

SEI BELLA TINTED BB MOISTURIZING CREME BROADSPECTRUM SPF 20 BEIGE 300

N- avobenzone and octinoxate 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.

Tinted BB Moisturizing Creme Broad-Spectrum SPF 20 Sunscreen

Active Ingredients

Avobenzone 3.0%

Octinoxate 7.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- is 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

Keep Out of the Reach of Children

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

When using

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

Do not use

Do not use on damaged or broken skin.

Directions

Directions

- apply smoothly on cleansed 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
- 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 10a.m.-2p.m
- wear long-sleeve shirts, pants, hats, and sunglasses

Other Information

- 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 120°F (49°C)

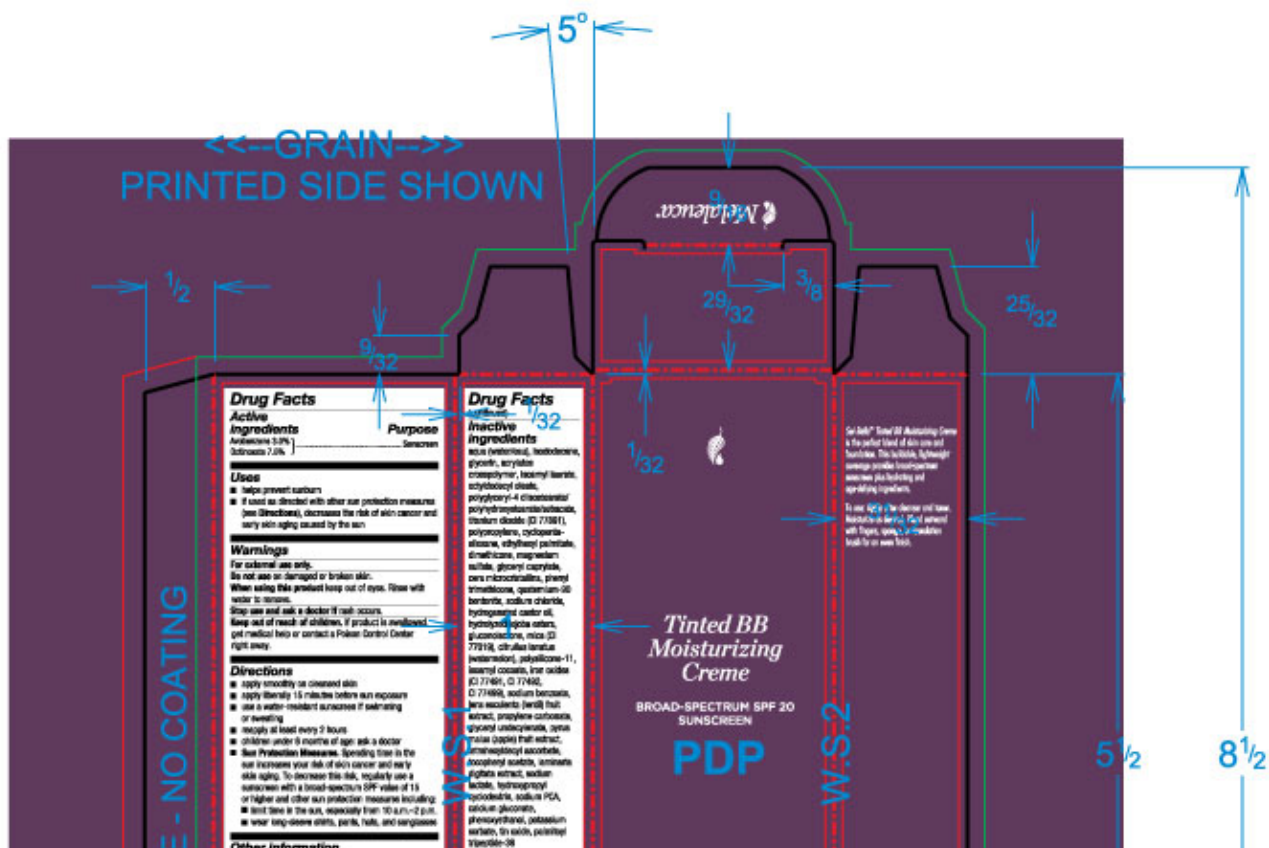
Other Information

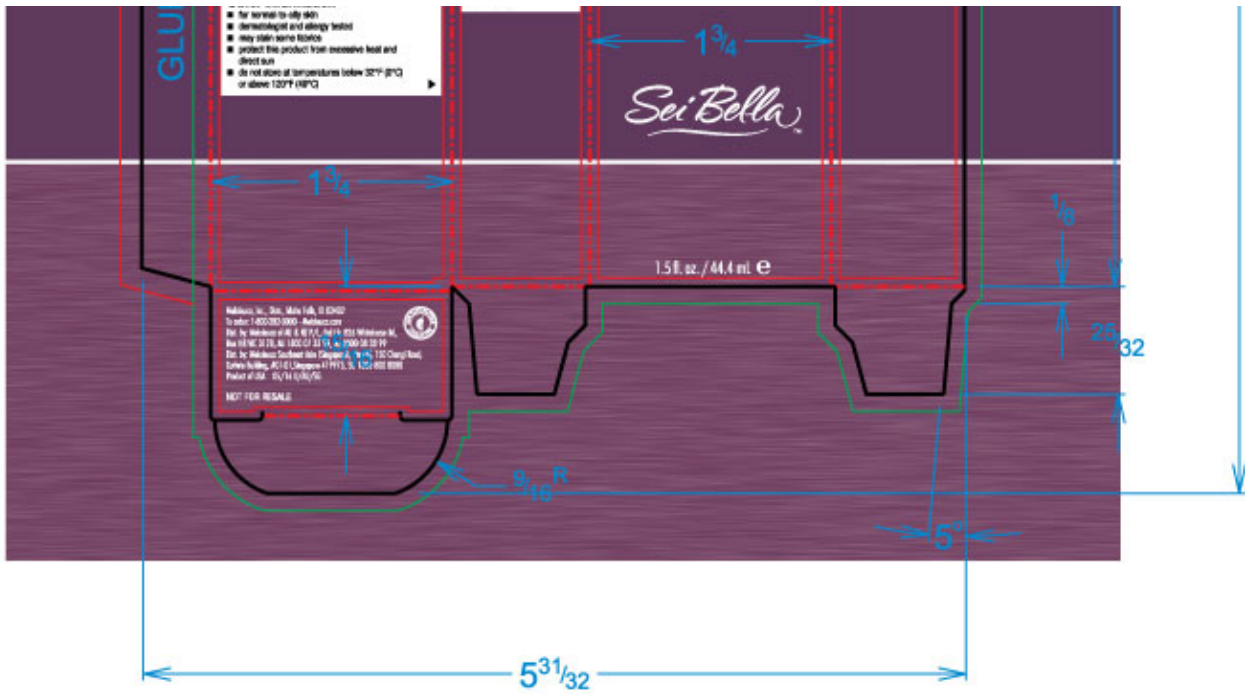
dermatologist and allergy tested

Inactive ingredients

aqua (water/eau), isododecane, glycerin, acrylates crosspolymer, isoamyl laurate, octyldodecyl oleate, polyglyceryl-4 diisostearate/polyhydroxystearate/sebacate, titanium dioxide (CI 77891), polypropylene, cyclopentasiloxane, ethylhexyl palmitate, dimethicone, magnesium sulfate, glyceryl caprylate, microcrystalline wax, phenyl trimethicone, quaternium-90 bentonite, sodium chloride, hydrogenated castor oil, hydrolyzed jojoba esters, gluconolactone, mica (CI 77019), citrullur lanatus (watermelon), polysilicone-11, isoamyl cocoate, iron oxides (CI 77491, CI 77492, CI 77499), sodium benzoate, lens esculenta (lentil) fruit extract, propylene carbonate, glyceryl undecylenate, pyrus malus (apple) fruit extract, tetrahexyldecyl ascorbate, tocopheryl acetate, laminaria digitata extract, sodium lactate, hydroxypropyl cyclodextrin, sodium PCA, calcium gluconate, phenoxyethanol, potassium sorbate, tin oxide, palmitoyl tripeptide-38

