SEI BELLA CC BRIGHTENING CREME MEDIUM TAN- octinoxate 7.5%, titanium dioxide 5%, zinc oxide 1% 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 CC Brightening Creme - Medium Tan

Active Ingredient

Octinoxate 7.5%

Titanium Dioxide 5%

Zinc Oxide 1%

Purpose

Sunscreen

Use

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), descreases 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. 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 you 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

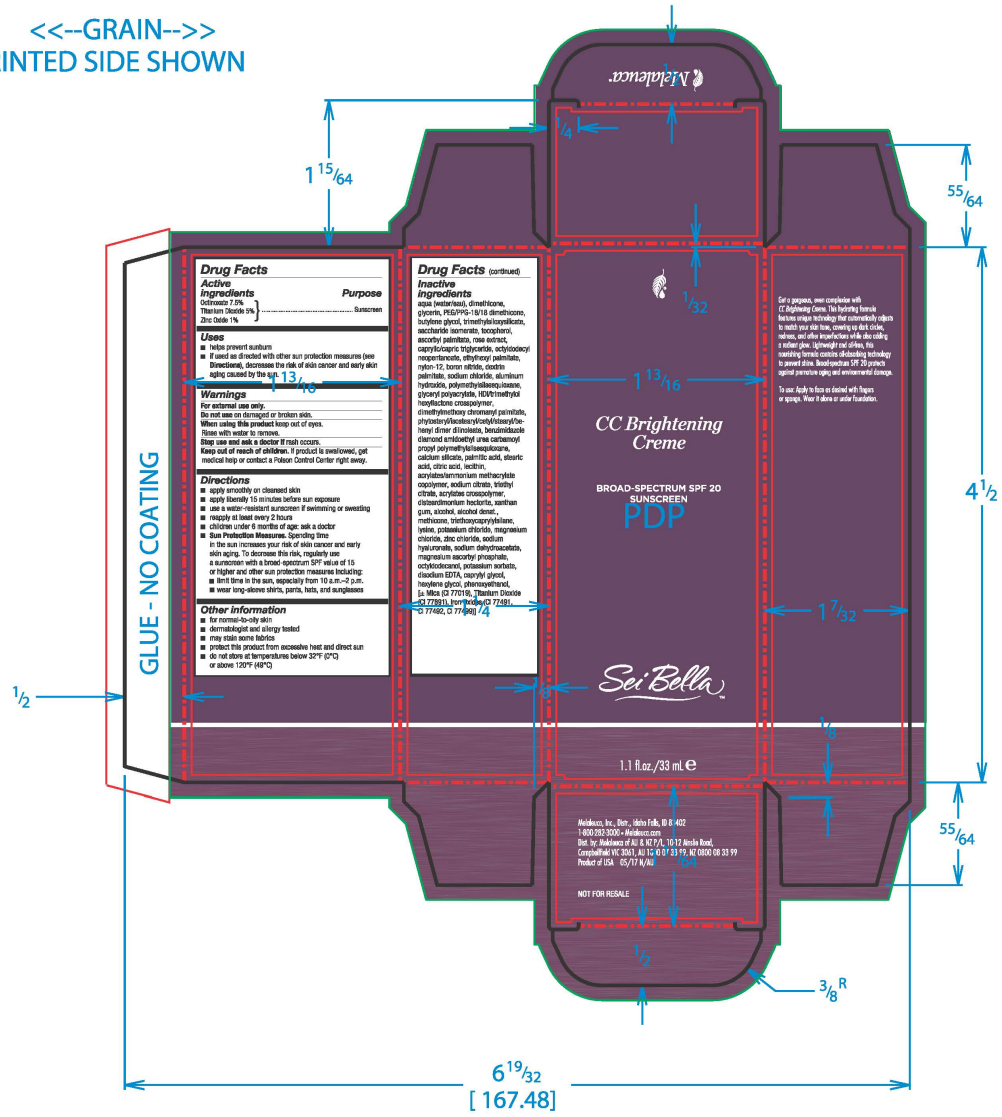
■ dermatologist and allergy tested

■ protect this product from excesssive heat and direct sun

Inactive ingredients

Aqua/Water/Eau, Dimethicone, Glycerin, PEG/PPG-18/18 Dimethicone, Butylene Glycol, Trimethylsiloxysilicate, Saccharide Isomerate, Tocopherol, Ascorbyl Palmitate, Rose Extract, Caprylic/Capric Triglyceride, Octyldodecyl Neopentanoate , Ethylhexyl Palmitate, Nylon-12, Boron Nitride, Dextrin Palmitate, Sodium Chloride, Aluminum Hydroxide, Polymethylsilsesquioxane, Glyceryl Polyacrylate, HDI/Trimethylol Hexyllactone Crosspolymer, Dimethylmethoxy Chromanyl Palmitate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Benzimidazole Diamond Amidoethyl Urea Carbamoyl Propyl Polymethylsilsesquioxane, Calcium Silicate, Palmitic Acid, Stearic Acid, Citric Acid , Lecithin, Acrylates/Ammonium Methacrylate Copolymer, Sodium Citrate, Triethyl Citrate , Acrylates Crosspolymer, Disteardimonium Hectorite, Xanthan Gum, Alcohol, Alcohol Denat., Methicone, Triethoxycaprylylsilane, Lysine, Potassium Chloride, Magnesium Chloride, Zinc Chloride, Sodium Hyaluronate, Sodium Dehydroacetate, Magnesium Ascorbyl Phosphate, Octyldodecanol, Potassium Sorbate, Disodium EDTA, Caprylyl Glycol, Hexylene Glycol, Phenoxyethanol

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



Melaleuca, Inc.

9/27/2016

CC CREAM

.018 SBS

1+13/16 x 1+1/4 x 4+1/2

J61258A

Melaleuca The Wellness Company® Artwork Information	
1. File name and Revision Date:	Brightening-CC-Cream-0517.ai
2. Part Number:	J61258A
3. Color: Process, PMS (up to 8):	For Colors and Finishes Match Lip GLoss Box
4. Label size:	1+13/16 X 1+1/4 X 4+1/2
5. Format:	Illustrator CC 2017
6. Artwork contact. Name & Phone #:	Robbie Reed 208-522-2547
7. Last Revision Date	14 Feb 2017

White	Metallic Pantone 8800C	DIE LINE
Black	7449 C (Inside of Box)	

SEI BELLA CC BRIGHTENING CREME MEDIUM TAN

octinoxate 7.5%, titanium dioxide 5%, zinc oxide 1% lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54473-282
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.65 g in 33 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.475 g in 33 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.3267 g in 33 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
NYLON-12 (UNII: 446U8J075B)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHYLMETHOXY CHROMANYL PALMITATE (UNII: 5G222ZDK7U)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AMMONIUM METHACRYLATE (UNII: J2243103QO)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PHYTOSTERYL/ISOSTEARYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE (UNII: 8N725H4EFN)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ALCOHOL (UNII: 3K9958V90M)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BENZIMIDAZOLE (UNII: E24GX49LD8)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-282-01	1 in 1 BOX	01/01/2018	
1	NDC:54473-282-30	33 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 monograph not final	part352	05/01/2017	

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Mana		078870292	manufacture(54473-282)

Revised: 1/2023 Melaleuca Inc.