

**STUDIO FIX FLUID SPF 15 BROAD SPECTRUM- octinoxate and titanium dioxide liquid**  
**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 SPF 15 BROAD SPECTRUM**

***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**

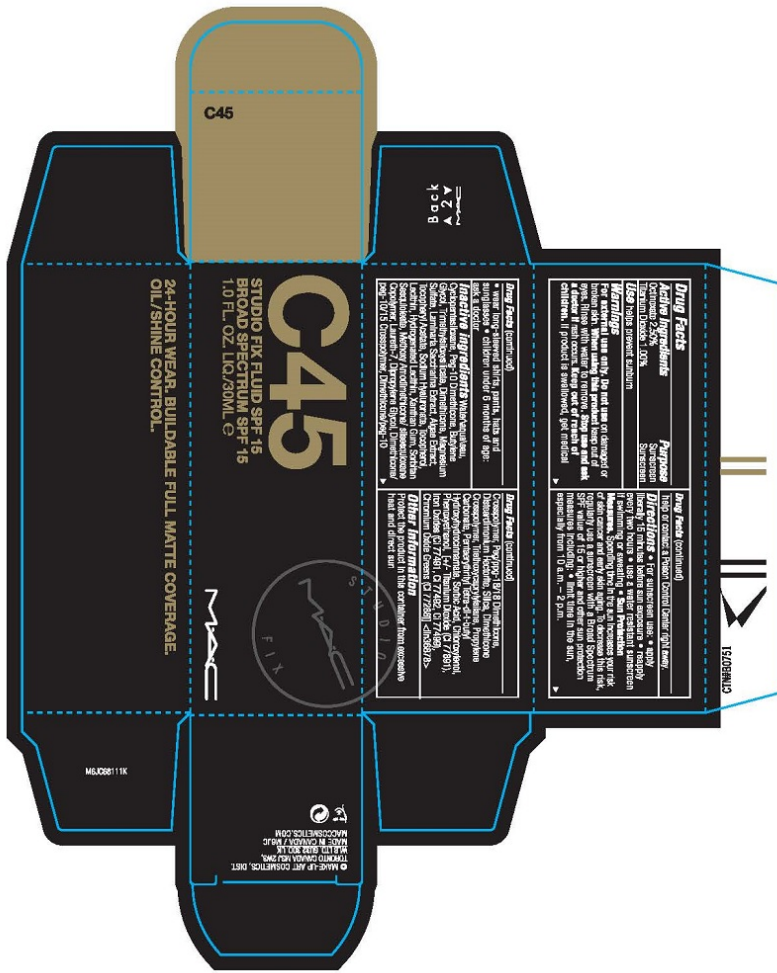
water/aqua/eau, cyclopentasiloxane, peg-10 dimethicone, butylene glycol, trimethylsiloxysilicate, dimethicone, magnesium sulfate, laminaria saccharina extract, algae extract, tocopheryl acetate, sodium hyaluronate, tocopherol, lecithin, hydrogenated lecithin, xanthan gum, sorbitan sesquioleate, methoxy 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, chloroxyleneol, phenoxyethanol [+/- titanium dioxide (ci 77891), iron oxides (ci 77491, ci 77492, ci 77499), chromium oxide greens (ci 77288)] <iln36878>

### **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 / M6JC

**PRINCIPAL DISPLAY PANEL - 30 ML Bottle Carton**



**M•A•C**  
**STUDIO FIX FLUID**  
**SPF 15**  
**BROAD SPECTRUM SPF 15**  
 30 ML/1.0 US FL OZ e

## STUDIO FIX FLUID SPF 15 BROAD SPECTRUM

octinoxate and titanium dioxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:40046-0072
<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	25 mg in 1 mL

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | **TITANIUM DIOXIDE** | 10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>SACCHARINA LATISSIMA</b> (UNII: 68CMP2MB55)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>CHROMIC OXIDE</b> (UNII: X5Z09SU859)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0072-1	1 in 1 CARTON	12/01/2005	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/01/2005	

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

**Registrant** - Estee Lauder Companies Inc. (790802086)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Estee Lauder Cosmetics Ltd.		202952982	manufacture(40046-0072)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Estee Lauder Cosmetics Ltd.		204132062	pack(40046-0072) , label(40046-0072)

Revised: 8/2023

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