

SPF 15 DEEP- titanium dioxide powder
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.

Label of Mineral Foundation Deep

Directions

Apply evenly before sun exposure as needed. Gently swirl your Sei Bella Brush across the top and tap to remove excess.

Make sure powder is evenly distributed on brush before applying to face. Blend foundation to the desired level of coverage.

Other Information

- dermatologist and allergy tested

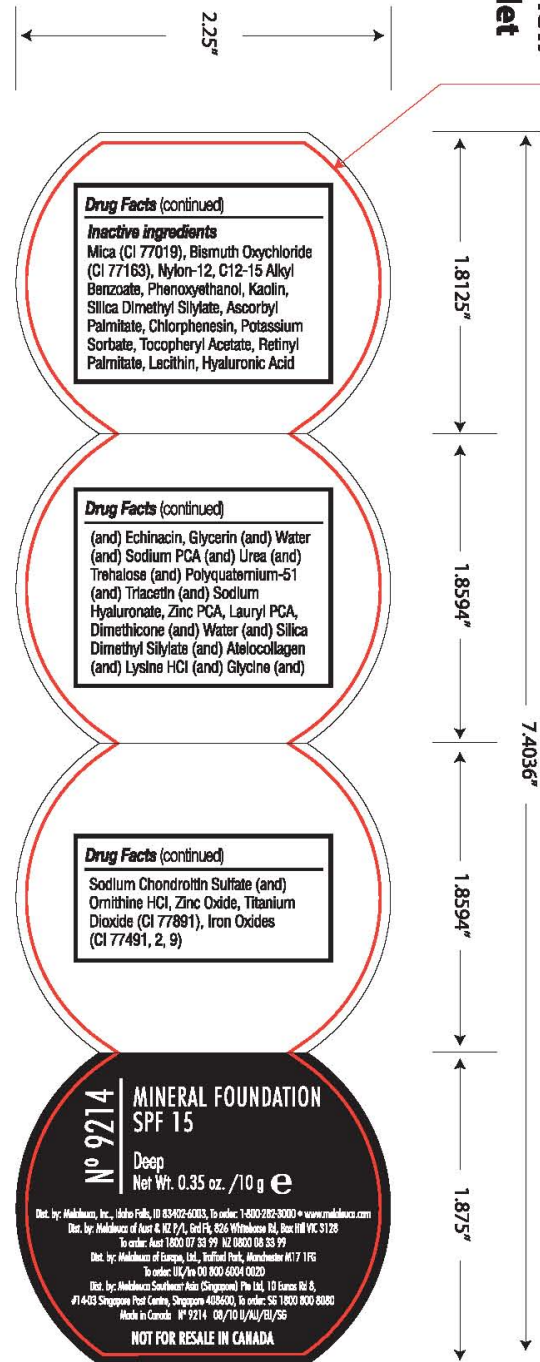
Other Information

- do not store at temperatures below 32°F (0° or above 120°F (49°C)

