

**STUDIO FIX FLUID BROAD SPECTRUM SPF 15 WITH ENRICHED ANTI-OXIDANT COMPLEX- octinoxate and 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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**STUDIO FIX FLUID BROAD SPECTRUM SPF 15 WITH ENRICHED ANTI-OXIDANT COMPLEX**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Octinoxate 2.50%	Sunscreen
Titanium Dioxide 1.00%	Sunscreen

**Use**

helps prevent sunburn

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if** rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply every two hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

**inactive ingredients**

water/aqua/eau, cyclopentasiloxane, dimethicone, peg-10 dimethicone, butylene glycol, trimethylsiloxysilicate, magnesium sulfate, dimethicone/peg-10/15 crosspolymer, tocopheryl acetate, sodium hyaluronate, algae extract, olea europaea (olive) leaf extract, oryza sativa (rice) bran extract, laminaria saccharina extract, polygonum cuspidatum root extract, lecithin, hydrogenated lecithin, methoxy amodimethicone/silsesquioxane copolymer, silica, peg/ppg-18/18 dimethicone, dimethicone crosspolymer, laureth-7, triethoxycaprylylsilane, xanthan gum, sorbitan sesquioleate, dipropylene

glycol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, chloroxylenol, sorbic acid [+/- titanium dioxide (ci 77891), iron oxides (ci 77491), iron oxides (ci 77492), iron oxides (ci 77499), chromium oxide greens (ci 77288)] <iln41302>