Principal Display Panel





Melaleuca, Inc.
 04/March/2016
 TINTED BB MOISTURIZER
 0.018 SBS
 1+3/4 x 1 x 5+1/2
 J51398A

| Melaleuca Artwork Information | |
|------------------------------------|---|
| 1. File name and Revision Date: | Tinted_BB_Moisturizing_Creme_Box_0516.ai |
| 2. Part Number: | 7000000000 |
| 3. Color Process, PMS (up to 8): | For Colors and Finishes Match Lip Gloss Box |
| 4. Label size: | |
| 5. Format: | Illustrator CC 2015 |
| 6. Artwork contact Name & Phone #: | Robbie Reed 208-522-0700 |
| 7. Last Revision Date | 4/March/2016 |

| | | | | | |
|--|-------|--|------------------------|--|----------|
| | White | | Metallic Pantone 8800C | | DIE LINE |
| | Black | | 7449 C (inside of Box) | | |

SEI BELLA TINTED BB MOISTURIZING CREME BROADSPECTRUM SPF 20 BEIGE 300 N

avobenzone and octinoxate lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54473-265 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 1.389 g in 44.4 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 3.473 g in 44.4 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LENTIL (UNII: 6O38V6B52O) | |
| PROPYLENE CARBONATE (UNII: 8D08K3S51E) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SODIUM LACTATE (UNII: TU7HW0W0QT) | |
| WATER (UNII: 059QF0K00R) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| 1,1'-((1-METHYL-1,2-ETHANEDIYL)2-PROPENOIC ACID, BIS(OXY(1-METHYL-2,1-ETHANEDIYL))) ESTER (UNII: 2O70KL79K2) | |
| ISOAMYL LAURATE (UNII: M1SLX00M3M) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| MAGNESIUM SULFATE (UNII: DE08037SAB) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| STANNIC OXIDE (UNII: KM7N50LOS6) | |
| CITRULLUS LANATUS VAR. LANATUS WHOLE (UNII: 3J5I6254YO) | |
| GLYCERYL MONOUNDECYLENATE (UNII: IK8A76Q5G8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| OCTYLDODECYL OLEATE (UNII: MCA43PK7MH) | |
| ISOLAN (UNII: K7716TIH63) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| ISOAMYL COCOATE (UNII: 14OG46E98E) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| GLUCONOLACTONE (UNII: WQ29KQ9POT) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| MICA (UNII: V8A1AW0880) | |
| APPLE FRUIT OIL (UNII: 9NT987I3A8) | |
| LAMINARIA DIGITATA (UNII: 15E7C67EE8) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W) | |
| CALCIUM GLUCONATE (UNII: SQE6VB453K) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

