

STUDIO FIX FLUID BROAD SPECTRUM SPF 15- octinoxate, titanium dioxide emulsion
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.

MAC STUDIO FIX FLUID BROAD SPECTRUM SPF 15

Active Ingredients

Octinoxate 3.0%

Titanium Dioxide 1.0%

Purpose

Sunscreen

USE

helps prevent sunburn

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 at least 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,METHYL
TRIMETHICONE,DIMETHICONE,TRIMETHYLSILOXYSILICATE,PEG-10
DIMETHICONE,BUTYLENE GLYCOL,ISODODECANE,POLYETHYLENE,CETYL PEG/PPG-10/1
DIMETHICONE,MAGNESIUM SULFATE,ALGAE EXTRACT,LAMINARIA SACCHARINA
EXTRACT,SODIUM HYALURONATE,SALIX NIGRA (WILLOW) BARK
EXTRACT,TOCOPHERYL ACETATE,CAFFEINE,LECITHIN,HYDROGENATED
LECITHIN,DISTEARDIMONIUM HECTORITE,SILICA,XANTHAN GUM,DIMETHICONE
CROSSPOLYMER,TRIETHOXYCAPRYLYLSILANE,DIMETHICONE/PEG-10/15
CROSSPOLYMER,METHOXY AMODIMETHICONE/SILSESQUIOXANE
COPOLYMER,SORBITAN SESQUIOLEATE,SALICYLIC ACID,SODIUM CITRATE,LAURETH-
7,METHYLDIHYDROJASMONATE,PROPYLENE CARBONATE,ALUMINA,DIPROPYLENE
GLYCOL,PENTAERYTHRITYL TETRA-DI-T-BUTYL
HYDROXYHYDROCINNAMATE,BHT,PHENOXYETHANOL,SORBIC ACID,CHLOROXYLENOL,
[+/- TITANIUM DIOXIDE (CI 77891),IRON OXIDES (CI 77491),IRON OXIDES (CI
77492),IRON OXIDES (CI 77499)] <ILN50543>

Other Information

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

PRINCIPAL DISPLAY PANEL

NC15

Back

Drug Facts (continued)
• wear long-sleeved shirts, pants, hats and sunglasses • children under 6 months of age: ask a doctor

Inactive Ingredients water, aqua (eau), methyl ermethicone, zinc behenate, trimethylsiloxysulfate, butyl-10 dimethicone, butylene glycol, behenocaine, polyethylene, cetyl pectate, 10-11 dimerthicone, magnesium stearate, algae extract, laminaria saccharina extract, sodium hyaluronate, salix nigra (willow) bark extract, tocopheryl acetate, carthene, lecithin, hydrogenated lecithin, disoleardronium hecotein.

Drug Facts (continued)
silica, xanthan gum, dimethicone crosspolymer, triethoxycarbonylsiloxane, dimethicone/propyl-10/15 crosspolymer, methoxy amodimethicone/sequoianone copolymer, sorbitan sesquileaeth sulfate and sodium citrate, laurath-7, methylhydrolesmonate, propylene carbonate, aluminum, dipropylene glycol, pentamethyl tetra-di-4-ethyl hydroxyhydroquinone bit, phenoxethanol, sorbic acid, dibutyltand [4- titanium dioxide (CI 77891), iron oxides (CI 77491), iron oxides (CI 77492), iron oxides (CI 77499), CI 550543] from excessive heat and direct sun

MAC

STUDIO FIX

FLUID BROAD SPECTRUM SPF 15

24HR MATTE FOUNDATION + OIL CONTROL

1.0 FL. OZ. LIQ./30 ML

24-HOUR WEAR, MEDIUM-TO-FULL BUILDABLE COVERAGE. BLURRING SOFT MATTE FINISH. WATER- AND TRANSFER-RESISTANT. OIL/SHINE-CONTROL. NON-DRYING. DOES NOT CLOG PORES. SHAKE WELL.

Drug Facts	
Active Ingredients	Purpose
Cinnobin 5.0%	Sunscreen
Titanium Dioxide 1.0%	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.	

Drug Facts (continued)	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.



C-181919



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100% Recycled Paper
25% Post Consumer Waste
MAC

SRM0011112

MAC
STUDIO FIX
FLUID BROAD SPECTRUM SPF 15
24 HR MATTE FOUNDATION + OIL CONTROL

1.0 FL.OZ.LIQ/30ML e

STUDIO FIX FLUID BROAD SPECTRUM SPF 15

octinoxate, titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0082
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	30 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
WATER (UNII: 059QF0KO0R)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
ISODODECANE (UNII: A8289P68Y2)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
PORPHYRIDIUM PURPUREUM (UNII: K2P8K2558N)	
SALIX NIGRA BARK (UNII: QU52J3A5B3)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
CAFFEINE (UNII: 3G6A5W338E)
LAURETH-7 (UNII: Z95S6G8201)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0082-1	1 in 1 CARTON	05/12/2023	
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	05/12/2023	

Labeler - MAKEUP ART COSMETICS (010597206)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd		202952982	manufacture(40046-0082)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		204132062	manufacture(40046-0082) , pack(40046-0082) , label(40046-0082)

Revised: 5/2023

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