

**MINERALIZE SATIN FOUNDATION SPF 15 FOUNDATION- octinoxate liquid
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.

ACTIVE INGREDIENT: OCTINOXATE 7.5%

INACTIVE INGREDIENTS: WATER [] BUTYLENE GLYCOL [] TRIETHYLHEXANOIN [] SQUALANE [] PROPYLENE GLYCOL STEARATE [] CAPRYLIC/CAPRIC TRIGLYCERIDE [] STEARIC ACID [] GLYCERIN [] KAOLIN [] BETA VULGARIS (BEET) ROOT EXTRACT [] HABERLEA RHODOPENSIS LEAF EXTRACT [] TAMARINDUS INDICA SEED GUM [] YEAST EXTRACT [] MAGNESIUM CHLORIDE [] SODIUM CHLORIDE [] ZINC CHLORIDE [] POTASSIUM CHLORIDE [] LYSINE [] TOCOPHEROL [] PANTHENOL [] POLYSORBATE 20 [] LECITHIN [] TROMETHAMINE [] XANTHAN GUM [] ASCORBYL PALMITATE [] RETINYL PALMITATE [] CAPRYLYL GLYCOL [] SIMETHICONE [] CETYL ALCOHOL [] HYDROGENATED LECITHIN [] MAGNESIUM ALUMINUM SILICATE [] ISOSTEARIC ACID [] HEXYLENE GLYCOL [] PENTYLENE GLYCOL [] DISODIUM EDTA [] POTASSIUM SORBATE [] PHENOXYETHANOL [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] CHROMIUM OXIDE GREENS (CI 77288)]

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

PRINCIPAL DISPLAY PANEL:

MAC

SATINFINISH SPF 15

FOUNDATION

30 ML/1 FL OZ

DISTR BY MAKE-UP ART COSMETICS

TORONTO, ONTARIO, CANADA, M5V 1R7

**FONDOTINTA SPF 15
GRUNDIERUNG SPF 15
MAQUILLAJE DE BASE SPF 15**

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

ACTIVE INGREDIENTS: OCTINOXATE 7.50%

**INGREDIENTS: WATER/AQUAVEAU, BUTYLENE
GLYCOL, TRIETHYLHEXANOIN, SQUALANE,
PROPYLENE GLYCOL STEARATE, CAPRYLIC/
CAPRIC TRIGLYCERIDE, STEARIC ACID, GLYCERIN,
KAOLIN, BETA VULGARIS (BEET) ROOT EXTRACT,
BETA VULGARIS/EXTRAIT DE RACINE DE BETTERAVE,
HABERLEA RHODOPENSIS LEAF EXTRACT,
TAMARINDUS INDICA SEED GUM, YEAST EXTRACT,
MAGNESIUM CHLORIDE, SODIUM CHLORIDE,
ZINC CHLORIDE, POTASSIUM CHLORIDE, LYSINE,
TOCOPHEROL, PANTHENOL, POLYSORBATE
20, LECITHIN, TROMETHAMINE, XANTHAN GUM,
ASCORBYL PALMITATE, RETINYL PALMITATE,
CAPRYLYL GLYCOL, DIMETHICONE, CETYL
ALCOHOL, HYDROGENATED LECITHIN, MAGNESIUM
ALUMINUM SILICATE, ISOSTEARIC ACID, HEXYLENE
GLYCOL, PENTYLENE GLYCOL, DISODIUM EDTA,
POTASSIUMSORBATE, PHENOXYETHANOL
[-/- MICA, TITANIUM DIOXIDE (CI 77891), IRON
OXIDES (CI 77491, CI 77492, CI 77499), CHROMIUM
OXIDE GREENS (CI 77288)] <ILN92395>**

M·A·C

**MINERALIZE
SATINFINISH SPF 15
FOUNDATION
FOND DE TEINT SPF 15
30 ML / 1.0 US FL OZ e**

MINERALIZE SATIN FOUNDATION SPF 15 FOUNDATION

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0042
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SQUALANE (UNII: GW89575KF9)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BEET (UNII: N487KM8COK)	
YEAST (UNII: 3NY3SM6B8U)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
LYSINE (UNII: K3Z4F929H6)	
ALPHA-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TROMETHAMINE (UNII: 023C2WHX2V)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
2-OCTANOL (UNII: 66B0DD5E40)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:40046-0042-1	1 in 1 CARTON	
1	NDC:40046-0042-2	30 mL in 1 BOTTLE, GLASS	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2006	

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
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

Establishment

Name	Address	ID/FEI	Business Operations
MANA COSMETICS INC		078870292	manufacture

Revised: 5/2011

MAKEUP ART COSMETICS