

**PREP AND PRIME FACE PROTECTION SPF 50- zinc oxide, 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 INGREDIENTS: ZINC OXIDE 16.10% [] OCTINOXATE 7.50%

INACTIVE INGREDIENTS: WATER\AQUA\EAU [] CYCLOPENTASILOXANE [] BUTYLENE GLYCOL [] PEG-7 DIMETHICONE [] CYCLOHEXASILOXANE [] DIMETHICONE [] PHENYL TRIMETHICONE [] VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER [] METHYL GLUCETH-10 [] GLYCERIN [] DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER [] CAFFEINE [] TOCOPHEROL [] SUCROSE [] STEARYL GLYCYRRHETINATE [] CELLULOSE ACETATE [] METHICONE [] PEG/PPG-19/19 DIMETHICONE [] MAGNESIUM SULFATE [] SILICA DIMETHYL SILYLATE [] SILICA [] SORBIC ACID [] PHENOXYETHANOL [] CHLORPHENESIN

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

PRINCIPAL DISPLAY PANEL

MAC

PREP + PRIME

FACE PROTECT

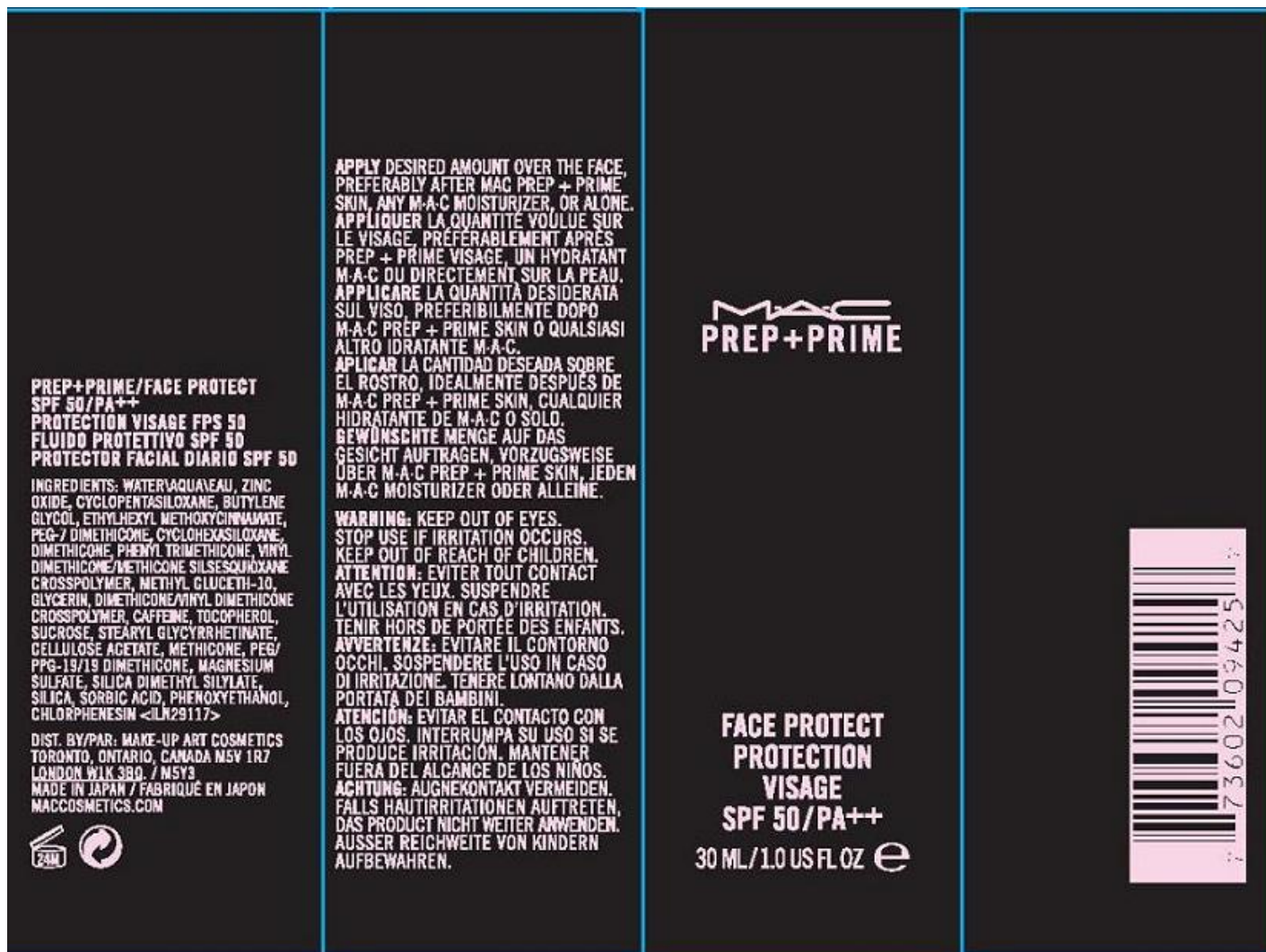
PROTECTION

SPF 50

1 FL OZ/ 30 ML

makeup art cosmetics

toronto, canada



## PREP AND PRIME FACE PROTECTION SPF 50

zinc oxide, octinoxate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:40046-0047
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16.1 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAFFEINE (UNII: 3G6A5W338E)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
SUCROSE (UNII: C151H8M554)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBIC ACID (UNII: X045WJ989B)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0047-1	1 in 1 CARTON		
1	NDC:40046-0047-2	30 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2006	

**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
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Aramis Inc.		042918826	manufacture
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## 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

Name	Address	ID/FEI	Business Operations
NIPPON SHIKIZAI INC		692572936	manufacture