

**STUDIO FINISH CONCEALER SPF 35- octinoxate, titanium dioxide paste
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 INGREDIENTS: OCTINOXATE 5.00% [] TITANIUM DIOXIDE 2.00%

INACTIVE INGREDIENTS: OCTYLDODECANOL [] SYNTHETIC BEESWAX [] COPERNICIA CERIFERA (CARNAUBA) WAX [] SILICA [] HYDROGENATED POLYISOBUTENE [] SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL [] TOCOPHEROL [] ASCORBYL PALMITATE [] POLYBUTENE [] PVP/HEXADECENE COPOLYMER [] ALUMINA [] STEARIC ACID [] [+/- (MAY CONTAIN) TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] CHROMIUM OXIDE GREENS (CI 77288)]

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

PRINCIPAL DISPLAY PANEL

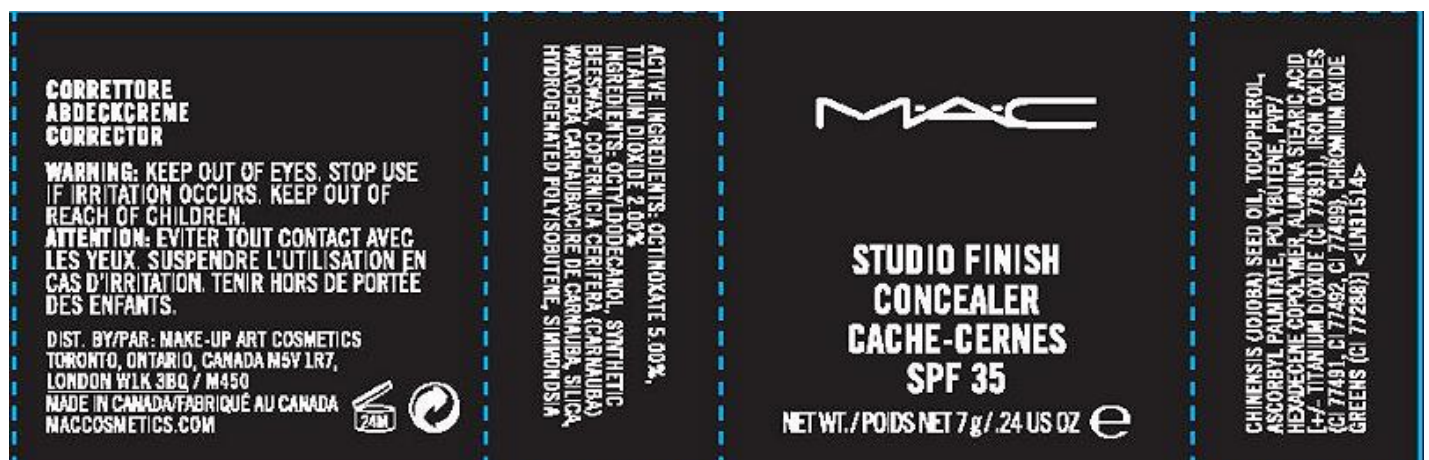
MAC

STUDIO FINISH CONCEALER
SPF 35

NET WT. 7 g/ 0.24 oz

MAKE UP ART COSMETICS

TORONTO, ONTARIO, CANADA, M5V 1R7



STUDIO FINISH CONCEALER SPF 35

octinoxate, titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5.0 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.00 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
JOJOBA OIL (UNII: 724GKU717M)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHROMIC OXIDE (UNII: X5Z09SU859)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0048-1	1 in 1 CARTON		
1	NDC:40046-0048-2	7 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2003	

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

Revised: 8/2011

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