

**STUDIO FIX FLUID SPF 15- octinoxate, titanium dioxide lotion**  
**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.*

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ACTIVE INGREDIENTS: OCTINOXATE 2.50% [] TITANIUM DIOXIDE 1.00%

INACTIVE INGREDIENTS: WATER\AQUA\EAU [] CYCLOPENTASILOXANE [] PEG-10  
DIMETHICONE [] BUTYLENE GLYCOL [] TRIMETHYLSILOXYSILICATE [] DIMETHICONE []  
MAGNESIUM SULFATE [] LAMINARIA SACCHARINA EXTRACT [] ALGAE EXTRACT []  
TOCOPHERYL ACETATE [] SODIUM HYALURONATE [] TOCOPHEROL [] LECITHIN []  
HYDROGENATED LECITHIN [] XANTHAN GUM [] SORBITAN SESQUIOLEATE [] METHOXY  
AMODIMETHICONE/SILSESQUIOXANE COPOLYMER [] LAURETH-7 [] DIPROPYLENE  
GLYCOL [] DIMETHICONE/PEG-10/15 CROSSPOLYMER [] DIMETHICONE/PEG-10  
CROSSPOLYMER [] PEG/PPG-18/18 DIMETHICONE [] DISTEARDIMONIUM HECTORITE []  
SILICA [] DIMETHICONE CROSSPOLYMER [] TRIETHOXYCAPRYLYLSILANE [] PROPYLENE  
CARBONATE [] PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE  
[] SORBIC ACID [] CHLOROXYLENOL [] PHENOXYETHANOL [] [+/- 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

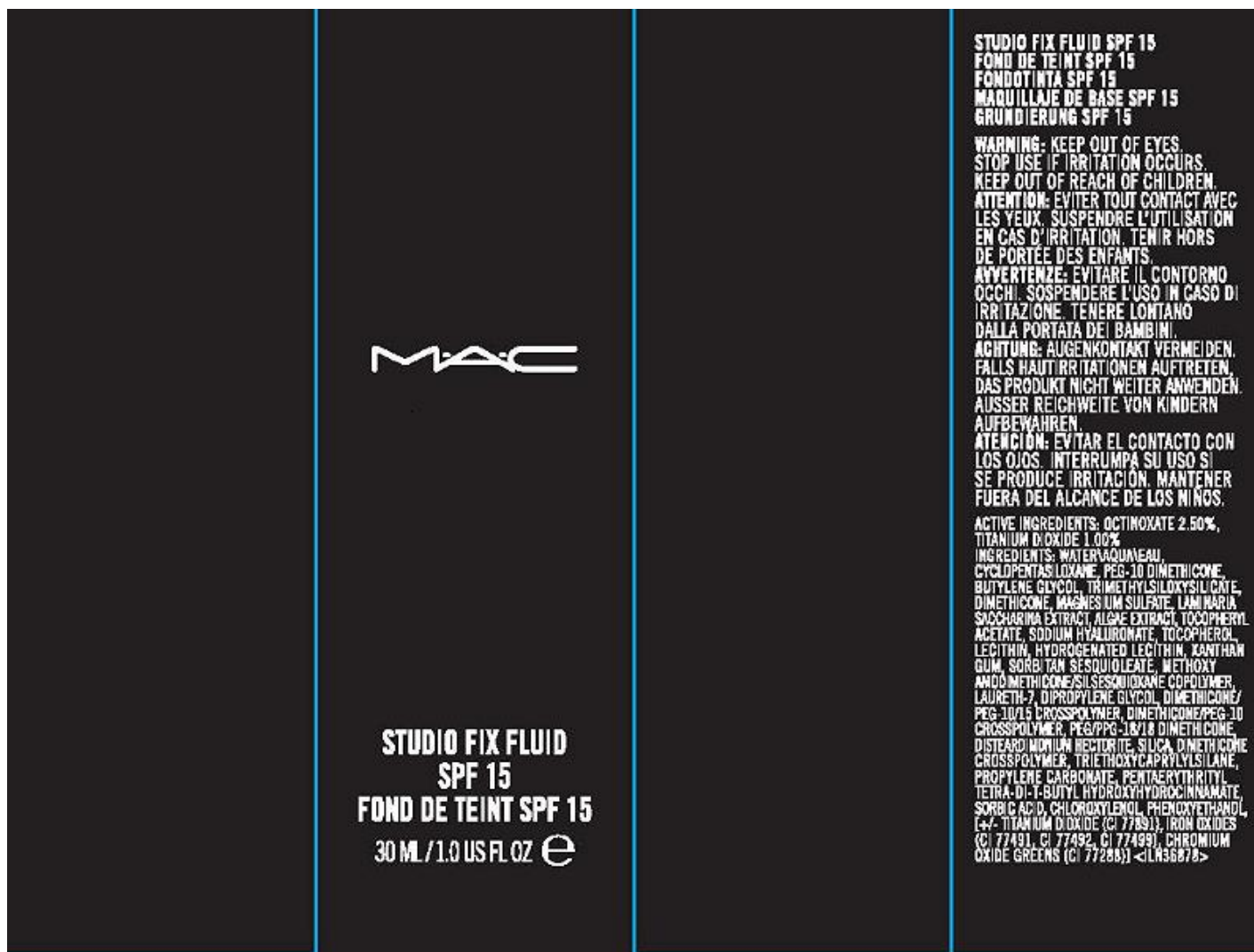
STUDIO FIX FLUID

SPF 15

1 FL OZ LIQ/ 30 ML

MAKEUP ART COSMETICS

TORONTO, ONTARIO, CANADA M5V 1R7



## STUDIO FIX FLUID SPF 15

octinoxate, titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:40046-0050
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 mL in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THF5PCI0R)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
TRIMETHYLSILANE (UNII: 9L70DJH2K0)
DIMETHICONE (UNII: 92RU3N3Y1O)
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
SEAWEED (UNII: 477TV3P5UX)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
XANTHAN GUM (UNII: TTV12P4NEE)
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)
LAURETH-7 (UNII: Z95S6G8201)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
SORBIC ACID (UNII: X045WJ989B)
CHLOROXYLENOL (UNII: 0F32U78V2Q)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
CHROMIC OXIDE (UNII: X5Z09SU859)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0050-1	1 in 1 CARTON		
1	NDC:40046-0050-2	30 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2005	

**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