

**MINERALIZE MOISTURE SPF 15 FOUNDATION- 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.

MINERALIZE MOISTURE SPF 15 FOUNDATION

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 7.50%	Sunscreen
Titanium Dioxide 2.00%	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, peg-30 dipolyhydroxystearate, dimethicone, ethylhexyl palmitate, caprylic/capric triglyceride, neopentyl glycol diethylhexanoate, triethylhexanoin, butylene glycol, glycerin, octyldodecyl neopentanoate, squalane, silica, tocopherol, tocopheryl acetate, sodium hyaluronate, lysine, butyrospermum parkii (shea butter), haberlea rhodopensis leaf extract, tamarindus indica seed extract, beta vulgaris (beet) root extract/beta vulgaris/extrait de racine de betterave, yeast extract/faex/extrait de levure, phytantriol, octyldodecyl pca, sodium pca, trehalose, magnesium chloride, sodium chloride, potassium chloride, zinc chloride, simethicone, synthetic fluorphlogopite, disteardimonium hectorite, polyglyceryl-3 beeswax, triethoxycaprylylsilane, dimethicone

crosspolymer-3, tin oxide, urea, triacetin, polyquaternium-51, caprylyl glycol, hexylene glycol, hydrogenated lecithin, disodium edta, phenoxyethanol, sodium dehydroacetate [+/- mica, titanium dioxide (ci 77891), iron oxides (ci 77491), iron oxides (ci 77492), iron oxides (ci 77499)] <iln 39648>

