

SKIN FOUNDATION MINERAL MAKEUP SPF 15- titanium dioxide, octinoxate powder
Bobbi Brown Professional Cosmetics 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.

ACTIVE INGREDIENTS: TITANIUM DIOXIDE 7.80% [] OCTINOXATE 3.60%

INACTIVE INGREDIENTS: VINYL DIMETHICONE/METHICONE SILSESQUIOXANE
CROSSPOLYMER [] HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER []
POLYSILICONE-11 [] SILICA [] POLYMETHYLSILSESQUIOXANE [] PHENYL TRIMETHICONE
[] GLYCINE SOJA (SOYBEAN) SEED EXTRACT [] PANTHENOL [] CERAMIDE 2 [] CERAMIDE
3 [] GLYCERIN [] ERGOTHIONEINE [] SODIUM HYALURONATE [] C9-15 FLUOROALCOHOL
PHOSPHATE [] TRIMETHYLSILOXYSILICATE [] TOCOPHERYL ACETATE [] ASCORBYL
PALMITATE [] CAPRYLYL GLYCOL [] ASCORBYL TOCOPHERYL MALEATE [] MAGNESIUM
STEARATE [] NYLON-12 [] LAURETH-12 [] ALUMINA [] AMINOPROPYL ASCORBYL
PHOSPHATE [] ALUMINUM HYDROXIDE [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) []
ZINC OXIDE (CI 77947) [] IRON OXIDES (CI 77491, CI 77492, CI 77499)

WARNING: KEEP OUT OF EYES. DISCONTINUE USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

BOBBI BROWN
SKIN FOUNDATION
MINERAL MAKEUP
SPF 15

0.2 OZ / 6 g

DISTR BOBBI BROWN PROFESSIONAL COSMETICS
NEW YORK, NY 10022

<p>Skin Foundation Mineral Makeup SPF 15 Weightless loose powder foundation lets skin's natural luminosity show through as it delivers a perfectly polished look. An exclusive vitamin and mineral blend helps condition and protect skin against future damage. To Use: For light to medium coverage, sweep on with Face Brush. For fuller coverage, apply with Powder Puff. WARNING: Keep out of eyes. Stop use if irritation occurs. Keep out of reach of children.</p> <p>Fond de Teint Minéral SPF 15 Un fond de teint poudre léger qui redonne à la peau son éclat naturel tout en uniformisant le teint. Une vitamine exclusive et un mélange de minéraux aident à protéger la peau contre les méfaits du temps. Utilisation: Pour une couvrance légère à moyenne, appliquer avec le Pinceau visage. Pour une couvrance soutenue, appliquer à l'aide de l'éponge. ATTENTION: Éviter tout contact avec les yeux. Suspendre l'utilisation en cas d'irritation. Teint hors de portée des enfants.</p> <p>ACTIVE INGREDIENTS: Titanium Dioxide 7.80% • Octinoxate 3.60% INGREDIENTS: Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer • HDI/Trimethylol Hexyllactone Crosspolymer • Polysilicone-11 • Silica • Polymethylsilsesquioxane • Phenyl Trimethicone • Glycine Soja (Soybean) Seed Extract • Panthenol • Ceramide 2 • Ceramide 3 • Glycerin • Ergothioneine • Sodium Hyaluronate • C9-15 Fluoroalcohol Phosphate • Trimethylsiloxysilicate • Tocopheryl Acetate • Ascorbyl Palmitate • Caprylyl Glycol • Ascorbyl Tocopheryl Maleate • Magnesium Stearate • Nylon-12 • Laureth-12 • Alumina • Aminopropyl Ascorbyl Phosphate • Aluminum Hydroxide • [+/- Mica • Titanium Dioxide (CI 77891) • Zinc Oxide (CI 77947) • Iron Oxides (CI 77491, CI 77492, CI 77499)] (L1431916)</p> <p><small>Dist. Bobbi Brown Professional Cosmetics N.Y., N.Y. 10022 • London W1K 3BQ • Paris Made in U.S.A. [E736] WWW.BOBBI.BROWN.COM</small></p>	<p style="text-align: center;">BOBBI BROWN</p> <p style="text-align: center;">Skin Foundation Mineral Makeup SPF 15 Fond de Teint Minéral SPF 15</p> <p style="text-align: center;">NET WT./POIDS NET. 2 OZ./6 g e</p>	
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SKIN FOUNDATION MINERAL MAKEUP SPF 15

titanium dioxide, octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64141-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.8 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSILICONE-15 (UNII: F8DRP5BB29)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SOYBEAN (UNII: L7HT8FIZOD)	
PANTHENOL (UNII: WV9CM0O67Z)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CERAMIDE 3 (UNII: 4370DF050B)	
GLYCERIN (UNII: PDC6A3C0OX)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TRIMETHYLSILANE (UNII: 9L70DJH2K0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LAURETH-12 (UNII: OAH19558U1)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
MICA (UNII: V8A1AW0880)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64141-111-01	1 in 1 CARTON		
1	NDC:64141-111-02	6 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2011	

Labeler - Bobbi Brown Professional Cosmetics Inc. (627131279)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture

Revised: 9/2011

Bobbi Brown Professional Cosmetics Inc.