

LONG-WEAR EVEN FINISH FOUNDATION BROAD SPECTRUM SPF 15- octinoxate and titanium dioxide liquid

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.

**Long-Wear
Even Finish Foundation
Broad Spectrum SPF 15**

Drug Facts

Active Ingredients

Octinoxate 2.90%

Titanium Dioxide 1.60%

Purpose

Sunscreen

Use

Helps prevent sunburn

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- **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 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Inactive ingredients

water • dimethicone • cetyl peg/ppg-10/1 dimethicone • butylene glycol • glycerin • trimethylsiloxysilicate • sodium chloride • polyglyceryl-3 diisostearate • disteardimonium hectorite • butyrospermum parkii (shea butter) • lavandula angustifolia (lavender) • glyceryl oleate • lecithin • methicone • dimethicone crosspolymer • tocopheryl acetate • tocopherol • ascorbyl palmitate • glyceryl stearate • alumina • stearic acid • citric acid • talc • disodium edta • linalool • sodium dehydroacetate • phenoxyethanol • [+/- titanium dioxide (ci 77891) • mica • iron oxides (ci 77491, ci 77492, ci 77499)]<iln38637>

Other information

Protect this product in this container from excessive heat and direct sun.

Dist. Bobbie Brown Professional Cosmetics
N.Y., N.Y. 10022 • London W1K 3BQ • Paris

PRINCIPAL DISPLAY PANEL - 30 ml Carton

**BOBBI
BROWN**

**Long-Wear
Even Finish Foundation**
Broad Spectrum SPF 15

1 FL. OZ./30 ml e

B O B B I
B R O W N

**Long-Wear
Even Finish Foundation**
Broad Spectrum SPF 15

1 FL. OZ./30 ml e

**Long-Wear
Even Finish Foundation**

Broad Spectrum SPF 15

Bobbi's unique long-lasting foundation offers oil-free coverage that looks like skin. Ultra comfortable, lightweight formula instantly hydrates skin and stays fresh for up to 12 hours. For normal to oily skin.

To Use: Apply with a Foundation Brush, fingers or sponge.

Dist. Bobbi Brown Professional Cosmetics
 N.Y., N.Y. 10022 • London W1K 3BQ • Paris
 Made in Belgium [E82N]
 WWW.BOBBIROWN.COM

COATING
 FREE AREA

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Drug Facts

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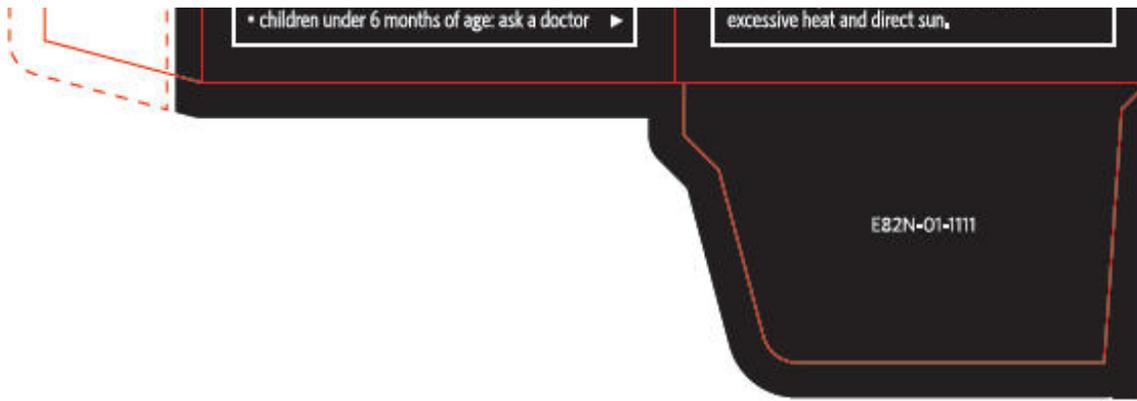
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 - limit time in the sun, especially from 10 a.m.–2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Drug Facts (continued)

Inactive ingredients
 water/aqua/eau • dimethicone • cetyl peg/ ppg-10/1 dimethicone • butylene glycol • glycerin • trimethylsiloxy silicate • sodium chloride • polyglyceryl-3 diisostearate • disteardimonium hectorite • butyrospermum parkii (shea butter) • lavandula angustifolia (lavender) • glyceryl oleate • lecithin • methicone • dimethicone crosspolymer • tocopheryl acetate • tocopherol • ascorbyl palmitate • glyceryl stearate • alumina • stearic acid • citric acid • talc • disodium edta • linoleol • sodium dehydroacetate • phenoxyethanol • [+/- titanium dioxide (ci 77891) • mica • iron oxides (ci 77491, ci 77492, ci 77499)] <ln38637>

Other information
 Protect this product in this container from



LONG-WEAR EVEN FINISH FOUNDATION BROAD SPECTRUM SPF 15

octinoxate and titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64141-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.9 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
glycerin (UNII: PDC6A3C0OX)	
sodium chloride (UNII: 451W47IQ8X)	
shea butter (UNII: K49155WL9Y)	
lavandula angustifolia flower (UNII: 19AHIRAF4M)	
glyceryl monooleate (UNII: 4PC054V79P)	
alpha-tocopherol acetate (UNII: 9E8X80D2L0)	
tocopherol (UNII: R0ZB2556P8)	
ascorbyl palmitate (UNII: QN83US2B0N)	
glyceryl monostearate (UNII: 230OU9XXE4)	
aluminum oxide (UNII: LMI26O6933)	
stearic acid (UNII: 4ELV7Z65AP)	
citric acid monohydrate (UNII: 2968PHW8QP)	
talc (UNII: 7SEV7J4RIU)	
edetate disodium (UNII: 7FLD91C86K)	
linalool, (+/-) (UNII: D81QY6I88E)	
sodium dehydroacetate (UNII: 8W46YN971G)	
phenoxyethanol (UNII: HIE492ZZ3T)	

mica (UNII: V8A1AW0880)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64141-011-01	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/01/2011	

Labeler - Bobbi Brown Professional Cosmetics Inc. (627131279)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL(64141-011) , REPACK(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(64141-011) , RELABEL(64141-011) , REPACK(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
ARAMIS, INC		042918826	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(64141-011) , RELABEL(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations

ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(64141-011)
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Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370 151326	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE(64141-011) , RELABEL(64141-011) , REPACK(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		949264774	MANUFACTURE(64141-011) , RELABEL(64141-011) , REPACK(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE(64141-011) , RELABEL(64141-011) , REPACK(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(64141-011)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(64141-011)