

EXTRA REPAIR MOISTURING 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.

ACTIVE INGREDIENTS: OCTINOXATE 7.50% [] HOMOSALATE 5.00% [] OXYBENZONE 3.00% [] AVOBENZONE 2.00%

INACTIVE INGREDIENTS: WATER [] C12-15 ALKYL ETHYLHEXANOATE [] BUTYLOCTYL SALICYLATE [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] PROPANEDIOL [] CETYL ALCOHOL [] CETEARYL ALCOHOL [] GLYCERYL STEARATE [] BIS-DIGLYCERYL POLYACYLADIPATE-2 [] POLYACRYLAMIDE [] TOCOPHERYL ACETATE [] NEOPENTYL GLYCOL DIHEPTANOATE [] SUCROSE [] POLYETHYLENE [] OLEA EUROPAEA (OLIVE) FRUIT EXTRACT [] SALVIA SCLAREA (CLARY) EXTRACT [] EPILOBIUM ANGUSTIFOLIUM EXTRACT [] TRITICUM VULGARE (WHEAT BRAN) EXTRACT [] PISUM SATIVUM (PEA) EXTRACT [] BAMBUSA VULGARIS (BAMBOO) EXTRACT [] ROSMARINUS OFFICINALIS (ROSEMARY) [] OENOTHERA BIENNIS (EVENING PRIMROSE) OIL [] PELARGONIUM GRAVEOLENS (GERANIUM) FLOWER OIL [] CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL [] CITRUS AURANTIUM AMARA (BITTER ORANGE) OIL [] ANTHEMIS NOBILIS (CHAMOMILE) [] WHEY PROTEIN\LACTIS PROTEIN\PROTEINE DU PETIT-LAIT [] CHOLESTEROL [] LINOLEIC ACID [] CAFFEINE [] ACETYL HEXAPEPTIDE-8 [] SORBITAN STEARATE [] PEG-40 STEARATE [] C13-14 ISOPARAFFIN [] CAPRYLYL GLYCOL [] DICETYL PHOSPHATE [] CETETH-10 PHOSPHATE [] LAURETH-7 [] GLUCOSAMINE HCL [] TETRAHEXYLDECYL ASCORBATE [] SODIUM HYALURONATE [] SODIUM HYDROXIDE [] HEXYLENE GLYCOL [] XANTHAN GUM [] CITRIC ACID [] TETRASODIUM EDTA [] GERANIOL [] LINALOOL [] LIMONENE [] CITRAL [] CITRONELLOL [] PHENOXYETHANOL

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

BOBBI BROWN

EXTRA

REPAIR MOISTURIZING

BALM SPF 25

1.7 OZ./50 ML

DISTR. BOBBI BROWN PROFESSIONAL COSMETICS

NEW YORK, NY 10022

CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)
CHAMAEMELUM NOBILE (UNII: 7NF3GE7IWR)
WHEY (UNII: 8617Z5FMF6)
CHOLESTEROL (UNII: 97C5T2UQ7J)
LINOLEIC ACID (UNII: 9KJL21T0QJ)
CAFFEINE (UNII: 3G6A5W338E)
ACETYL HEXAPEPTIDE-3 (UNII: L4EL31FWIL)
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)
PEG-40 STEARATE (UNII: ECU18C66Q7)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)
LAURETH-7 (UNII: Z95S6G8201)
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
XANTHAN GUM (UNII: TTV12P4NEE)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
EDETATE SODIUM (UNII: MP1J8420LU)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64141-112-01	1 in 1 CARTON		
1	NDC:64141-112-02	50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/16/2011	

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
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Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture
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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