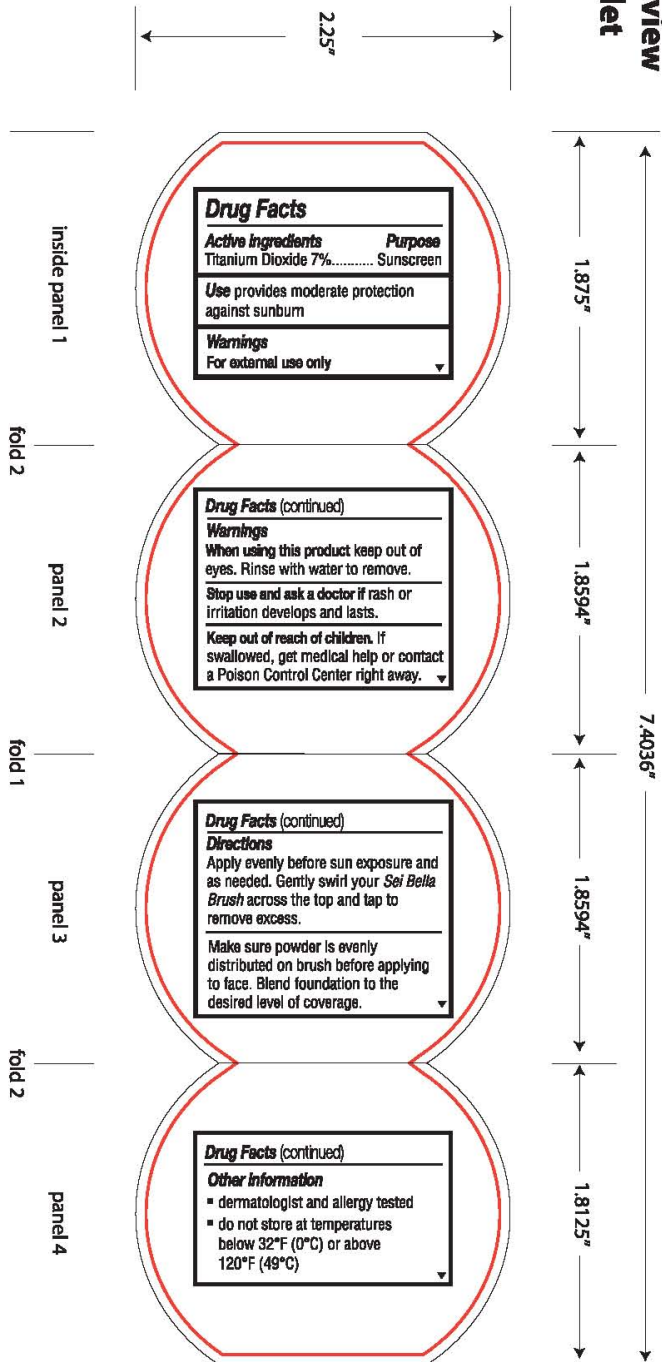
Ingredients

Mica (CI 77019), Bismuth Oxichloride (CI 77163), Nylon-12, C12-15 Alkyl Benzoate, Phenoxyethanol, Kaolin, Silica Dimethyl Silylate, Ascorbyl Palmitate, Chlorophensin, Potassium Sorbate, Retinyl Palmitate, Lecithin, Hyaluronic Acid (and) Echinacin, Glycerin (and) Water (and) Urea (and) Trehalose (and) Polyquaternium-51 (and) Triacetin (and) Sodium Hyaluronate, Zinc PCA, Lauryl PCA, Dimethicone (and) Water (and) Silica Dimethyl Silylate (and) Atelocollagen (and) Lysine HCl (and) Glycine (and) Sodium Chondroitin Sulfate (and) Ornithine HCl, Zinc Oxide, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, 2, 9)

front view
of leaflet



inside view
of leaflet



Melaleuca Artwork Information

1. File name and Revision Date:	Mineral Pwdr Lbl_Deep o8_10.ai
2. Part Number:	00000 0000
3. Color: Process, PMS (up to 8):	black ink
4. Label size:	see dieline
5. Format:	Illustrator CS3
6. Artwork contact. Name & Phone #:	Amber Bare 208-534-2196

black

Active Ingredients Purpose
Titanium Dioxide 7%.....Sunscreen

SPF 15 DEEP

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-179
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.7 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
KAOLIN (UNII: 24H4NWX5CO)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
HYALURONIC ACID (UNII: S270N0TRQY)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
UREA (UNII: 8W8T17847W)	
TREHALOSE (UNII: B8WCK70T7I)	
TRIACETIN (UNII: XHX3C3X673)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
GLYCINE (UNII: TE7660XO1C)	
CHONDROITIN SULFATE (PORCINE) (UNII: V5E8ELO4W9)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ORNITHINE HYDROCHLORIDE (UNII: HBK84K66XH)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-179-01	10 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/15/2010	

Labeler - Melaleuca, Inc. (139760102)

Revised: 12/2010

Melaleuca, Inc.