**Other information**

protect the product in this container from excessive heat and direct sun

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

**PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton**

**M•A•C**

**STUDIO FIX FLUID**

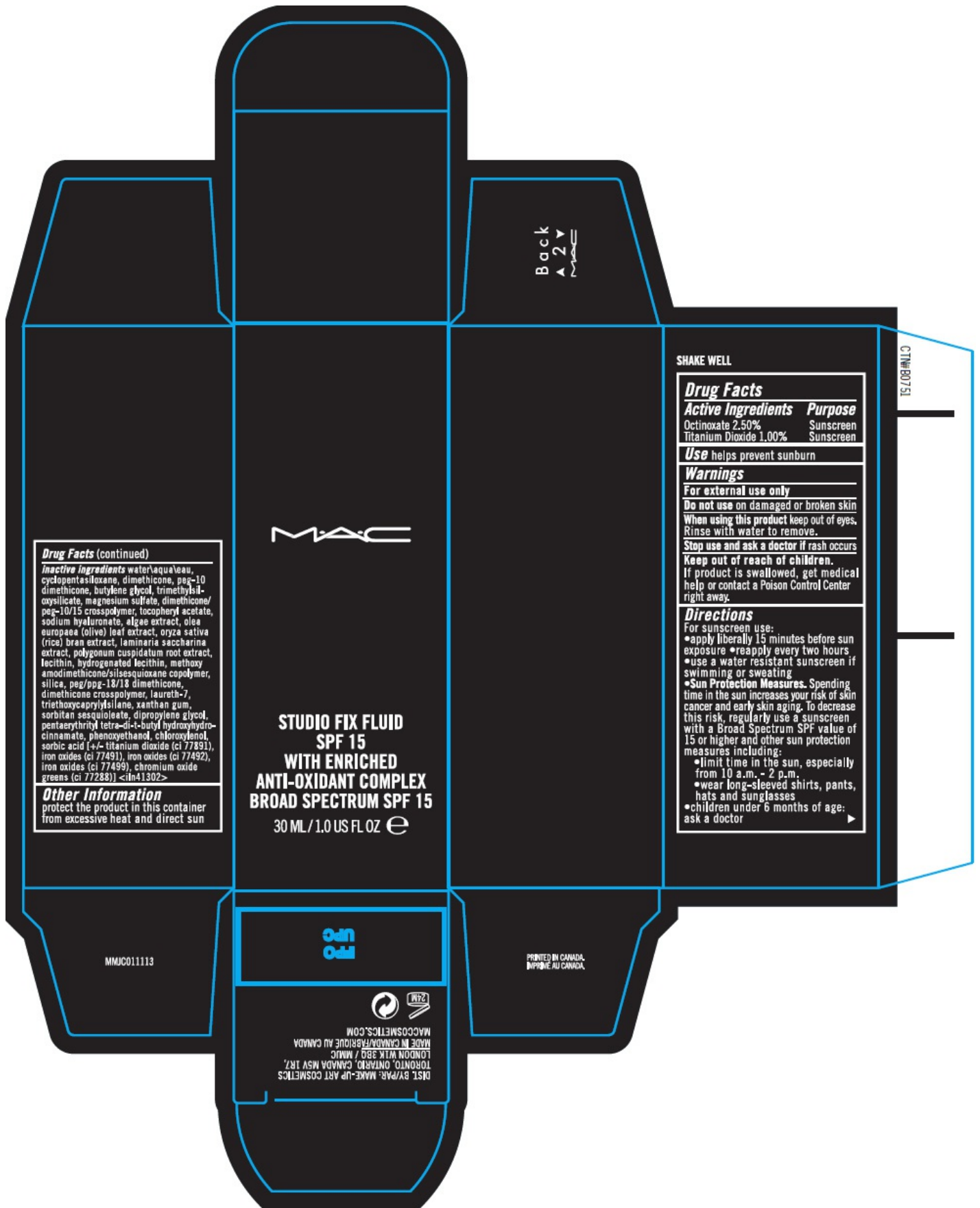
**SPF 15**

**WITH ENRICHED**

**ANTI-OXIDANT COMPLEX**

**BROAD SPECTRUM SPF 15**

30 ML/1.0 US FL OZ e



Back  
▲ 2 ▼  
MAC

**Drug Facts (continued)**  
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MAC

**STUDIO FIX FLUID  
 SPF 15  
 WITH ENRICHED  
 ANTI-OXIDANT COMPLEX  
 BROAD SPECTRUM SPF 15**

30 ML / 1.0 US FL OZ e

SHAKE WELL

**Drug Facts**

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CT#B0751

MMJC011113

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

**STUDIO FIX FLUID BROAD SPECTRUM SPF 15 WITH ENRICHED ANTI-OXIDANT COMPLEX**  
 octinoxate and titanium dioxide lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0073
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.02775 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0111 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
magnesium sulfate (UNII: DE08037SAB)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
olea europaea leaf (UNII: MJ95C3OH47)	
rice bran (UNII: R60QEP13IC)	
saccharina latissima (UNII: 68CMP2MB55)	
polygonum cuspidatum root (UNII: 7TRV45YZF7)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
laureth-7 (UNII: Z95S6G8201)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
xanthan gum (UNII: TTV12P4NEE)	
sorbitan sesquioleate (UNII: 0W8RRI5W5A)	
dipropylene glycol (UNII: E107L85C40)	
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (UNII: 255PIF62MS)	
phenoxyethanol (UNII: HIE492ZZ3T)	
chloroxyleneol (UNII: 0F32U78V2Q)	
sorbic acid (UNII: X045WJ989B)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
chromic oxide (UNII: X5Z09SU859)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0073-1	1 in 1 CARTON		
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/01/2014	

**Labeler** - MAKEUP ART COSMETICS (010597206)

## Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(40046-0073) , REPACK(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(40046-0073) , REPACK(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(40046-0073) , REPACK(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC LLC		959338336	MANUFACTURE(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(40046-0073) , REPACK(40046-0073)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0073)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveda Corporation		071352058	MANUFACTURE(40046-0073)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Pennsylvania Logistics Center (PALC)		078364654	REPACK(40046-0073) , RELABEL(40046-0073)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(40046-0073)

Revised: 12/2014

MAKEUP ART COSMETICS