

**STUDIO SCULPT SPF 15 FOUNDATION- octinoxate, titanium dioxide liquid
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 7.00% [] TITANIUM DIOXIDE 2.00%

INACTIVE INGREDIENTS: WATER [] CYCLOPENTASILOXANE [] GLYCERIN [] BUTYLENE GLYCOL [] OCTYLDODECYL NEOPENTANOATE [] PEG/PPG-18/18 DIMETHICONE [] POLYMETHYLSILSESQUIOXANE [] ISOSTEARIC ACID [] C4-24 ALKYL DIMETHICONE/DIVINYLDIMETHICONE CROSSPOLYMER [] ISONONYL ISONONANOATE [] TAMARINDUS INDICA SEED EXTRACT [] TOCOPHEROL [] TOCOPHERYL ACETATE [] SODIUM HYALURONATE [] HABERLEA RHODOPENSIS LEAF EXTRACT [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE [] QUERCUS SUBER BARK EXTRACT [] PHYTANTRIOL [] DEXTRIN PALMITATE [] DEXTRIN PALMITATE/ETHYLHEXANOATE [] CELLULOSE GUM [] TETRAHEXYLDECYL ASCORBATE [] XANTHAN GUM [] DIMETHICONE [] METHICONE [] PROPYLENE CARBONATE [] SODIUM CHLORIDE [] PALMITIC ACID [] POLYGLYCERYL-4 ISOSTEARATE [] CETYL PEG/PPG-10/1 DIMETHICONE [] HEXYL LAURATE [] POLYMETHYL METHACRYLATE [] OCTYLDODECYL PCA [] DISTEARDIMONIUM HECTORITE [] STEARIC ACID [] CAPRYLYL GLYCOL [] DIPROPYLENE GLYCOL [] PHENOXYETHANOL [] ALUMINUM STEARATE [] HEXYLENE GLYCOL [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] CHROMIUM OXIDE GREENS (CI 77288)]

WARNING: KEEP OUR OF EYES. STOP USE IF IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

MAC

STUDIO SCULPT

SPF 15 FOUNDATION

40 ML/ 1.3 US FL OZ

DISTR BY MAKE-UP ART COSMETICS

TORONTO, ONTARIO

CANADA

MAC

STUDIO SCULPT
SPF 15
FOUNDATION
FOND DE TEINT
SPF 15

40 ML / 1.3 US FL. OZ e

STUDIO SCULPT
SPF 15 FOUNDATION
FOND DE TEINT SPF 15
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 7.00%,
TITANIUM DIOXIDE 2.00%

INGREDIENTS: WATER/AQUA/EAU,
CYCLOPENTASILOXANE, GLYCERIN, BUTYLENE
GLYCOL, OCTYLDODECYL NEOPENTANOATE,
PEG/PPG-18/18 DIMETHICONE,
POLYMETHYLSILSESQUIOXANE, ISOSTEARIC
ACID, C-24 ALKYL DIMETHICONE/
DIVINYLDIMETHICONE COPOLYMER,
ISONONYL ISONONANOATE, TAMARINDUS INDICA
SEED EXTRACT, TOCOPHEROL, TOCOPHERYL
ACETATE, SODIUM HYALURONATE, HABERLEA
RHODOPENSIS LEAF EXTRACT, BETA VULGARIS
(BEET) ROOT EXTRACT/BETA VULGARIS/EXTRAIT
DE RACINE DE BETTERAVE, BUTYROSPERMUM
PARKII (SHEA BUTTER), YEAST EXTRACT/LEVURE,
EXTRAIT DE LEVURE, QUERCUS SUBER BARK
EXTRACT, PHYTANTRIOL, DEXTRIN PALMITATE,
DEXTRIN PALMITATE/ETHYLHEXANOATE,
CELLULOSE GUM, TETRAHEXYLDECYL
ASCORBATE, XANTHAN GUM, DIMETHICONE,
METHICONE, PROPYLENE CARBONATE, SODIUM
CHLORIDE, PALMITIC ACID, POLYGLYCERYL-4
ISOSTEARATE, CETYL PEG/PPG-10/1
DIMETHICONE, HEXYL LAURATE, POLYMETHYL
METHACRYLATE, OCTYLDODECYL PCA,
D-STEARDIMONIUM HECTORITE, STEARIC ACID,
CAPRYLYL GLYCOL, DIPROPYLENE GLYCOL,
PHENOXYETHANOL, ALUMINUM STEARATE,
HEXYLENE GLYCOL [+/- MICA, TITANIUM DIOXIDE
(CI 77891), IRON OXIDES (CI 77491, CI 77492,
CI 77499), CHROMIUM OXIDE GREENS
(CI 77288)] <LN35219>

DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7,
LONDON W1K 3BQ / MADE
MADE IN U.S.A./FABRIQUE AUX É.-U.
MACCOSMETICS.COM



STUDIO SCULPT SPF 15 FOUNDATION

octinoxate, titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.0 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
TAMARINDUS INDICA SEED (UNII: 6AHP8A7OML)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALPHA-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0032-1	1 in 1 CARTON		
1	NDC:40046-0032-2	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	09/01/2008	

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
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: 2/2010

MAKE UP ART COSMETICS