

**MINERALIZE SPF 15 FOUNDATION LOOSE- titanium dioxide powder**  
**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.*

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ACTIVE INGREDIENT: TITANIUM DIOXIDE 7.0%

INACTIVE INGREDIENTS: MICA [] HORDEUM DISTICHON (BARLEY) EXTRACT\EXTRAIT D'ORGE A DEUX RANGS [] TRITICUM VULGARE (WHEAT) GERM OIL [] ASCORBYL PALMITATE [] TOCOPHERYL ACETATE [] SQUALANE [] METHICONE [] POTASSIUM SORBATE [] CHLORPHENESIN [] [+/- TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] BISMUTH OXYCHLORIDE (CI 77163) [] BLUE 1 (CI 42090) [] CARMINE (CI 75470) [] CHROMIUM HYDROXIDE GREEN (CI 77289) [] CHROMIUM OXIDE GREENS (CI 77288) [] FERRIC FERROCYANIDE (CI 77510) [] YELLOW 5 LAKE (CI 19140) [] ZINC OXIDE (CI 77947)

WARNING: KEEP OUT OF EYES. DISCONTINUE USE IF IRRITATION DEVELOPS. KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

MAC

MINERALIZE

SPF 15 FOUNDATION

LOOSE

8.5 g/ 0.30 US oz

makeup art cosmetics distr.  
toronto, CANADA M3J 2W3

FACTORY ORDER  
**M9X6-01-1111**

CUSTOMER  
**MAC**

APPROVAL FOR



	YES	NO
SIZE	<input type="checkbox"/>	<input type="checkbox"/>
STYLE	<input type="checkbox"/>	<input type="checkbox"/>
COPY	<input type="checkbox"/>	<input type="checkbox"/>
COLOUR BREAK	<input type="checkbox"/>	<input type="checkbox"/>
ACTUAL COLOUR	<input type="checkbox"/>	<input type="checkbox"/>

AS APPROVED COLOUR STANDARDS

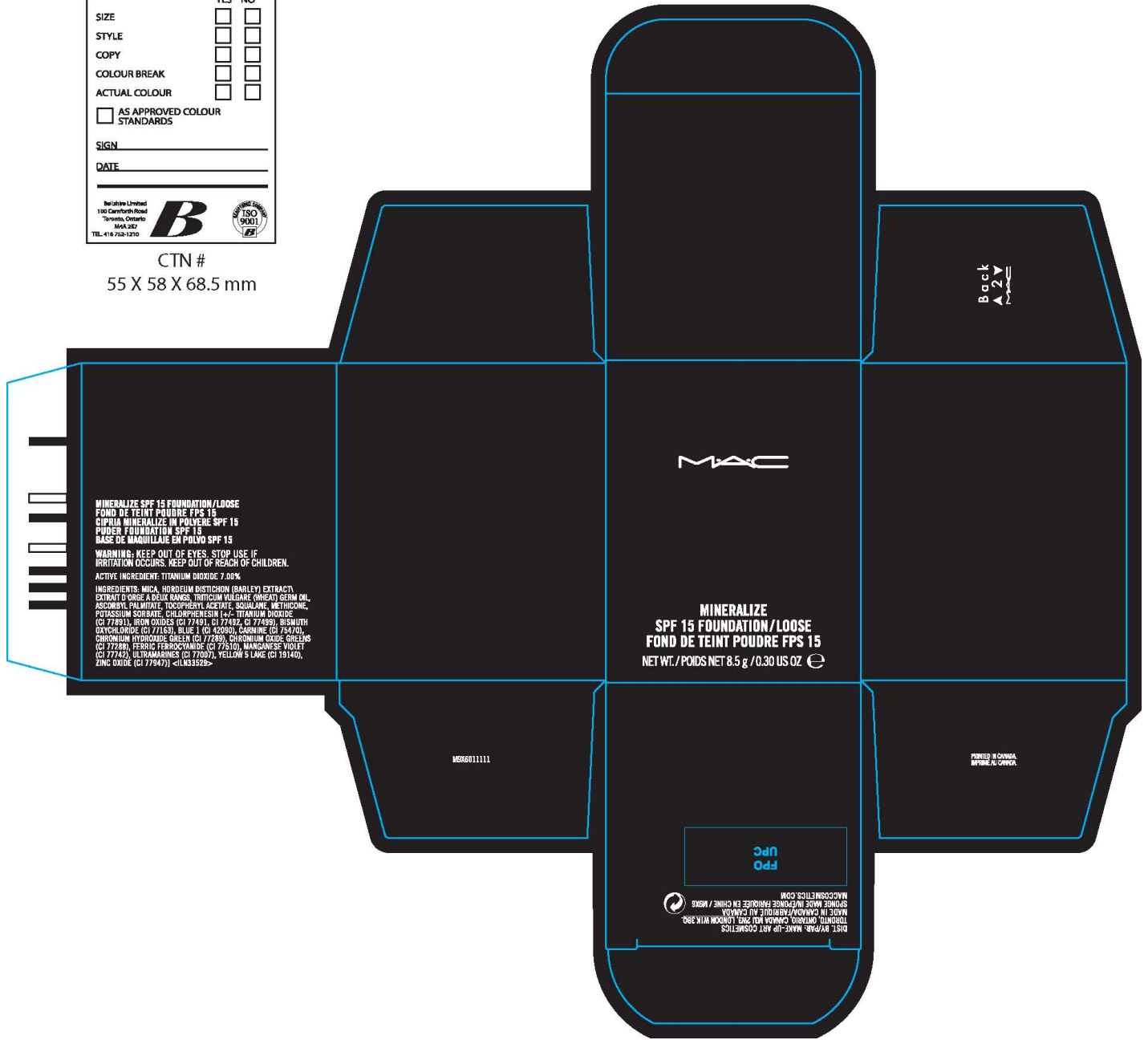
SIGN \_\_\_\_\_

DATE \_\_\_\_\_

Bel Litho Limited  
 110 Camforth Road  
 Toronto, Ontario  
 M9A 3E7  
 TEL: 416 753-1210

CTN #  
 55 X 58 X 68.5 mm



# MINERALIZE SPF 15 FOUNDATION LOOSE

titanium dioxide powder

## Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:40046-0031

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.0 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BARLEY BRAN (UNII: 2TXV6Z67KP)	
WHEAT GERM OIL (UNII: 14C97E680P)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SQUALANE (UNII: GW89575KF9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
COCHINEAL (UNII: TZ8Z31B35M)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0031-1	1 in 1 CARTON		
1	NDC:40046-0031-2	8.5 g in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2007	

**Labeler** - MAKEUP 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
Estee Lauder Cosmetics, Ltd		253616536	manufacture

## 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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
CRYSTAL CLAIRE COSMETICS		205493484	manufacture

Revised: 9/2011

MAKEUP ART COSMETICS