

**SELECT SPF 15 FOUNDATION- octinoxate 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.*

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ACTIVE INGREDIENT: OCTINOXATE 7.50%

INACTIVE INGREDIENTS: WATER [] DIMETHICONE [] PHENYL TRIMETHICONE [] TALC [] BUTYLENE GLYCOL [] POLYMETHYL METHACRYLATE [] POLYDECENE [] GLYCERYL DILAURATE [] CAPRYLYL GLYCOL [] TEA-ISOSTEARATE [] TEA-STEARATE [] KAOLIN [] TOCOPHERYL ACETATE [] ASCORBYL PALMITATE [] RETINYL PALMITATE [] HYDROGENATED LECITHIN [] PANTETHINE [] XANTHAN GUM [] CELLULOSE GUM [] TETRADIBUTYL PENTAERITHRITYL HYDROXYHYDROCINNAMATE [] HEXYLENE GLYCOL [] STEARETH-21 [] MAGNESIUM ALUMINUM SILICATE [] STEARETH-2 [] POLYPERFLUOROMETHYLISOPROPYL ETHER [] STEARYL ALCOHOL [] DISODIUM EDTA [] PHENOXYETHANOL [] [+/- TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] CHROMIUM OXIDE GREENS (CI 77288)]

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OR REACH OF CHILDREN.

MAC

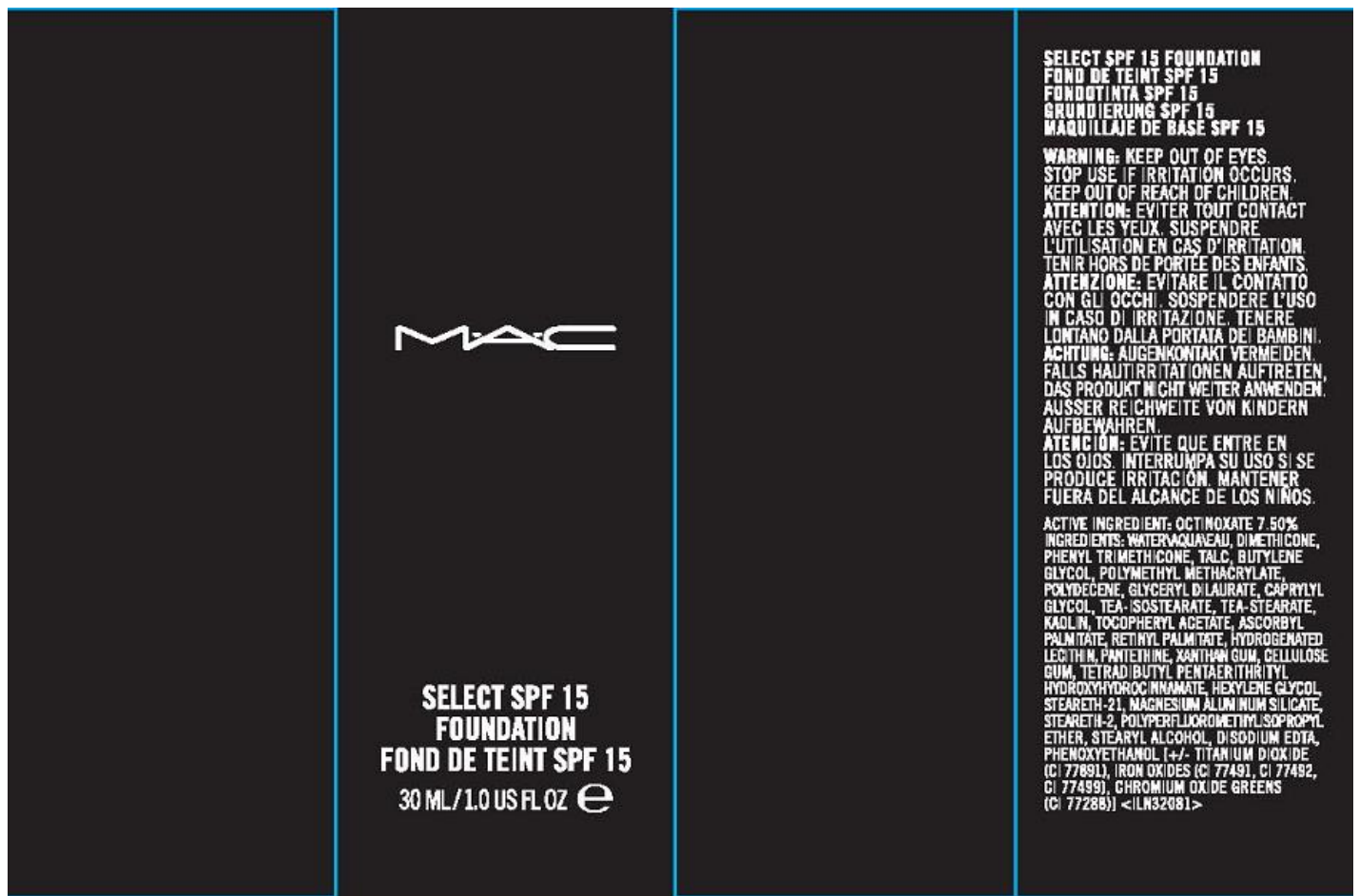
SELECT

SPF 15

FOUNDATION

1.0 FL/OZ/ 30 ML

DISTR. MAKEUP ART COSMETICS  
ONTARIO, CANADA



## SELECT SPF 15 FOUNDATION

octinoxate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0052
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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
TALC (UNII: 7SEV7J4R1U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

TROLAMINE (UNII: 9O3K93S3TK)
STEARIC ACID (UNII: 4ELV7Z65AP)
KAOLIN (UNII: 24H4NWX5CO)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
PANTETHINE (UNII: 7K81IL792L)
XANTHAN GUM (UNII: TTV12P4NEE)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
STEARETH-21 (UNII: 53J3F32P58)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
CHROMIC OXIDE (UNII: X5Z09SU859)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0052-1	1 in 1 CARTON		
1	NDC:40046-0052-2	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	12/01/2001	

**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