

PRO-LONGWEAR SPF 10 FOUNDATION- titanium dioxide lotion
MAKE UP 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.

ACTIVE INGREDIENT: TITANIUM DIOXIDE, 4.7%

WARNINGS: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. IF IRRITATION PERSISTS, CONSULT A HEALTH CARE PRACTITIONER. KEEP OUT OF REACH OF CHILDREN. APPLY BEFORE SUN EXPOSURE

MAC

PRO LONGWEAR

SPF 10

FOUNDATION

30 ML/1.0 OZ US FL

MAKE UP ART COSMETICS
NEW YORK, NY

**PRO LONGWEAR
SPF 10 FOUNDATION
FOND DE TEINT SPF 10**

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ACTIVE INGREDIENT: TITANIUM DIOXIDE 4.70%

INGREDIENTS: WATER/AQUA/EAU, CYCLOPENTASILOXANE, TRIMETHYLSILOXYSILICATE, BUTYLENE GLYCOL, TRIMETHYL PENTAPHENYL TRISILOXANE, PHENYL TRIMETHICONE, POLYGLYCERYL-3 DIISOSTEARATE, MAGNESIUM SULFATE, TRIBEHENYL, PEG-10 DIMETHICONE, BIS-PEG/PPG-14/14 DIMETHICONE, TOCOPHERYL ACETATE, SODIUM HYALURONATE, DIMETHICONE, PHENYL METHICONE, POLYGLYCERYL-4 ISOSTEARATE, CETYL PEG/PPG-10/1 DIMETHICONE, METHICONE, TETRAMETHYL HEXAPHENYL TETRASILOXANE, GLYCERIN, ETHYLHEXYLGLYCERIN, SILICA, DISTEARDIMONIUM HECTORITE, LAURETH-7, HEXYL LAURATE, XANTHAN GUM, CELLULOSE GUM, PROPYLENE CARBONATE, ALUMINA, POLYMETHYLSILSESQUOXANE, DIMETHICONE Silylate, PHENOXYETHANOL, SORBIC ACID, CHLORPHENESIN (+/-) MICA, IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891), CHROMIUM OXIDE GREENS (CI 77288)1 <ILM36562>



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SPF 10 FOUNDATION
FOND DE TEINT SPF 10
30 ML/1.0 US FL OZ e**

PRO-LONGWEAR SPF 10 FOUNDATION

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	4.7 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0038-1	1 in 1 CARTON		
1	NDC:40046-0038-2	30 mL in 1 BOTTLE, GLASS		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/09/2010	

Labeler - MAKE UP ART COSMETICS (010597206)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
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Estee Lauder Cosmetics, Ltd		253616536	manufacture
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Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture

Revised: 8/2010

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