

**STUDIO FOUNDATION SPF 15- octinoxate and titanium dioxide stick
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.

STUDIO STICK FOUNDATION SPF 15

WARNING

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

ACTIVE INGREDIENTS

OCTINOXATE 5.00%, TITANIUM DIOXIDE 2.90%

INGREDIENTS

DI-PPG-3-MYRISTYL ETHER ADIPATE, PHENYL TRIMETHICONE, SILICA, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, DIMETHICONE, TRIBEHENIN, C20-40 ALCOHOLS, ISONONYL ISONONANOATE, OZOKERITE, ALOE BARBADENSIS LEAF EXTRACT, TOCOPHERYL ACETATE, ASCORBYL PALMITATE, RETINYL PALMITATE, LECITHIN, ALUMINUM STEARATE, TRIMETHYLSILOXYSILICATE, SORBITAN LAURATE, PROPYLENE GLYCOL LAURATE, PROPYLENE GLYCOL STEARATE, POLYSORBATE 20, STEARIC ACID [+/- TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499)] <ILN29118>

DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7, LONDON W1K 3BQ.

PRINCIPAL DISPLAY PANEL - 9 g Tube Carton

M•A•C

STUDIO STICK FOUNDATION SPF 15

NET WT./POIDS NET 9 g/.31 US OZ e

88

M447-01-111E



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

ACTIVE INGREDIENTS: OCTINOXATE 5.00%, TITANIUM DIOXIDE 2.90%

INGREDIENTS: DI-PPG-3-MYRISTYL ETHER ADIPATE, PHENYL TRIMETHICONE, SILICA, HDI/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER, DIMETHICONE, TRIBEHENIN, C20-40 ALCOHOLS, ISONONYL ISONONANOATE, OZONERITE, ALOE BARBADENSIS LEAF EXTRACT, TOCOPHERYL ACETATE, ASCORBYL PALMITATE, RETINYL PALMITATE, LECITHIN, ALUMINUM STEARATE, TRIMETHYLSILOXYMETHYLACRYLATE, SORBITAN LAURATE, PROPYLENE GLYCOL LAURATE, PROPYLENE GLYCOL STEARATE, POLYSORBATE 20, STEARIC ACID [+/- TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499)] -ILN29118-

STUDIO STICK FOUNDATION SPF 15/FOND DE TEINT FPS 15/FONDOTINTA SPF 15
GRÜNDERUNG SPF 15/MAQUILLAGE DE BASE SPF 15

DIST. BY/PAR. MAKE-UP ART COSMETICS
 TORONTO, ONTARIO, CANADA M5V 1R7, LONDON W1K 3BQ.
 MADE IN U.S.A./FABRIQUE AUX E.-U. / M447
 MACCOSMETICS.COM



M4470111E

STUDIO STICK FOUNDATION SPF 15 FOND DE TEINT FPS 15

NET WT./POIDS NET 9 g/.31 US OZ e

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STUDIO FOUNDATION SPF 15

octinoxate and titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

ASCORBYL PALMITATE (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
PROPYLENE GLYCOL MONOLAURATE (UNII: 668Z5835Z3)	
PROPYLENE GLYCOL STEARATE (UNII: MZM1I680W0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0057-1	1 in 1 CARTON		
1		9 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/06/2003	

Labeler - MAKEUP ART COSMETICS (010597206)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(40046-0057) , REPACK(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(40046-0057) , RELABEL(40046-0057) , REPACK(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(40046-0057) , RELABEL(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(40046-0057) , RELABEL(40046-0057) , REPACK(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(40046-0057) , RELABEL(40046-0057) , REPACK(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(40046-0057) , RELABEL(40046-0057) , REPACK(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(40046-0057) , RELABEL(40046-0057)

Establishment

Name	Address	ID/FEI	Business Operations
PRIVATE LABEL SELECT LTD		005415463	MANUFACTURE(40046-0057)