Other Information

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

DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7
LONDON W1K 3BQ / MM2Y

PRINCIPAL DISPLAY PANEL - 30 ML Bottle Carton

M•A•C

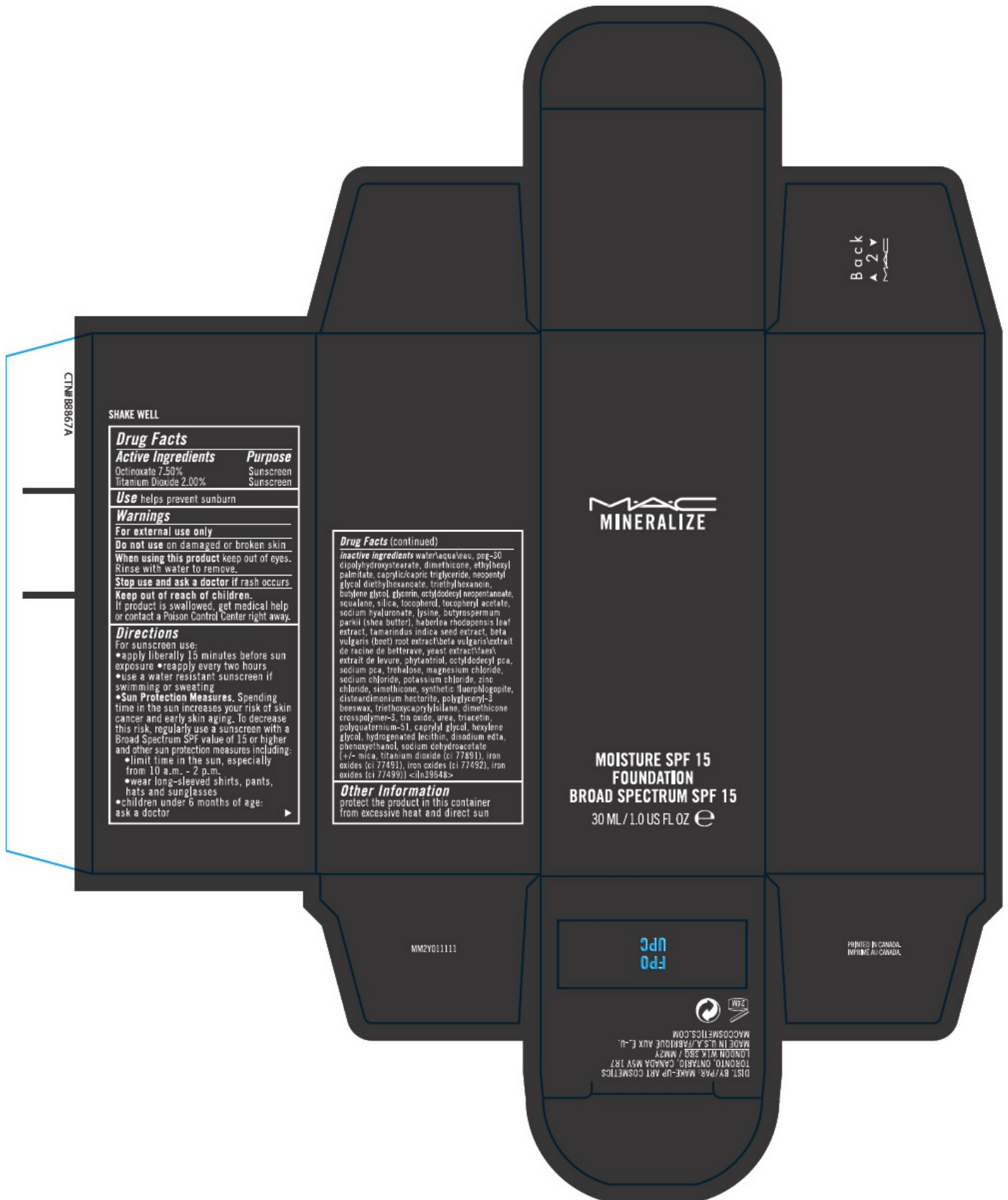
MINERALIZE

MOISTURE SPF 15

FOUNDATION

BROAD SPECTRUM SPF 15

30 ML/1.0 US FL OZ e



CTN# B8867A

SHAKE WELL

Drug Facts

Active Ingredients	Purpose
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Titanium Dioxide 2.00%	Sunscreen

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Drug Facts (continued)

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MAC
MINERALIZE

MOISTURE SPF 15
FOUNDATION
BROAD SPECTRUM SPF 15
30 ML / 1.0 US FL. OZ e

Back
▲ 2 ▼
MAC

MMZYQ11111

UPC
FPO

PRINTED IN CANADA
IMPRIME AU CANADA

MADE IN U.S.A. / FABRIQUE AUX E.-U.
LONDON W1K 3SD / MMZY
TORONTO, ONTARIO, CANADA M5V 1R7
DIST. BY/PAR: MAKE-UP ART COSMETICS
MACCOSMETICS.COM

MINERALIZE MOISTURE SPF 15 FOUNDATION

octinoxate and titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
peg-30 dipolyhydroxystearate (UNII: 9713Q0S7FO)	
dimethicone (UNII: 92RU3N3Y1O)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
neopentyl glycol diethylhexanoate (UNII: U68ZV6W62C)	
triethylhexanoin (UNII: 7K3W1BIU6K)	
butylene glycol (UNII: 3XUS85K0RA)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
squalane (UNII: GW89575KF9)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
tocopherol (UNII: R0ZB2556P8)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
lysine (UNII: K3Z4F929H6)	
shea butter (UNII: K49155WL9Y)	
haberlea rhodopensis leaf (UNII: N042Q65701)	
tamarind seed (UNII: 6AHP8A7OML)	
beta vulgaris (UNII: 4G174V5051)	
yeast (UNII: 3NY3SM6B8U)	
phytantriol (UNII: 8LVI07A72W)	
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)	
trehalose (UNII: B8WCK70T7D)	
magnesium chloride (UNII: 02F3473H9O)	
sodium chloride (UNII: 451W47IQ8X)	
potassium chloride (UNII: 660YQ98I10)	
zinc chloride (UNII: 86Q357L16B)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
stannic oxide (UNII: KM7N50LOS6)	
urea (UNII: 8W8T17847W)	
triacetin (UNII: XHX3C3X673)	
caprylyl glycol (UNII: 00YIU5438U)	
hexylene glycol (UNII: KEH0A3F75J)	
edetate disodium (UNII: 7FLD91C86K)	
phenoxyethanol (UNII: HIE492ZZ3T)	
sodium dehydroacetate (UNII: 8W46YN971G)	

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:40046-0061-1	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/02/2012	

Labeler - MAKEUP ART COSMETICS (010597206)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(40046-0061) , REPACK(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(40046-0061) , RELABEL(40046-0061) , REPACK(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	RELABEL(40046-0061) , REPACK(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(40046-0061)

Establishment			
Name	Address	ID/FEI	Business Operations

ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(40046-0061)
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Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(40046-0061) , RELABEL(40046-0061) , REPACK(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(40046-0061) , RELABEL(40046-0061) , REPACK(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(40046-0061) , RELABEL(40046-0061) , REPACK(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(40046-0061) , RELABEL(40046-0061)

Establishment

Name	Address	ID/FEI	Business Operations
MANA PRODUCTS, INC.		078870292	MANUFACTURE(40046-0061)