

FACE AND BODY SUNSCREEN SPRAY SPF 35- homosalate, oxybenzone, octinoxate, octisalate, octocrylene lotion

Jafra Cosmetics International Inc

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.

Face and Body Sunscreen Spray SPF 35

Sunscreen active ingredients (SPF 35):

Homosalate, Octinoxate/Ethylhexyl Methoxycinnamate , Oxybenzone/Benzophenone-3, Octisalate/Ethylhexyl Salicylate, Octocrylene

Purpose: Sunscreen

Keep out of reach of children

Discontinue use if signs of irritation appear.

Caution: For external use only. Avoid contact with eyes. Seek the advice of a physician prior to use on children under six months of age.

To use: Apply sunscreen product before exposure. Re-apply frequently to maintain protection, especially after perspiring, swimming, or toweling.

Other Ingredients:

Water/Aqua, Acrylates Copolymer, Glycerin, Thermus Thermophilus Ferment, Polysorbate 20, Sorbitan Oleate, DMDM Hydantoin, Cetearyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Trethanolamine, Glycyrrhiza Glabra (Licorice) Extract, Moringa Oliefera Extract, Vetivera Zinzanoids (Khus Root) Extract, Withania Somnifera (winter Cherry) Extract, Panthenol, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Trisodium EDTA, Tocopheryl Acetate, Butyrospermum Parkii (Shea Butter) Fruit, Zingiber Officinale (Ginger) Extract, Bisabolol, Butylene Glycol, Pentylene Glycol, Propamidobenzoic Acid.

**Sonnenschutz Spray für
Gesicht und Körper SPF 35
Fortschrittlicher UVB - Schutz**

**Crema Protezione Solare
Viso & Corpo SPF 35
Protezione Avanzata UV**

Oil-free, fragrance-free, paba-free, water-resistant. Contains Ayurvedic botanicals and a heat activated protector.

To use: Apply sunscreen product before exposure. Re-apply frequently to maintain protection, especially after perspiring, swimming or toweling.

Caution: For external use only. Avoid contact with the eyes. Discontinue use if signs of irritation appear. Seek the advice of a physician prior to use on children under six months of age. Keep out of reach of children.

Resistente al agua. No contiene aceite, fragancia ni ácido para-aminobenzoico (PABA). Contiene un protector termoactivado e ingredientes ayurvédicos de origen botánico.

Instrucciones de uso: Aplicar bloqueador solar antes de la exposición al sol. Y aplicarlo frecuentemente para mantener la protección solar, principalmente después de una sudoración abundante, nadar o secarse.

Precaución: Sólo para uso externo. Evite el contacto con los ojos. Suspnda su uso en caso de irritación o salpullido. Para uso en niños menores de 6 meses, consulte a su médico. No se deje al alcance de los niños. FPS=Factor de Protección Solar

SUNSCREEN ACTIVE INGREDIENTS (SPF 35):

Homosalate, Octinoxate/Ethylhexyl Methoxycinnamate, Oxybenzone/Benzophenone-3, Octisalate/Ethylhexyl Salicylate, Octocrylene OTHER INGREDIENTS:

Water/Aqua, Acrylates Copolymer, Glycerin, Thermus Thermophilus Ferment, Polysorbate 20, Sorbitan Oleate, DMDM Hydantoin, Cetearyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glycyrrhiza Glabra (Licorice) Extract, Moringa Oliefera Extract, Vetivera Zinzanoids (Khus Root) Extract, Withania Somniferia (Winter Cherry) Extract, Panthenol, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Trisodium EDTA, Tocopheryl Acetate, Butyrospermum Parkii (Shea Butter) Fruit, Zingiber Officinale (Ginger) Extract, Bisabolol, Butylene Glycol, Pentylene Glycol, Propamidobenzoic Acid.

INGREDIENTES: Agua, Homosalato, Metoxicinamato de Octilo, Benzofenona-3, Salicilato de Octilo, Copolímero de acrilatos, Glicerina, Octocrileno, Fermento de Thermus Thermophilus, Polisorbato 20, Oleato de Sorbitán, Hidantoína DMDM, Alcohol cetearílico, Cospolímero de Acrilatos/C10-30 Alquíl Acrilato, Trietanolamina, Extracto de Regaliz (Glycyrrhiza Glabra), Extracto de Moringa Oliefera, Extacto de Vetiver (Vetivera Zinzanoids), Extracto de Withania Somniferia, Pantenol, Fenoxietanol, Hexilen Glicol, Caprilil Glicol, Sorbato de Potasio, EDTA Trisódico, Acetato de Tocoferilo, Manteca de Karité (Butyrospermum parkii), Extracto de Jengibre (Zingiber officinale), Bisabolol, Butilenglicol, Pentilen Glicol, Ácido Propamidobenzóico.

Contains: Oxybenzone

Enthält: Oxybenzon

Contiene: Oxybenzona

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. Tlacopac, México, D. F., 01040.
JAFRA es Marca Registrada



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Jafra Sun

Face and Body Sunscreen Spray SPF 35

Advanced UV protection

Protector Solar en Spray

Facial y Corporal FPS 35

Proteccion Avanzada

contra rayos

JAFRA
SUN

35

Face & Body Sunscreen Spray SPF 35
Advanced UV Protection

Protector Solar en Spray
Facial y Corporal FPS 35
Protección Avanzada
contra Rayos UV

Ölfrei, parfümfrei, PABA-frei, wasserfest.
Enthält ayurvedische Pflanzenstoffe und
einen Hitze-Aktiv-Schutz

Anwendung: Tragen Sie das
Sonnenschutzprodukt vor dem Sonnenbad
auf. Anwendung wiederholen, vor allem
nach längeren Aufenthalten im Wasser, bei
starkem Schwitzen oder nach dem
Abtrocknen, um den Sonnenschutz zu
bewahren.

Warnung: Nur für den äußeren Gebrauch.
Den Kontakt mit den Augen vermeiden.
Anwendung absetzen, wenn
Hautirritationen auftreten. Fragen Sie einen
Arzt, wenn Sie das Produkt bei Kindern
unter 6 Monaten anwenden möchten. Von
Kindern fern halten.

Blieben Sie nicht zu lange in der Sonne –
auch nicht mit Sonnenschutzmittel.
Schützen Sie Ihre Babys und Kleinkinder
vor direktem Sonnenlicht. Ausgedehnte
Sonnenbäder können Ihre Gesundheit
ernsthaft gefährden.

Privo di olii, fragranze e PABA; resistente
all'acqua. Contiene estratti ayurvedici e
una protezione contro l'eccessivo calore.

Uso: Applicare prima dell'esposizione al
sole. Riapplicare frequentemente dopo un
prolungato contatto con l'acqua, in caso di
sudorazione abbondante o dopo essersi
asciugati con l'asciugamano.

Attenzione: Solo per uso esterno. Evitare il
contatto con gli occhi. Evitarne l'uso in
caso di irritazione. