

SKIN DEFENSE MAKEUP SPF-15- octinoxate octisalate oxybenzone lotion
JAFRA COSMETICS INTERNATIONAL

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.

SKIN DEFENSE MAKEUP SPF-15

SUNSCREEN ACTIVE INGREDIENT (SPF 15):

OCTINOXATE/ETHYLHEXYL METHOXYCINNAMATE, OCTISALATE/ETHYLHEXYL SALICYLATE, OXYBENZONE/BENZOPHENONE-3

PURPOSE: SUNSCREEN

OTHER INGREDIENTS: WATER/AQUA, BUTYLENE GLYCOL, ISOPROPYL ISOSTEARATE, DI-PPG-3 MYRISTYL ETHER ADIPATE, STEARIC ACID, POTASSIUM CETHYL PHOSPHATE, HYDROGENATED PALM GLYCERIDES, GLYCERYL STEARATE, LECITHIN, POLYETHYLENE, METHYL METHACRYLATE COPOLYMER, SILICA, DIMETHICONE, SODIUM HYALURONATE, TREHALOSE, SODIUM PCA, POLYQUATERNIUM-51, UREA, GLYCERIN, AVENA SATIVA (OAT) KERNEL EXTRACT, POLYSORBATE 20, TRIETHANOLAMINE, TAGETUS ERECTA (AFRICAN MARIGOLD) EXTRACT, IPOMOEA DIGITATA (FINGERLEAF MORNING GLORY) EXTRACT, PROPYLENE GLYCOL, MACROCYSTIS PYRIFERA EXTRACT, HYDROLYZED WHEAT PROTEIN, PVP, DMDM HYDANTOIN, BIOSACCHARIDE GUM-4, MAGNESIUM ALUMINUM SILICATE, XANTHAN GUM, CHONDRUS CRISPUS (CARRAGEENAN) EXTRACT, FRAGRANCE/PARFUM, PANTHENOL, TOCOPHERYL ACETATE, PEG-4 LAURATE, IODOPROPYNYL BUTYLCARBAMATE, TRISODIUM EDTA [MAY CONTAIN, +/-: TITANIUM DIOXIDE/CI 77891, IRON OXIDES/CI 77491/CI 77492/CI 77499] [FRAGRANCE/PARFUM CONTAINS: CITRONELLOL, ALPHA-ISOMETHYL IONONE, GERANIOL, LIMONENE, LINALOOL].

SPF 15 PROTECTS AGAINST DAMAGING ULTRAVIOLET RAYS. MATTE FINISH. SHEER TO MEDIUM COVERAGE.

TO USE: SMOOTH ON WITH FINGERS OR SPONGE.

CAUTION: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.

DISCONTINUE USE IF SIGNS OF IRRITATION OCCUR.

KEEP OUT OF REACH OF CHILDREN.

JAFRA

SKIN DEFENSE MAKEUP SPF 15

**MAKE-UP MIT
SCHUTZFUNKTION SPF 15
FONDOTINTA DIFESA
PELLE SPF 15**

To use: Smooth on with fingers or sponge.
Caution: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation occur. Keep out of reach of children. Clinically, Allergy and Irritancy tested. Dermatologist tested.

Instrucciones de uso: Aplicar suavemente con las yemas de los dedos o con una esponja para maquillaje.

Precauciones: Sólo para uso externo. Evite el contacto con los ojos. Descontinúe su uso si hubiere irritación. No se deje al alcance de los niños. Clínicamente probado contra alergia e irritación. Probado dermatológicamente.

Anwendung: Mit den Fingern oder einem Schwämmchen auftragen.

Warnung: Nur für den externen Gebrauch. Kontakt mit den Augen vermeiden. Nicht weiter verwenden falls Unverträglichkeiten auftreten. Außer Reichweite von Kindern aufbewahren. Klinisch auf Allergien und Unverträglichkeiten getestet. Dermatologisch getestet.

Uso: Applicare con la punta delle dita o con una spugnetta.

Attenzione: solo per uso esterno. Evitare il contatto con gli occhi. Sospendere l'uso in caso di irritazione. Tenere fuori dalla portata dei bambini. Clínicamente testato contro allergie ed irritazioni. Testato dermatologicamente.

