

**PREP AND PRIME FORTIFIED SKIN ENHANCER SPF 35- octinoxate, octisalate, zinc oxide, oxybenzone cream**

**MAKEUP 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.*

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

**INACTIVE INGREDIENTS:** WATER\AQUA\EAU [] DIMETHICONE [] BUTYLENE GLYCOL [] PHENYL TRIMETHICONE [] PENTYLENE GLYCOL [] GLYCERYL STEARATE [] BEHENYL ALCOHOL [] TRIOCTYLDODECYL CITRATE [] POLYMETHYLSILSESQUIOXANE [] 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 [] TREHALOSE [] SODIUM PCA [] ORYZANOL [] AMMONIUM ACRYLOYLDIMETHYLTaurate/VP COPOLYMER [] SUCROSE [] SODIUM STEAROYL LACTYLATE [] XANTHAN GUM [] POLYQUATERNIUM-51 [] ISOPROPYL TITANIUM TRIISOSTEARATE [] TRIETHOXYCAPRYLYLSILANE [] SILICA [] ALUMINA [] LINOLEIC ACID [] STEARIC ACID [] PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE [] DISODIUM EDTA [] PHENOXYETHANOL [] CHLORPHENESIN [] SODIUM DEHYDROACETATE [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] BISMUTH OXYCHLORIDE (CI 77163) [] BLUE 1 LAKE (CI 42090) [] CARMINE (CI 75470) [] CHROMIUM HYDROXIDE GREEN (CI 77289) [] FERRIC FERROCYANIDE (CI 77510) [] YELLOW 5 LAKE (CI 19140)]

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

**WARNING:** KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. IF IRRITATION PERSISTS, DISCONTINUE USE AND CONTACT A HEALTH CARE PRACTITIONER.

KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

MAC

PREP + PRIME

FORTIFIED SKIN ENHANCER

SPF 35

NT WT 1.0 FL OZ/ 30 ML

DISTR BY MAKE UP ART COSMETICS

TORONTO, ONTARIO, CANADA M5V 1R7

**PREP+PRIME/FORTIFIED  
SKIN ENHANCER SPF 35  
ILLUMINATEUR DE TEINT SPF 35**

**SMOOTH EVENLY ALL OVER THE FACE  
OR TO THE DESIRED AREAS AFTER  
MOISTURIZER WITH FINGER TIPS,  
SPONGE, OR BRUSH.**

**WARNING: KEEP OUT OF EYES.  
STOP USE IF IRRITATION OCCURS.  
IF IRRITATION PERSISTS, CONSULT  
A HEALTH CARE PRACTITIONER.  
KEEP OUT OF REACH OF CHILDREN.**

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

**INGREDIENTS: WATER/AQUA/EAU, DIMETHICONE,  
BUTYLENE GLYCOL, PHENYL TRIMETHICONE,  
PENTYLENE GLYCOL, GLYCERYL STEARATE,  
BEHENYL ALCOHOL, TRIOCTYLDODECYL  
CITRATE, POLYMETHYLSILSESQUIOXANE,  
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-8  
POLYRICINOLEATE, CHOLESTEROL, TREHALOSE,  
SODIUM PCA, ORYZANOL, AMMONIUM  
ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER,  
SUCROSE, SODIUM STEAROYL LACTYLATE,  
XANTHAN GUM, POLYQUATERNIUM-51,  
ISOPROPYL TITANIUM TRIISOSTEARATE,  
TRIETHOXYCAPRYLYLSILANE, SILICA,  
ALUMINA, LINOLEIC ACID, STEARIC ACID,  
PENTAERYTHRITYL TETRA-DI-T-BUTYL  
HYDROXYHYDROCINNAMATE, DISODIUM EDTA,  
PHENOXYETHANOL, CHLORPHENESIN, SODIUM  
DEHYDROACETATE [+/- MICA, TITANIUM  
DIOXIDE (CI 77891), IRON OXIDES (CI 77491,  
CI 77492, CI 77499), BISMUTH OXYCHLORIDE  
(CI 77163), BLUE 1 LAKE (CI 42090),  
CARMINE (CI 75470), CHROMIUM HYDROXIDE  
GREEN (CI 77289), FERRIC FERROCYANIDE  
(CI 77510), YELLOW 5 LAKE (CI 19140)]  
<ILN37485>**

**MAC  
PREP+PRIME**

**FORTIFIED  
SKIN ENHANCER  
ILLUMINATEUR  
DE TEINT  
SPF 35**

**30 ML / 1.0 US FL OZ e**

**DIST. BY/PAR. MAKE-UP ART COSMETICS  
TORONTO, ONTARIO, CANADA M5V 1R7  
LONDON W1K 3BD / MKE1  
MADE IN CANADA/FABRIQUÉ AU CANADA  
MACCOSMETICS.COM**

**MKE1041111**



## PREP AND PRIME FORTIFIED SKIN ENHANCER SPF 35

octinoxate, octisalate, zinc oxide, oxybenzone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0039
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.0 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.5 mL in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2.5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.1 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DOCOSANOL (UNII: 9G1OE216XY)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAFFEINE (UNII: 3G6A5W338E)	
ENOXOLONE (UNII: P540XA09DR)	
UREA (UNII: 8W8T17847W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SQUALANE (UNII: GW89575KF9)	
BARLEY (UNII: 5PWM7YLI7R)	
WHEAT GERM (UNII: YR3G369F5A)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
TREHALOSE (UNII: B8WCK70T7I)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	

GAMMA ORYZANOL (UNII: SST9XCL51M)
SUCROSE (UNII: C151H8M554)
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)
XANTHAN GUM (UNII: TTV12P4NEE)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ALUMINUM OXIDE (UNII: LM26O6933)
LINOLEIC ACID (UNII: 9KJL21T0QJ)
STEARIC ACID (UNII: 4ELV7Z65AP)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CHLORPHENESIN (UNII: I670DAL4SZ)
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0039-1	1 in 1 CARTON		
1	NDC:40046-0039-2	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	04/01/2011	

**Labeler** - MAKEUP 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
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Aramis Inc.		042918826	manufacture
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### 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