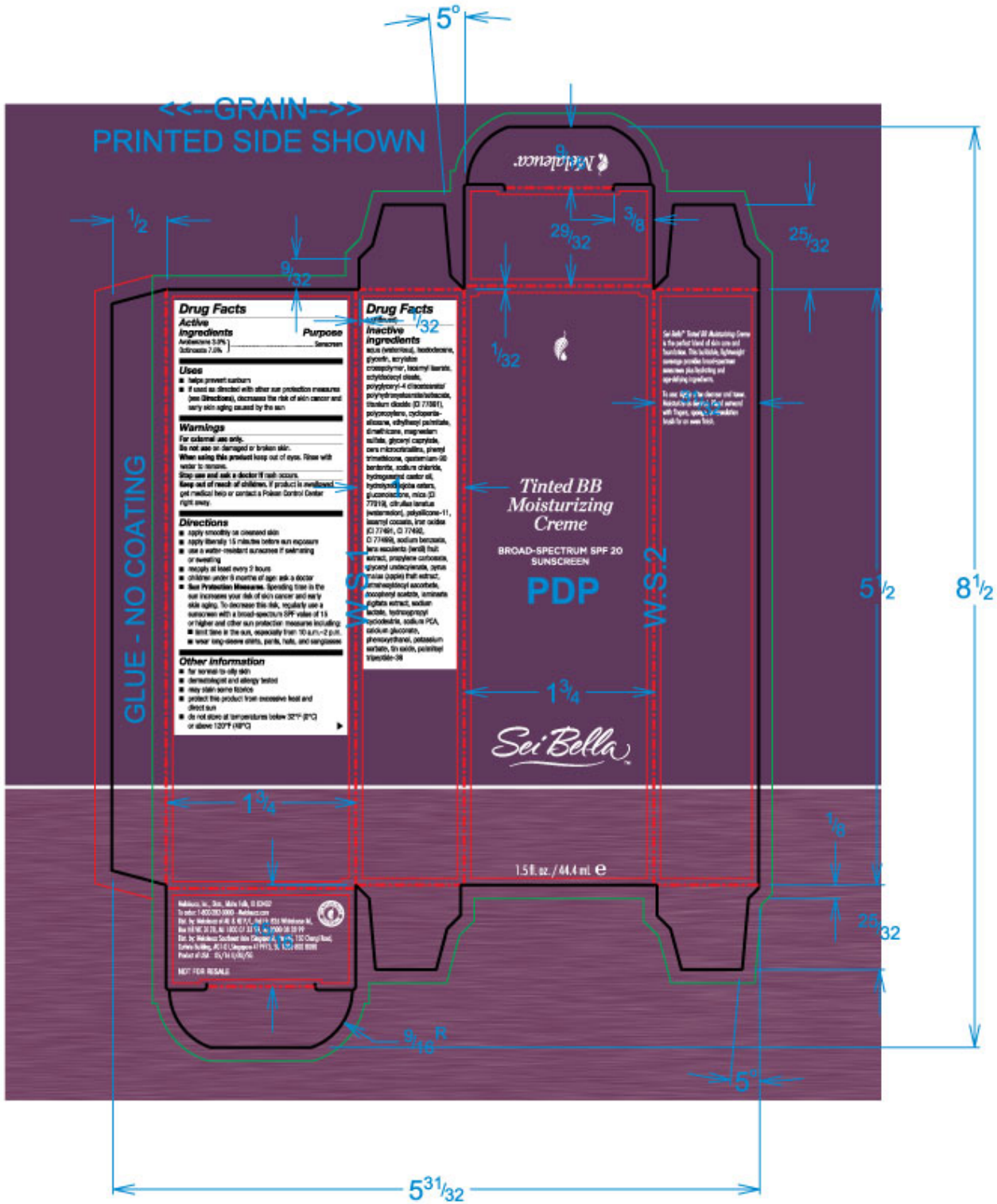
Product Characteristics

| | | | |
|----------|--|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54473-265-01 | 1 in 1 BOX | 09/01/2016 | |

| | | | |
|---|--|--|--|
| 1 | 44.4 mL in 1 TUBE; Type 0: Not a Combination Product | | |
|---|--|--|--|



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04/March/2016

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0.018 SBS

1+3/4 x 1 x 5+1/2

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|  White |  Metallic Pantone 8800C |  DIE LINE |
|  Black |  7649 C (inside of Box) | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 09/01/2016 | |

Labeler - Melaleuca Inc (139760102)

Registrant - Melaleuca Inc (079287544)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| Northwest Cosmetic Labs | | 929572014 | manufacture(54473-265) |

Revised: 5/2016

Melaleuca Inc