

MAC PREP AND PRIME FACE PROTECT BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion
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.

MAC PREP AND PRIME FACE PROTECT LOTION BROAD SPECTRUM SPF 50

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Avobenzone 3.00%	Sunscreen
Homosalate 5.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 2.70%	Sunscreen
Oxybenzone 3.00%	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, butyloctyl salicylate, methyl trimethicone, neopentyl glycol diheptanoate, aleurites moluccana (kukui) seed oil, lauryl peg-9 polydimethylsiloxyethyl dimethicone, peg-100 stearate, butylene glycol, glyceryl stearate, dipentaerythrityl tri-polyhydroxystearate, sodium hyaluronate,

lavandula angustifolia (lavender) flower water, laminaria ochroleuca extract, laminaria digitata extract, algae extract, caffeine, ethylhexylglycerin, caprylic/capric triglyceride, sorbitol, methyl dihydrojasmonate, ergothioneine, dehydroxanthan gum, vp/eicosene copolymer, saccharide isomerate, ammonium acryloyldimethyltaurate/vp copolymer, potassium cetyl phosphate, caprylyl glycol, citric acid, stearic acid, cetyl alcohol, linalool, limonene, disodium edta, phenoxyethanol, sodium dehydroacetate, mica <iln40739>

Other information

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

DIST. BY: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7
LONDON W1K 3BQ / MTX7

PRINCIPAL DISPLAY PANEL - 30 ML Tube Carton

M•A•C

PREP+PRIME

FACE PROTECT

LOTION SPF 50

BROAD SPECTRUM

SPF 50

30 ML/1.0 US FL OZ e

CTN# 356

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Drug Facts (continued)

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USAGE: APPLY DESIRED AMOUNT OVER THE FACE, PREFERABLY AFTER M-A-C PREP+PRIME SKIN. ANY M-A-C MOISTURIZER OR ALONE.

**M-A-C
PREP+PRIME**

**FACE PROTECT
LOTION SPF 50
BROAD SPECTRUM
SPF 50**

30 ML / 1.0 US FL OZ e

Back
▲ 2 ▼
M-A-C



MTX7011111

PRINTED IN CANADA,
IMPRIME AU CANADA.



DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7
LONDON W1K 3BD / MTX7
MADE IN U.S.A./FABRIQUE AUX E.-U.
MACCOSMETICS.COM

MAC PREP AND PRIME FACE PROTECT BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0309 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.0515 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.0515 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.0278 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0309 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CAFFEINE (UNII: 3G6A5W338E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBITOL (UNII: 506T60A25R)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
DEHYDROXANTHAN GUM (UNII: 63ZP711BQO)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	

MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0063-1	1 in 1 CARTON	02/02/2012	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/02/2012	

Labeler - MAKEUP ART COSMETICS (010597206)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(40046-0063) , REPACK(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(40046-0063) , REPACK(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(40046-0063) , REPACK(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0063)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(40046-0063)

Revised: 1/2019

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