Made in Mexico for:
JAFRA Cosmetics International, Inc.
Westlake Village, CA 91361
Distributed in EU: JAFRA Cosmetics D-80636 Munich
www.JAFRA.com

Hecho en México para:
Distribuidora Comercial JAFRA, S.A. de C.V.
Bd. Adolfo López Mateos 515,
Col. Tiacopac, México, D. F., 01040
JAFRA es Marca Registrada



**LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - MILAN - MOSCOW**

SUNSCREEN ACTIVE INGREDIENT (SPF 15):

Octinoxate/Ethylhexyl Methoxycinnamate, Octisalate/Ethylhexyl Salicylate, Oxybenzone/Benzophenone-3
OTHER INGREDIENTS:
Water/Aqua, Butylene Glycol, Isopropyl Isostearate, Di-PPG-3 Myristyl Ether Adipate, Stearic Acid, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Glyceryl Stearate, Lecithin, Polyethylene, Methyl Methacrylate Copolymer, Silica, Dimethicone, Sodium Hyaluronate, Trehalose, Sodium PCA, Polyquaternium-51, Urea, Glycerin, Avena Sativa (Oat) Kernel Extract, Polysorbate 20, Triethanolamine, Tagetes Erecta (African Marigold) Extract, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Propylene Glycol, Macrocystis Pyrifera Extract, Hydrolyzed Wheat Protein, PVP, DMDM Hydantoin, Biosaccharide Gum-4, Magnesium Aluminum Silicate, Xanthan Gum, Chondrus Crispus (Carrageenan) Extract, Fragrance/Parfum, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropinyl Butylcarbamate, Trisodium EDTA, [May Contain +/- Titanium Dioxide/CI 77891, Iron Oxides/CI 77491/CI 77492/CI 77499] [Fragrance/Parfum contains: Citronellol, Alpha-Isomethyl Ionone, Geraniol, Limonene, Linalool]

INGREDIENTES: Agua, Dióxido de Titanio, Butilenglicol, Metoxicinamato de Octilo, Salicilato de Octilo, Isoestearato de Isopropilo, Adipato de Di-PPG-3 Miristil Eter, Benzofenona-3, Ácido Estearico, Cetil Fosfato de Potasio, Glicéridos de Palma Hidrogenados, Estearato de Glicerilo, Lecitina, Polietileno, Copolímero de Metilmetacrilato, Sílice, Dimeticona, Hialuronato de Sodio, Trehalosa, PCA Sódico, Policuaturnio-51, Urea, Glicerina, Extracto de Semilla de Avena (Avena sativa), Polisorbato 20, Trietanolamina, Extracto de Tagetes Erecta (African Marigold), Extracto de Ipomoea Digitata, Propilenglicol, Extracto de Alga Marina (Macrocystis pyrifera), Proteína Hidrolizada de Trigo, PVP, Hidantoína DMDM, Biosacárido Goma-4, Silicato de Magnesio y Aluminio, Goma Xantán, Extracto de carragenina (Chondrus crispus), Fragancia, Pantenol, Acetato de Tocoferilo, PEG-4 Laurato, Yodopropinil Butilcarbamato, EDTA Trisódico. Puede contener: Dióxido de Titanio, Óxidos de Hierro. [Fragancia contiene: Citronelol, 3-metil-4-(2,6,6-trimetil-2-ciclohexen-1-il) buten-2-ona, Geraniol, d-limoneno, Linalol]

Contains: Oxybenzone
Enthält: Oxybenzon
Contiene: Oxybenzone

JAFRA®

SKIN DEFENSE
MAKEUP SPF 15
MAQUILLAJE FACIAL LÍQUIDO
EXTRA-PROTECCIÓN *FPS 15
30 ml e 1 FL OZ (US)



JAFRA®

TESTER SKIN DEFENSE MAKEUP SPF 15

MUESTRARIO DE MAQUILLAJE FACIAL LÍQUIDO EXTRA-PROTECCIÓN *FPS 15

Contains: 10 testers at .27 FL OZ each

Contenido: 10 pzas de 8 ml c/u / 80 ml

80 ml e 2.7 FL OZ (US)

MAKE-UP MIT SCHUTZFUNKTION SPF 15 - TESTER / FONDOTINTA DIFESA PELLE SPF 15 - TESTER

Caution: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation occur. Keep out of reach of children.
Precauciones: Sólo para uso externo. Evite el contacto con los ojos. Descontinúe su uso si hubiere irritación. No se deje al alcance de los niños. *FPS = Factor de Protección Solar
Warnung: Nur äußerlich anwenden. Augenkontakt vermeiden. Sollte es zu Unverträglichkeiten der Haut kommen, Produkt absetzen. Außer Reichweite von Kindern aufbewahren.
Attenzione: solo per uso esterno. Evitare il contatto con gli occhi. Sospendere l'uso in caso di irritazione. Tenere fuori dalla portata dei bambini.

