       |                 |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                 |                 |
| <b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC) |                 |
| <b>BETAINE</b> (UNII: 3SCV180C9W)                     |                 |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)               |                 |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                 |                 |
| <b>ALLANTOIN</b> (UNII: 344S277G0Z)                   |                 |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)               |                 |
| <b>DISODIUM EDTA-COPPER</b> (UNII: 6V475AX06U)        |                 |
| <b>ADENOSINE</b> (UNII: K72T3FS567)                   |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                         | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:67510-0378-3 | 40 mg in 1 TUBE; Type 0: Not a Combination Product | 10/11/2013                  |                           |
| 2        | NDC:67510-0378-1 | 30 mg in 1 TUBE; Type 0: Not a Combination Product | 10/11/2013                  |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part352   | 10/11/2013                  |                           |

**Labeler** - Kareway Product, Inc. (121840057)

