

PREP (PLUS) PRIME BEAUTY BALM SPF 35- octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide cream

MAKE-UP ART COSMETICS

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 7.40% [] OCTISALATE 4.00% [] OXYBENZONE 2.50% [] TITANIUM DIOXIDE 1.10% [] ZINC OXIDE 3.50%

DIRECTIONS:SMOOTH EVENLY ALL OVER THE FACE OR TO THE DESIRED AREA AFTER MOISTURIZER WITH FINGERTIPS, SPONGE OR BRUSH

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

PRINCIPAL DISPLAY PANEL:

MAC

PREP + PRIME

BB

BEAUTY BALM

SPF 35

30 ML/1.0 US FL OZ

DIST. BY MAKEUP ART COSMETICS

TORONTO, ONTARIO CANADA M5V 1R7

MAC COSMETICS.COM

CTN#80970

**PREP+PRIME BB BEAUTY BALM
SPF 35
CRÈME TEINTÉE SPF 35**

**SMOOTH EVENLY ALL OVER THE FACE
OR TO THE DESIRED AREAS AFTER
MOISTURIZER WITH FINGER TIPS,
SPONGE, OR BRUSH.
APRÈS VOTRE CRÈME HYDRATANTE,
APPLIQUER LE PRODUIT UNIFORMÈMENT
SOIT DU BOUT DES DOIGTS, SOIT AVEC
UNE ÉPONGE OU UN PINCEAU SUR TOUT
LE VISAGE OU UNE PARTIE CIBLÉE.**

**WARNING: KEEP OUT OF EYES.
STOP USE IF IRRITATION OCCURS.
KEEP OUT OF REACH OF CHILDREN.
ATTENTION: ÉVITER TOUT CONTACT
AVEC LES YEUX. SUSPENDRE
L'UTILISATION EN CAS D'IRRITATION.
TENIR HORS DE PORTEE DES ENFANTS.**

**ACTIVE INGREDIENTS: OCTINOXATE 7.40%,
OCTISALATE 4.00%, OXYBENZONE 2.50%,
TITANIUM DIOXIDE 1.10%, ZINC OXIDE 3.50%**

**INGREDIENTS: WATER/AQUA/EAU, DIMETHICONE,
BUTYLENE GLYCOL, PHENYL TRIMETHICONE,
PENTYLENE GLYCOL, GLYCERYL STEARATE,
BEHENYL ALCOHOL, TRIOCTYLDODECYL
CITRATE, POLYMETHYLSILSESQUOXANE,
OCTYLDODECYL STEAROYL STEARATE, PEG-40
STEARATE, POLYGLYCERYL-10 PENTASTEARATE,
OCTYLDODECYL NEOPENTANOATE, TOCOPHERYL
ACETATE, CAFFEINE, GLYCYRRHETINIC ACID,
UREA, SODIUM HYALURONATE, SQUALANE,
HORDEUM VULGARE (BARLEY) EXTRACT/
EXTRAIT D'ORGE, TRITICUM VULGARE (WHEAT)
GERM EXTRACT, LAMINARIA SACCHARINA
EXTRACT, GLYCERIN, LECITHIN, POLYGLYCERYL-6
POLYRICINOLEATE, CHOLESTEROL, TREHALLOSE,
SODIUM PCA, DRYZANOL, AMMONIUM
ACRYLOYLDIMETHYLTAURATE/PP COPOLYMER,
SUCROSE, SODIUM STEAROYL LACTYLATE,
XANTHAN GUM, POLYQUATERNIUM-51,
ISOPROPYL TITANIUM TRIISOSTEARATE, SILICA,
ALUMINUM STEARATE, LINOLEIC ACID, STEARIC
ACID, PENTAERYTHRITYL TETRA-DI-T-BUTYL
HYDROXYHYDROCINNAMATE, DISODIUM
EDTA, PHENOXYETHANOL, CHLORPHENESIN,
SODIUM DEHYDROACETATE, MICA, IRON
OXIDES (CI 77491, CI 77492, CI 77499),
TITANIUM DIOXIDE (CI 77891) <LN36505>**

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PREP+PRIME**

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BEAUTY BALM
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CRÈME TEINTÉE
SPF 35**

30 ML / 1.0 US FL OZ e

Back
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MAC



DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7
LONDON W1K 3BQ / MGWT
MADE IN CANADA/FABRIQUÉ AU CANADA
MACCOSMETICS.COM



MGWT01112

PRINTED IN CANADA
IMPRIMÉ AU CANADA



PREP (PLUS) PRIME BEAUTY BALM SPF 35

octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.4 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2.5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1.1 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0036-1	1 in 1 CARTON		
1	NDC:40046-0036-2	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2010	

Labeler - MAKE-UP ART COSMETICS (010597206)

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
PADC 1		110482184	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
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Revised: 5/2010

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