

SEI BELLA TINTED BB MOISTURIZING CREME BROADSPECTRUM SPF 20 TAN 500 W-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)

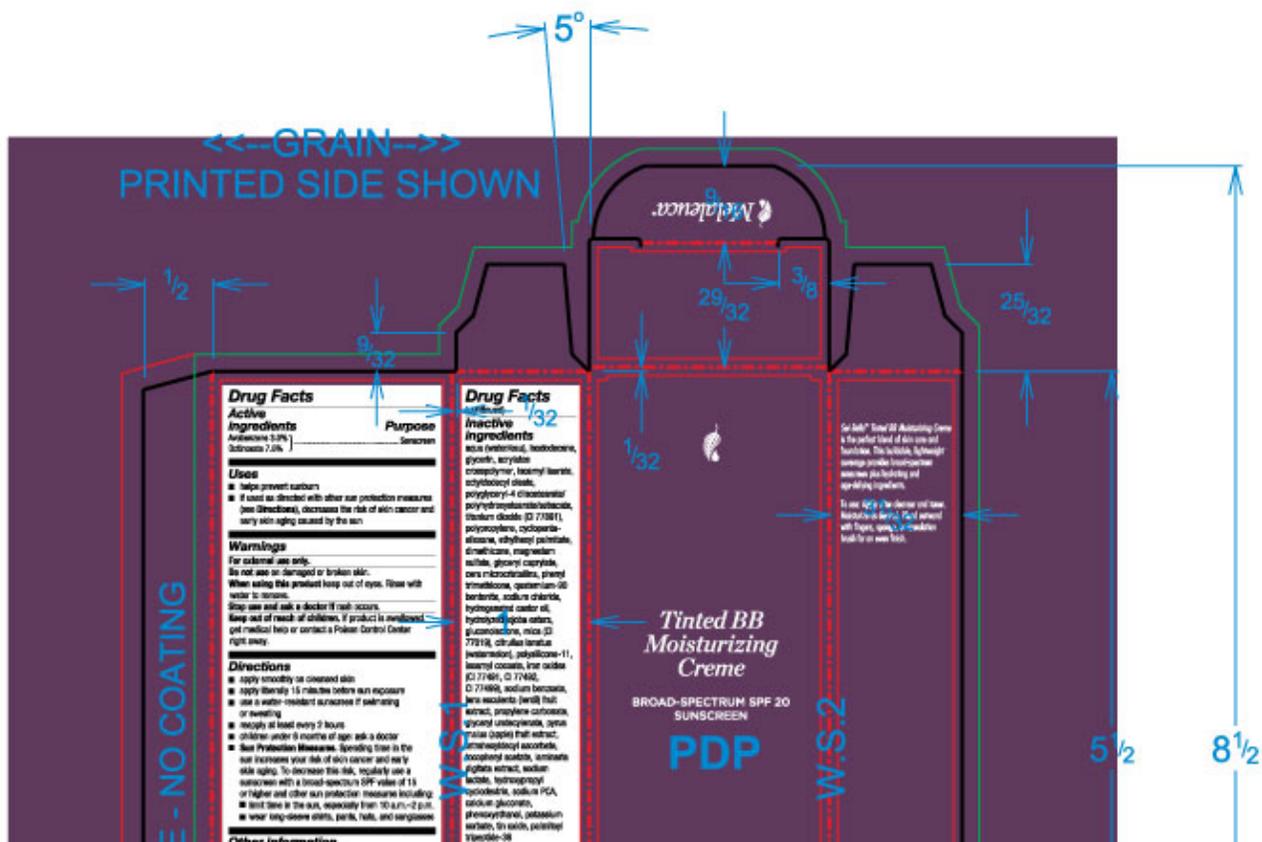
Other Information

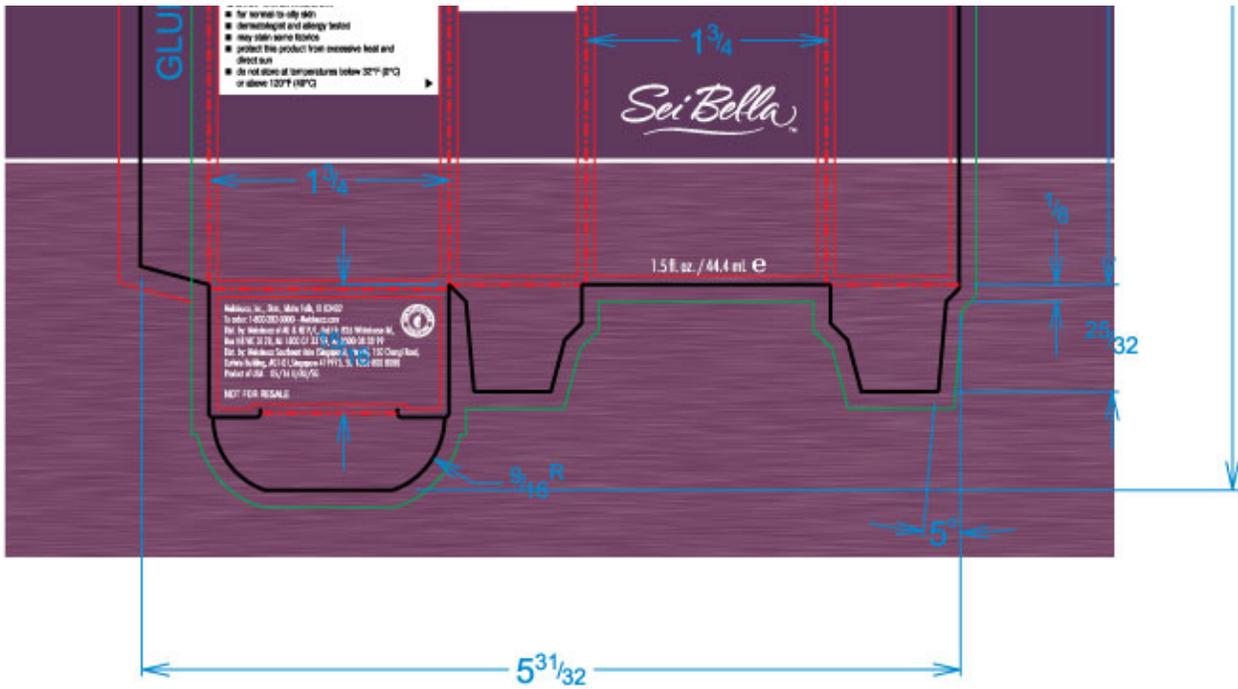
dermatologist and allergy tested

Inactive ingredients

aqua (water/eau), isododecane, glycerin, acrylates crosspolymer, isoamyl laurate, octyldodecyl oleate, polyglyceryl-4 diisostearate/polyhydroxustearate/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 TAN 500 W

avobenzone and octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-269
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)	
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)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
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:54473-269-01	1 in 1 BOX	09/01/2016	

1	44.4 mL in 1 TUBE; Type 0: Not a Combination Product		
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1+3/4 x 1 x 5+1/2

J51398A

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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(54473-269)

Revised: 5/2016

Melaleuca Inc