

**MAC PRO LONGWEAR SPF 20 COMPACT FOUNDATION BROAD SPECTRUM SPF 20-  
octinoxate and titanium dioxide cream  
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 PRO LONGWEAR SPF 20 COMPACT FOUNDATION BROAD SPECTRUM SPF 20**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Octinoxate 2.40%	Sunscreen
Titanium Dioxide 2.30%	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**

dimethicone, nylon-12, polyethylene, dimethicone crosspolymer, isododecane, dimethicone silylate, tocopheryl acetate, sodium hyaluronate, butyrospermum parkii (shea butter), caryocar brasiliense fruit oil, persea gratissima (avocado) oil, olea europaea (olive) fruit oil, ceramide 2, ethylhexylglycerin, ethylhexyl palmitate, cetyl peg/ppg-10/1 dimethicone, phytosterols, alumina, silica dimethyl silylate, triethoxycaprylylsilane, butylene glycol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate [+/- mica, titanium dioxide (ci 77891), iron oxides (ci 77491, ci 77492, ci 77499)] <iln40537>

**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

**PRINCIPAL DISPLAY PANEL - 10 g Jar Carton**

**M•A•C**

**PRO LONGWEAR  
SPF 20 COMPACT FOUNDATION  
BROAD SPECTRUM SPF 20**

NET WT./POIDS NET 10g/0.35 US OZ e

M·A·C

**PRO LONGWEAR  
SPF 20 COMPACT FOUNDATION  
BROAD SPECTRUM SPF 20**

NET WT. / POIDS NET 10g / 0.35 US OZ e

Back  
▲ 2 ▼  
M·A·C

PRINTED IN CANADA.  
IMPRIMÉ AU CANADA.

DIST. BY/PAR: MAKE-UP ART COSMETICS  
TORONTO, ONTARIO, CANADA M5V 1R7  
LONDON W1K 3BQ / MPE9  
MADE IN CANADA/  
FABRIQUÉ AU CANADA  
MACCOSMETICS.COM



CTN#28

**Drug Facts**

Active Ingredients	Purpose
Octinoxate 2.40%	Sunscreen
Titanium Dioxide 2.30%	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 ▶

**Drug Facts (continued)**

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** dimethicone, nylon-12, polyethylene, dimethicone crosspolymer, isododecane, dimethicone silylate, tocopheryl acetate, sodium hyaluronate, butyrospermum parkii (shea butter), caryocar brasiliense fruit oil, persea gratissima (avocado) oil, olea europaea (olive) fruit oil, ceramide 2, ethylhexylglycerin, ethylhexyl palmitate, cetyl peg/ppg-10/1 dimethicone, phytosterols, alumina, silica dimethyl silylate, triethoxycaprylsilane, butylene glycol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate [+/- mica, titanium dioxide (ci 77891), iron oxides (ci 77491, ci 77492, ci 77499)] <ln40537>

**Other information**

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

**USAGE:** APPLY TO FACE USING A SPONGE OR FOUNDATION BRUSH. BLEND WITH FINGERS, SPONGE OR BRUSH.

MPE9011113

**MAC PRO LONGWEAR SPF 20 COMPACT FOUNDATION BROAD SPECTRUM SPF 20**

octinoxate and titanium dioxide cream

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0071
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.4 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.3 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
dimethicone (UNII: 92RU3N3Y1O)	
nylon-12 (UNII: 446U8J075B)	
high density polyethylene (UNII: UG00KM4WR7)	
isododecane (UNII: A8289P68Y2)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
shea butter (UNII: K49155WL9Y)	
caryocar brasiliense fruit oil (UNII: WD19AGC94F)	
avocado oil (UNII: 6VNO72PFC1)	
olive oil (UNII: 6UYK2W1W1E)	
ceramide 2 (UNII: C04977SRJ5)	
ethylhexylglycerin (UNII: 147D247K3P)	
ethylhexyl palmitate (UNII: 2865993309)	
aluminum oxide (UNII: LM26O6933)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
butylene glycol (UNII: 3XUS85K0RA)	
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (UNII: 255PIF62MS)	
mica (UNII: V8A1AW0880)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0071-1	1 in 1 CARTON		
1		10 g in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2014	

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

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(40046-0071) , REPACK(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(40046-0071) , RELABEL(40046-0071) , REPACK(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(40046-0071) , RELABEL(40046-0071) , REPACK(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(40046-0071) , RELABEL(40046-0071) , REPACK(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(40046-0071) , RELABEL(40046-0071) , REPACK(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(40046-0071)

## Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 3/2014

MAKEUP ART COSMETICS