

BOBBI BROWN EXTRA TINTED MOISTURIZING BALM SPF 25- octinoxate, homosalate, oxybenzone, avobenzone cream

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.

DRUG FACTS

ACTIVE INGREDIENTS:

AVOBENZONE 2.00%

HOMOSALATE 5.00%

OCTINOXATE 7.50%

OXYBENZONE 5.00%

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:

- o limit time in the sun, especially from 10 a.m.–2 p.m.
- o wear long-sleeved shirts, pants, hats and sunglasses
- * children under 6 months of age: ask a doctor

INACTIVE INGREDIENTS

INGREDIENTS: WATER/AQUA/EAU [] GLYCERIN [] PEG-4 DIHEPTANOATE [] BIS-DIGLYCERYL POLYACYLADIPATE-2 [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] CETEARYL ALCOHOL [] CETYL ALCOHOL [] GLYCERYL STEARATE [] HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER [] EPILOBIUM ANGUSTIFOLIUM EXTRACT [] SODIUM HYALURONATE [] TOCOPHERYL ACETATE [] SQUALANE [] ETHYLHEXYLGLYCERIN [] OENOTHERA BIENNIS (EVENING PRIMROSE) OIL [] ROSMARINUS OFFICINALIS (ROSEMARY) [] ANTHEMIS NOBILIS (CHAMOMILE) [] PELARGONIUM GRAVEOLENS (GERANIUM) FLOWER OIL [] ANGELICA ARCHANGELICA SEED OIL [] CITRUS AURANTIUM AMARA (BITTER ORANGE) OIL [] PHENYL TRIMETHICONE [] DIMETHICONE [] LECITHIN [] BUTYLENE GLYCOL [] PEG-12 DIMETHICONE [] DICETYL PHOSPHATE [] CETETH-10 PHOSPHATE [] ASTROCARYUM MURUMURU SEED BUTTER [] SORBITAN STEARATE [] POLYSORBATE 60 [] PEG-40 STEARATE [] CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL [] ALUMINA [] PROPYLENE GLYCOL STEARATE [] POLYSORBATE 20 [] ACETYL HEXAPEPTIDE-8 [] SORBITAN LAURATE [] PROPYLENE GLYCOL LAURATE [] PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE [] XANTHAN GUM [] CITRIC ACID [] TETRASODIUM EDTA [] POTASSIUM SORBATE [] CHLORPHENESIN [] PHENOXYETHANOL [] LIMONENE [] CITRONELLOL [] GERANIOL [] LINALOOL [] CITRAL [] [+/- TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] MICA

OTHER INFORMATION

protect the product in this container from excessive heat and direct sun

BOBBI BROWN

EXTRA

SPF 25 TINTED MOISTURIZING BALM

BROAD SPECTRUM SPF 25

NET WT./POIDS NT 1 OZ/ 30 ML

DIST. BOBBI BROWN PROFESSIONAL COSMETICS

NY, NY 10022

Drug Facts	
Active Ingredients	Purpose
Avobenzone 2.00%	Sunscreen
Homosalate 5.00%	
Octinoxate 7.50%	
Oxybenzone 5.00%	
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. Rise 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.	

Drug Facts (continued)
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 ▶

Drug Facts (continued)
Inactive ingredients
water/aqua/eau • glycerin • peg-4 diheptanoate • bis-diglyceryl polyacyladipate-2 • butyrospermum parkii (shea butter) • cetearyl alcohol • cetyl alcohol • glyceryl stearate • hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer • epilobium angustifolium extract • sodium hyaluronate • tocopheryl acetate • squalane • ethylhexylglycerin • oenothera biennis (evening primrose) oil • rosmarinus officinalis (rosemary) • anthemis nobilis (chamomile) • pelargonium graveolens (geranium) flower oil • angelica archangelica seed oil • citrus aurantium amara (bitter orange) oil • phenyl trimethicone • dimethicone • lecithin • butylene glycol • peg-12 dimethicone • dicetyl phosphate • ceteth-10 phosphate • astrocaryum murumuru seed butter • sorbitan stearate • polysorbate 60 • peg-40 stearate • citrus grandis (grapefruit) peel oil • alumina • propylene glycol stearate • polysorbate ▶

Drug Facts (continued)
20 • acetyl hexapeptide-8 • sorbitan laurate • propylene glycol laurate • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • xanthan gum • citric acid • tetrasodium edta • potassium sorbate • chlorphenesin • phenoxyethanol • limonene • citronellol • geraniol • linalool • citral • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499) • mica] <lin38335▶
Other information
Protect the product in this container from excessive heat and direct sun
Dist. Bobbi Brown Professional Cosmetics, N.Y., N.Y., 10022 • London W1K 3BQ • Paris Made In Canada [E2AC] 

BOBBI BROWN
EXTRA

SPF 25 Tinted Moisturizing Balm
Broad Spectrum SPF 25

NET WT./POIDS NET 1 OZ./30 ml e

BOBBI BROWN EXTRA TINTED MOISTURIZING BALM SPF 25

octinoxate, homosalate, oxybenzone, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64141-814
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-4 DIHEPTANOATE (UNII: 2DQ7O61VHJ)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SQUALANE (UNII: GW89575KF9)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
ROSEMARY (UNII: IJ67X351P9)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
ANGELICA SEED OIL (UNII: 67IO7RRV7A)	
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
ALUMINUM OXIDE (UNII: LM26O6933)	
PROPYLENE GLYCOL STEARATE (UNII: MZM1I680W0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
PROPYLENE GLYCOL MONOLAURATE (UNII: 668Z5835Z3)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
XANTHAN GUM (UNII: TTV12P4NEE)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
EDETATE SODIUM (UNII: MP1J8420LU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
CHLORPHENESIN (UNII: I670DAL4SZ)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64141-814-01	1 in 1 CARTON		
1	NDC:64141-814-02	30 mL in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2004	

Labeler - Bobbi Brown Professional Cosmetics Inc. (627131279)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Inc		042918826	manufacture

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

Establishment			
Name	Address	ID/FEI	Business Operations
Northtec Bristol		959338336	manufacture, relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Northtec Keystone		943871157	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.		205952385	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		244669714	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 Centre		208579636	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center (PALC)		078364654	repack, relabel