

**MAC STUDIO WATERWEIGHT SPF 30 BROAD SPECTRUM
FOUNDATION SUNSCREEN- octinoxate, titanium dioxide, and zinc oxide 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.

**MAC STUDIO WATERWEIGHT SPF 30 BROAD SPECTRUM FOUNDATION
SUNSCREEN**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 5.0%	Sunscreen
Titanium Dioxide 3.1%	Sunscreen
Zinc Oxide 2.1%	Sunscreen

Use

helps prevent sunburn

Apply directly to face. Blend with finger, sponge or appropriate foundation brush.

Warnings

For external use only

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help 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\aquaeau, methyl trimethicone, phenyl trimethicone, silica, butyloctyl salicylate, dimethicone, neopentyl glycol diheptanoate, c12-15 alkyl benzoate, butylene glycol, dimethicone silylate, lauryl peg-9 polydimethylsiloxyethyl dimethicone, ethylhexyl palmitate, glycerin, polysilicone-11, citrullus vulgaris (watermelon) fruit extract, sodium hyaluronate, lecithin, pyrus malus (apple) fruit extract, lens esculenta (lentil) fruit extract, glycine soja (soybean) protein, litchi chinensis seed extract, laminaria saccharina extract, peg-10 dimethicone, tocopheryl acetate, methicone, trimethylsiloxysilicate, sodium pca, sodium lactate, thermus thermophilus ferment, triethyl citrate, laureth-7, silica dimethyl silylate, polymethylsilsesquioxane, magnesium aluminum silicate, xanthan gum, dimethicone/peg-10/15 crosspolymer, sodium chloride, dextrin, triethoxycaprylylsilane, disteardimonium hectorite, caprylyl glycol, hexylene glycol, polyglutamic acid, zinc stearate, disodium edta, phenoxyethanol, potassium sorbate, sodium dehydroacetate [+/- mica, titanium dioxide (ci 77891), iron oxides (ci 77491), iron oxides (ci 77492), iron oxides (ci 77499)] <iln41311>

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 / MXCT

PRINCIPAL DISPLAY PANEL - 30 ML Bottle Carton

**M•A•C
STUDIO**

**STUDIO WATERWEIGHT
SPF 30 FOUNDATION
BROAD SPECTRUM SPF 30**

30 ML/1.0 FL OZ e

Back
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MAC

MAC
STUDIO

STUDIO WATERWEIGHT
SPF 30 FOUNDATION
BROAD SPECTRUM SPF 30
30 ML / 1.0 FL OZ e

SHAKE WELL.

Drug Facts

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Drug Facts (continued)

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Red:009



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 TORONTO, ONTARIO, CANADA M5V 1R7
 LONDON W1K 3BD / MXCT
 MADE IN BELGIUM/FABRIQUE EN BELGIQUE
 MACCOSMETICS.COM



MXCT011111

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IMPRIME EN POLONE.

MAC STUDIO WATERWEIGHT SPF 30 BROAD SPECTRUM FOUNDATION SUNSCREEN

octinoxate, titanium dioxide, and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0075
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05425 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.03364 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.02279 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
PHENYL TRIMETHICONE (UNII: DROK5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
WATERMELON (UNII: 231473QB6R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
APPLE (UNII: B423VGH5S9)	
LENS CULINARIS FRUIT (UNII: ZYZ076G9JH)	
SOYBEAN (UNII: L7HT8F1ZOD)	
LITCHI CHINENSIS SEED (UNII: 9294024N9Q)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

LAURETH-7 (UNII: Z95S6G8201)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
XANTHAN GUM (UNII: TTV12P4NEE)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ICODEXTRIN (UNII: 2NX48Z0A9G)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
ZINC STEARATE (UNII: H92E6QA4FV)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0075-1	1 in 1 CARTON	08/01/2015	
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	08/01/2015	

Labeler - MAKEUP ART COSMETICS (010597206)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture(40046-0075) , pack(40046-0075) , label(40046-0075)