SUNSCREEN ACTIVE INGREDIENT (SPF 15): Octinoxate/Ethylhexyl Methoxycinnamate, Octisalate/Ethylhexyl Salicylate, Oxybenzone/Benzophenone-3 **OTHER INGREDIENTS:** Water/Aqua, Butylene Glycol, Isopropyl Isostearate, Di-PPG-3 Myristyl Ether Adipate, Stearic Acid, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Glyceryl Stearate, Lecithin, Polyethylene, Methyl Methacrylate Copolymer, Silica, Dimethicone, Sodium Hyaluronate, Trehalose, Sodium PCA, Polyquaternium-51, Urea, Glycerin, Avena Sativa (Oat) Kernel Extract, Polysorbate 20, Triethanolamine, Tagetes Erecta (African Marigold) Extract, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Propylene Glycol, Macrocystis Pyrifera Extract, Hydrolyzed Wheat Protein, PVP, DMDM Hydantoin, Biosaccharide Gum-4, Magnesium Aluminum Silicate, Xanthan Gum, Chondrus Crispus (Carrageenan) Extract, Fragrance/Parfum, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA, [May Contain +/-: Titanium Dioxide/Ci 77891, Iron Oxides/Ci 77491/Ci 77492/Ci 77499] [Fragrance/Parfum contains: Citronellol, Alpha-Isomethyl Ionone, Geraniol, Limonene, Linalool].

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Contains: Oxybenzone / Enthält: Oxybenzon / Contiene: Oxybenzone

Tester - not for resale
 Muestra solamente. No etiquetado para su venta individual.
 Tester - nicht zum Wiederverkauf bestimmt
 Tester - vietata la vendita

Made in Mexico for:
 JAFRA Cosmetics International, Inc.
 Westlake Village, CA 91361
 Distributed in EU: JAFRA Cosmetics D-80636 Munich
 www.JAFRA.com

Hecho en México para:
 Distribuidora Comercial JAFRA, S.A. de C.V.
 Blvd. Adolfo López Mateos 515,
 Col. Tiscapac, México, D. F., 01040
 JAFRA es Marca Registrada

LOS ANGELES - ZURICH
 MUNICH - MEXICO CITY
 MILAN - MOSCOW



SKIN DEFENSE MAKEUP SPF-15

octinoxate octisalate oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-147
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL ISOSTEARATE (UNII: C671XB9Y7T)	
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
METHYL METHACRYLATE (UNII: 196OC77688)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TREHALOSE (UNII: B8WCK70T7I)	

SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
POLIDRONIUM CHLORIDE (UNII: 6716Z5YR3G)
UREA (UNII: 8W8T17847W)
GLYCERIN (UNII: PDC6A3C0OX)
OAT (UNII: Z6J799EAJK)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
TROLAMINE (UNII: 9O3K93S3TK)
TAGETES ERECTA FLOWER (UNII: UH5X33P33E)
IPOMOEA MAURITIANA TUBER (UNII: K67Y2SGX79)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
MACROCYSTIS PYRIFERA (UNII: K31S30G5C4)
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)
POVIDONE K30 (UNII: U725QWY32X)
DMDM HYDANTOIN (UNII: BYR0546TOW)
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
XANTHAN GUM (UNII: TTV12P4NEE)
CHONDRUS CRISPUS (UNII: OQS23HUA1X)
PANTHENOL (UNII: WV9CM0O67Z)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PEG-4 LAURATE (UNII: AYP4VM3N1Z)
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)
EDETATE TRISODIUM (UNII: 420IP921MB)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-147-11	1 in 1 BOX		
1	NDC:68828-147-67	30 mL in 1 BOTTLE		
2	NDC:68828-147-10	10 in 1 BOX		
2	NDC:68828-147-17	8 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/24/2012	

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Registrant - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 5/2012

JAFRA COSMETICS INTERNATIONAL