

STUDIO MOISTURE TINT SPF 15- octinoxate gel
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 INGREDIENT: OCTINOXATE, 3.5%

INACTIVE INGREDIENTS: WATER [] CYCLOPENTASILOXANE [] BUTYLENE GLYCOL []
STEARETH-21 [] GLYCERYL STEARATE [] DIMETHICONE [] ISOSTEARIC ACID []
TROMETHAMINE [] TOCOPHERYL ACETATE [] LECITHIN [] CHOLESTEROL [] ASCORBYL
PALMITATE [] SODIUM HYALURONATE [] CAFFEINE [] ALOE BARBADENSIS LEAF WATER
[] HYDROGENATED LECITHIN [] SUCROSE [] SORBITOL [] SILICA [] TREHALOSE []
MAGNESIUM ALUMINUM SILICATE [] CARBOMER [] STEARETH-2 [] CELLULOSE GUM []
PVP [] PALMITOYL OLIGOPEPTIDE [] GLYCERYL POLYMETHACRYLATE []
METHYLDIHYDROJASMONATE [] XANTHAN GUM [] CAPRYLYL GLYCOL [] STEARIC ACID
[] SODIUM CITRATE [] PEG-8 [] GLYCERIN [] DISODIUM EDTA [] HEXYLENE GLYCOL []
BHT [] PHENOXYETHANOL [] CHLORPHENESIN [] CHLOROXYLENOL [] [+/- MICA []
TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499)

DIRECTIONS: AFTER CLEANSING, APPLY TO CLEAN SKIN 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
STUDIO MOISTURE TINT

SPF 15

40 ML/1.3 US FL OZ

DISTR MAKE UP ART COSMETICS
TORONTO, ONTARIO, CANADA, M5V 1R7

STUDIO MOISTURE TINT SPF 15
FLUIDE HYDRATANT TEINTÉ SPF 15
CREMA COLORATA SPF 15
GETÖNTE TAGESCREME SPF 15
CREMA HIDRATANTE CON COLOR SPF 15

**AFTER CLEANSING, APPLY DIRECTLY
TO CLEAN SKIN WITH FINGERTIPS,
SPONGE OR BRUSH.**

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

ACTIVE INGREDIENT: OCTINOXATE 3.50%
**INGREDIENTS: WATER/AQUA/EAU,
CYCLOPENTASILOXANE, BUTYLENE GLYCOL,
STEARETH-21, GLYCERYL STEARATE,
DIMETHICONE, ISOSTEARIC ACID,
TROMETHAMINE, TOCOPHERYL ACETATE,
LECITHIN, CHOLESTEROL, ASCORBYL PALMITATE,
SODIUM HYALURONATE, CAFFEINE, ALOE
BARBADENSIS LEAF WATER, HYDROGENATED
LECITHIN, SUCROSE, SORBITOL, SILICA,
TREHALDSE, MAGNESIUM ALUMINUM SILICATE,
CARBOMER, STEARETH-2, CELLULOSE GUM,
PVP, PALMITOYL OLIGOPEPTIDE, GLYCERYL
POLYMETHACRYLATE, METHYLDIHYDROQUINONE,
XANTHAN GUM, CAPRYLYL GLYCOL, STEARIC
ACID, SODIUM CITRATE, PEG-8, GLYCERIN,
DISODIUM EDTA, HEXYLENE GLYCOL, BHT,
PHENOXYETHANOL, CHLORPHENESIN,
CHLOROXYLENOL [+/- MICA, TITANIUM
DIOXIDE (CI 77891), IRON OXIDES (CI 77491,
CI 77492, CI 77499)] <LN35601>**

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



MACCOSMETICS.COM

MAC

**STUDIO
MOISTURE TINT
SPF 15
FLUIDE HYDRATANT
TEINTÉ SPF 15
40 ML / 1.3 US FL OZ e**

STUDIO MOISTURE TINT SPF 15

octinoxate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
TROMETHAMINE (UNII: 023C2WHX2V)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CAFFEINE (UNII: 3G6A5W338E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TREHALOSE (UNII: B8WCK70T7I)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
STEARETH-2 (UNII: V56DFE46J5)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)
XANTHAN GUM (UNII: TTV12P4NEE)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
STEARIC ACID (UNII: 4ELV7Z65AP)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
GLYCERIN (UNII: PDC6A3C0OX)
EDETATE DISODIUM (UNII: 7FLD91C86K)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CHLORPHENESIN (UNII: I670DAL4SZ)
CHLOROXYLENOL (UNII: 0F32U78V2Q)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0033-1	1 in 1 CARTON		
1	NDC:40046-0033-2	40 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2009	

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
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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