

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

TESTER SKIN DEFENSE MAKEUP SPF 15

CONTAINS: 10 TESTERS AT .27 FL OZ EACH

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, 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 Esteárico, Cetil Fosfato de Potasio, Glicéridos de Palma Hidrogenados, Estearato de Glicerilo, Lecitina, Polietileno, Copolímero de Metilmetacrilato, Sílice, Dimeticona, Hialuronato de Sodio, Trehalosa, PCA Sódico, Policuaternio-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 carragena (Chondrus crispus), Fragancia, Pantenol, Acetato de Tocoferilo, PEG-4 Laurato, Yodopropinil Butilcarbamat, 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

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:
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Hecho en México para:
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 MUNICH - MEXICO CITY
 MILAN - MOSCOW



**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)

SKIN DEFENSE MAKEUP SPF 15

octinoxate octisalate oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-047 |
| 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: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y) | OXYBENZONE | 2 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |

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| ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T) |
| 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: K31S3OG5C4) |
| 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: AYF4VM3N1Z) |
| IODOPROPYNYL BUTYLCARBAMATE (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:68828-047-67 | 1 in 1 BOX | | |
| 1 | NDC:68828-047-11 | 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 | 04/24/2012 | |

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Revised: 4/2012

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