

**SEI BELLA TINTED BB MOISTURIZING CREME LIGHT TO MEDIUM 160 N- titanium dioxide 5% and zinc oxide 5% lotion**

**Melaleuca 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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**Sei Bella Tinted BB Moisturizing Creme Light to Medium 160 N**

**Active Ingredient**

Titanium Dioxide 5%

Zinc Oxide 5%

**Purpose**

Sunscreen

**Use**

- helps prevent sunburn

**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 after cleanser, toner, and foundation primer. Blend outward with Sei Bella foundation brush or fingers.
- apply liberally 15 minutes before sun exposure
- use a water-resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: 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-sleeve shirts, pants, hats, and sunglasses

**Other information**


- dermatologist and allergy tested
- protect this product from excessive heat and direct sun

## Inactive ingredients

Water (Aqua), Cyclopentasiloxane, Butylene Glycol, Octyldodecyl Neopentanoate, PEG/PPG-18/18 Dimethicone, Dimethicone, Magnesium Chloride, Potassium Chloride, Sodium Chloride, Zinc Chloride, Lysine, Tocopherol, Tetrahexyldecyl Ascorbate, Magnesium Ascorbyl Phosphate, Retinyl Palmitate, Camellia Oleifera Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Ginkgo Biloba Leaf Extract, Panax Ginseng Root Extract, Octyldodecanol, Sodium Hyaluronate, Phytantriol, Glycerin, Triethoxycaprylylsilane, Boron Nitride, Dextrin Palmitate, Palmitic Acid, Methicone, Stearic Acid, Aluminum Hydroxide, Hexylene Glycol, Disodium EDTA, Potassium Sorbate, Sodium Dehydroacetate, Caprylyl Glycol, Phenoxyethanol

May Contain (+/-): Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)

*Melaleuca*



### Drug Facts

Active Ingredients	Purpose
Thiazolidine 9%	Sunscreen
Zinc Oxide 5%	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. Rubs with water to remove.

Stop use and seek medical help if rash occurs.

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

**Directions**

- Apply smoothly on clean, moist skin
- Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: ask a doctor

**See Precautions/Warnings.** 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. to 4 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

**Other information**

- For normal to dry skin
- Irritant and allergy tested
- May stain some fabrics
- Protect this product from excessive heat and direct sun
- Do not store at temperatures below 32°F (0°C) or above 122°F (49°C)

### Drug Facts

(continued)

**Inactive Ingredients**

aqua (water), cyclopentasiloxane, butylene glycol, octyldodecyl neopentanoate, PEG/PPG-18/18 dimethicone, dimethicone, magnesium chloride, potassium chloride, sodium chloride, zinc chloride, lysine, tocopherol, tetrahexyldecyl ascorbate, magnesium ascorbyl phosphate, retinyl palmitate, panax ginseng root extract, ginkgo biloba leaf extract, camellia oleifera leaf extract, chamomilla recutita (matricaria) flower extract, cetylalcohol, sodium hyaluronate, phytantriol, glycerin, triethoxycaprylylsilane, boron nitride, dextrin palmitate, palmitic acid, methicone, stearic acid, aluminum hydroxide, hexylene glycol, disodium EDTA, potassium sorbate, sodium dehydroacetate, caprylyl glycol, phenoxyethanol.


[s Iron Oxides (CI 77492), Titanium Dioxide (CI 77891), Zinc Oxide (CI 77947), Iron Oxides (CI 77499)]

**Sei Bella® Tinted BB Moisturizing Creme**

**BROAD-SPECTRUM SPF 20 SUNSCREEN**

*Sei Bella®*

1 fl. oz. / 30 mL e



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For information on all of our products, visit us at melaleuca.com  
Sei Bella® Tinted BB Moisturizing Creme (CI 77891) is a Broad Spectrum Sunscreen with SPF 20. It is not intended for use on children under 6 years of age. For more information, visit us at melaleuca.com



## ARTWORK INFORMATION

1. File name and Revision Date: 505058875\_Tinted\_BB\_Moisturizing\_Creme\_Box\_0516.ai  
2. Part Number: 505058875  
3. Color:  Digital  Flexo PMS: 7449C & Metallic 5125C  
4. Format: Carton, two-sided  
5. Die size: 5.4687 x 9.5312 in  
6. Stock: Metallic SBS  
7. Finish: Gloss UV, Spot Satin  
8. Dispense Direction: N/A  
9. Designer Name & Phone #: Anita Aviles • 208.522.0700  
10. Last Revised Date: 14 February 2018

### COLORS USED:



### ADDITIONAL NOTES:



## SEI BELLA TINTED BB MOISTURIZING CREME LIGHT TO MEDIUM 160 N

titanium dioxide 5% and zinc oxide 5% lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-283
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.5 g in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.5 g in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GLYCERIN (UNII: PDC6A3C0OX)	

HEXYLENE GLYCOL (UNII: KEH0A3F75J)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ZINC CHLORIDE (UNII: 86Q357L16B)
LYSINE (UNII: K3Z4F929H6)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
DIMETHICONE (UNII: 92RU3N3Y1O)
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)
PHYTANTRIOL (UNII: 8LVI07A72W)
PALMITIC ACID (UNII: 2V16EO95HI)
METHICONE (20 CST) (UNII: 6777U11MKT)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
WATER (UNII: 059QF0KO0R)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-283-01	1 in 1 BOX	05/01/2018	
1	NDC:54473-283-30	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part352	05/01/2018	

**Labeler** - Melaleuca Inc. (139760102)

**Registrant** - Melaleuca Inc. (139760102)

### Establishment

Name	Address	ID/FEI	Business Operations
Mana		078870292	manufacture(54473-283)