

STUDIO MOISTURE FIX SPF 15- zinc oxide, octinoxate 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 INGREDIENTS: ZINC OXIDE 6.70% [] OCTINOXATE 3.50%

INACTIVE INGREDIENTS: WATER [] DIMETHICONE [] C12-15 ALKYL BENZOATE [] BUTYLENE GLYCOL [] SILICA [] ISONONYL ISONONANOATE [] GLYCERIN [] TOCOPHERYL ACETATE [] CHOLESTEROL [] ASTROCARYUM MURUMURU BUTTER [] CAFFEINE [] SODIUM RNA [] SODIUM HYALURONATE [] PHYTOSPHINGOSINE [] HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE [] PORIA COCOS SCLEROTIUM EXTRACT [] THERMUS THERMOPHILLUS FERMENT [] POLYGONUM CUSPIDATUM ROOT EXTRACT [] SACCHAROMYCES LYSATE EXTRACT [] YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE [] TRITICUM VULGARE (WHEAT) GERM EXTRACT [] SUCROSE [] MAGNESIUM ASCORBYL PHOSPHATE [] POLYSORBATE 20 [] SQUALANE [] POLYSORBATE 80 [] GLYCERYL STEARATE [] PEG-100 STEARATE [] STEARETH-21 [] PVP [] SODIUM CITRATE [] CITRIC ACID [] DISTEARDIMONIUM HECTORITE [] CETYL ESTERS [] HEXYLENE GLYCOL [] POLYETHYLENE [] POLYHYDROXYSTEARIC ACID [] ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER [] AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER [] ISOHEXADECANE [] CAPRYLYL GLYCOL [] TRIETHOXYCAPRYLYLSILANE [] LINOLEIC ACID [] DISODIUM EDTA [] PROPYLENE GLYCOL DICAPRATE [] FRAGRANCE (PARFUM) [] BHT [] PHENOXYETHANOL [] CHLORPHENESIN

DIRECTIONS: SMOOTH OVER CLEAN FACE AND THROAT

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

PRINCIPAL DISPLAY PANEL

MAC

STUDIO

MOISTURE FIX

SPF 15

1.7 US FL OZ/ 50 ML

DISTR MAKE-UP ART COSMETICS

TORONTO, ONTARIO, CANADA, M5V1R7

STUDIO MOISTURE FIX SPF 15
LOTION HYDRATANTE STUDIO SPF 15
EMULSIONE IDRATANTE SPF 15
STUDIO FEUCHTIGKEITSLOTION SPF 15
LOCION HIDRATANTE STUDIO SPF 15

**ACTIVE INGREDIENTS: ZINC OXIDE 6.7%,
OCTINOXATE 3.5%**

**INGREDIENTS: WATER/AQUA/EAU, DIMETHICONE,
C12-15 ALKYL BENZOATE, BUTYLENE GLYCOL,
SILICA, ISODONYL ISONONANOATE, GLYCERIN,
TOCOPHERYL ACETATE, CHOLESTEROL,
ASTROCARYUM MURUMURU BUTTER, CAFFEINE,
SODIUM RNA, SODIUM HYALURONATE,
PHYTOSPHINGOSINE, HORDEUM VULGARE
(BARLEY) EXTRACT/EXTRAIT D'ORGE, PORUA
COCOS SCLEROTIUM EXTRACT, THERMUS
THERMOPHILLUS FERMENT, POLYGONUM
CUSPIDATUM ROOT EXTRACT, SACCCHAROMYCES
LYSATE EXTRACT, YEAST EXTRACT/EXTRAIT
DE LEVURE, TRITICUM VULGARE (WHEAT) GERM
EXTRACT, SUCROSE, MAGNESIUM ASCORBYL
PHOSPHATE, POLYSORBATE 20, SQUALANE,
POLYSORBATE 80, GLYCERYL STEARATE, PEG-100
STEARATE, STEARETH-21, PVP, SODIUM CITRATE,
CITRIC ACID, DISTEARDIMONIUM HECTORITE,
CETYL ESTERS, HEXYLENE GLYCOL, POLYETHYLENE,
POLYHYDROXYSTEARIC ACID, ACRYLAMIDE/
SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER,
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP
COPOLYMER, ISOHEXADECANE, CAPRYLYL GLYCOL,
TRIETHOXYCAPRYLYLSILANE, LINOLEIC ACID,
DISODIUM EDTA, PROPYLENE GLYCOL DICAPRATE,
FRAGRANCE (PARFUM), BHT, PHENOXYETHANOL,
CHLORPHENESIN <LN31992>**

**DIST. BY/PAR: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA MSV 1R7
LONDON W1K 3BQ / M6HH-01
MADE IN CANADA/FABRIQUE AU CANADA
MACCOSMETICS.COM**



**SMOOTH OVER CLEAN FACE AND THROAT.
ETENDRE SU LE VISAGE ET LE COU
NETTOYES.
STENDERE SU VISO E COLLO PULITI.
SAMFT AUF DAS GEREINIGTE GESICHT
UND DEN HALS AUFTRAGEN.
APLICAR SOBRE EL ROSTRO Y EL CUELLO
LIMPIOS.**

**WARNING: KEEP OUT OF EYES.
STOP USE IF IRRITATION OCCURS.
KEEP OUT OF REACH OF CHILDREN.
ATTENTION: EVITER TOUT CONTACT
AVEC LES YEUX. SUSPENDRE
L'UTILISATION EN CAS D'IRRITATION.
TENIR HORS DE PORTEE DES ENFANTS.
ATTENZIONE: EVITARE IL CONTATTO
CON GLI OCCHI. SOSPENDERE L'USO
IN CASO DI IRRITAZIONE. TENERE
LONTANO DALLA PORTATA DEI BAMBINI.
ACHTUNG: AUGENKONTAKT VERMEIDEN.
FALLS HAUTIRRITATIONEN AUFRETEN,
DAS PRODUKT NICHT WEITER ANWENDEN.
AUSSER REICHWEITE VON KINDERN
AUFBEWAHREN.
ATENCION: EVITE QUE ENTRE EN
LOS OJOS. INTERRUMPA SU USO SI SE
PRODUCE IRRITACION. MANTENER
FUERA DEL ALCANCE DE LOS NIÑOS.**

M·A·C

**STUDIO
MOISTURE FIX
SPF 15
LOTION HYDRATANTE
STUDIO SPF 15
50 ML / 1.7 US FL OZ e**

STUDIO MOISTURE FIX SPF 15

zinc oxide, octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.7 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
CAFFEINE (UNII: 3G6A5W338E)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BARLEY (UNII: 5PWM7YLI7R)	
FU LING (UNII: XH37TWY5O4)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
YEAST (UNII: 3NY3SM6B8U)	
WHEAT GERM (UNII: YR3G369F5A)	
SUCROSE (UNII: C15IH8M554)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARETH-21 (UNII: 53J3F32P58)	
POVIDONE K17 (UNII: C67P1734QJ)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ISOHEXADECANE (UNII: 918X10UF1E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0046-1	1 in 1 CARTON		

1	NDC:40046-0046-2	50 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	09/01/2006		

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
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

Revised: 7/2011

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