

**SEI BELLA SKIN REFINING TINTED MOISTURIZER FAWN- titanium dioxide 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 Skin-Refining Tinted Moisturizer - Broad spectrum SPF 20 - Fawn**

**Active Ingredients**

Titanium Dioxide 6.5%

**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**

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

**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**

for normal-to-oily skin

dermatologist 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 120°F (49°C)

### **Inactive Ingredients**

1,2-hexandiol, aloe barbadensis leaf juice, alumina, aminomethyl propanol, aqua (water/eau), beta-glucan, butylene glycol, butyrospermum parkii (shea butter), caprylic/capric triglyceride, caprylyl glycol, carnosine, cetearyl alcohol, ceteth-10 phosphate, cetyl palmitate, cucumis sativus (cucumber) fruit extract, cyclopentasiloxane, dicetyl phosphate, disodium EDTA, ethylhexylglycerin, glycerin, glycine soja (soybean) oil, hydrogenated cottonseed oil, hydrogenated palm glycerides, iron oxides (CI77491, CI77492, CI77499), isostearic acid, lecithin, octyldodecyl neopentanoate, PEG/PPG-20/15 dimethicone, pentylene glycol, phenyl methicone, polyethylene, polyglyceryl-3, polyricinoleate, polyhydroxystearic acid, polymethylsilsesquioxane, polysorbate 60, polysorbate 80, potassium cetyl phosphate, propylheptyl caprylate, simethicone, stearic acid, tetrahexyldecyl ascorbate, tetrapeptide-21, titanium dioxide (CI77891), tocopheryl acetate, tremella fuciformis sporocarp extract, vitis vinifera (grape) leaf extract, xanthan gum



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-249
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.866 g in 44.4 mL

### Inactive Ingredients

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM OXIDE (UNII: LM26O6933)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARNOSINE (UNII: 8HO6PVN24W)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CUCUMBER (UNII: YY7C30VXJT)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
glycerin (UNII: PDC6A3C00X)	
SOYBEAN OIL (UNII: 241ATL177A)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
ISO STEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG/PPG-20/15 DIMETHICONE (UNII: 06R6X77P9C)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TETRAPEPTIDE-21 (UNII: 179JUC43HU)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
VITIS VINIFERA LEAF (UNII: R1H893D80E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-249-01	1 in 1 BOX		
1		44.4 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2013	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca Inc.		079287544	manufacture(54473-249)

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Melaleuca Inc.