

BOBBI BROWN TINTED MOISTURIZER BROAD SPECTRUM SPF 15- octinoxate and titanium dioxide lotion

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.

BOBBI BROWN TINTED MOISTURIZER BROAD SPECTRUM SPF 15

Drug Facts

Active Ingredients

Octinoxate 7.50%

Titanium Dioxide 3.00%

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/aqua/eau • phenyl trimethicone • butylene glycol • pentaerythrityl tetraoctanoate • simmondsia chinensis (jojoba) seed oil • petrolatum • biosaccharide gum - 1 • steareth-21 • glyceryl stearate •

sodium hyaluronate • tocopheryl acetate • polymethyl methacrylate • magnesium aluminum silicate • ethylhexylglycerin • caprylyl glycol • cetyl alcohol • acrylamide/sodium acryloyldimethyltaurate copolymer • peg-12 dimethicone • isohexadecane • lecithin • xanthan gum • steareth-2 • potassium stearate • citric acid • fragrance (parfum) • limonene • linalool • benzyl salicylate • polysorbate 80 • disodium edta • phenoxyethanol • sorbic acid • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499)] <iln33789>

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Tube Carton

SPF 15

Tinted

Moisturizer

Broad

Spectrum

SPF 15

BOBBI BROWN

1.7 FL. OZ./50 ml e

SPF 15
Tinted
Moisturizer
Broad
Spectrum
SPF 15

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.50% Titanium Dioxide 3.00%	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/aqua/eau • phenyl trimethicone • butylene glycol • pentaerythrityl tetraoctanoate • simmondsia chinensis (jojoba) seed oil • petrolatum • biosaccharide gum -1 • steareth-21 • glyceryl stearate • sodium hyaluronate • tocopheryl acetate • polymethyl methacrylate • magnesium aluminum silicate • ethylhexylglycerin • caprylyl glycol • cetyl alcohol • acrylamide/sodium acryloyldimethyltaurate copolymer • peg-42 dimethicone • isohexadecane • lecithin • xanthan gum • steareth-2 • potassium stearate • citric acid • fragrance (parfum) • limonene • linalool • benzyl salicylate • polysorbate 80 • disodium edta • phenoxyethanol • sorbic acid • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499)] <ln33789>

Other information

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

Dist. Bobbi Brown Professional Cosmetics
New York, NY 10022 • London W1K 3BQ • Paris
Made in Belgium [E75K]
WWW.BOBBI-BROWN.COM



C154658

BOBBI BROWN

1.7 FL. OZ./50 ml e

BOBBI BROWN TINTED MOISTURIZER BROAD SPECTRUM SPF 15

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64141-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.07725 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0309 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
JOJOBA OIL (UNII: 724GKU717M)	
PETROLATUM (UNII: 4T6H12BN9U)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
ISOHEXADECANE (UNII: 918X10UF1E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARETH-2 (UNII: V56DFE46J5)	
POTASSIUM STEARATE (UNII: 17V812XK50)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBIC ACID (UNII: X045WJ989B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64141-027-01	1 in 1 CARTON	01/01/2001	
1		50 mL in 1 TUBE; 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	01/01/2001	

Labeler - Bobbi Brown Professional Cosmetics Inc. (627131279)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(64141-027) , REPACK(64141-027)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(64141-027)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(64141-027)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(64141-027)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(64141-027)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(64141-027) , REPACK(64141-027)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(64141-027) , REPACK(64141-027)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(64141-027)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(64141-027)

Revised: 12/2018

Bobbi Brown Professional Cosmetics Inc.