

SEI BELLA TINTED BB MOISTURIZING CREME MEDIUM 320 C- 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.

Sei Bella Tinted BB Moisturizing Creme Medium 320 C

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



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 MEDIUM 320 C

titanium dioxide 5% and zinc oxide 5% lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54473-286 |
| 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) | |
| TRIETHOXYCAPRYL YLSILANE (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:54473-286-01 | 1 in 1 BOX | 05/01/2018 | |
| 1 | NDC:54473-286-30 | 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(54473-286) |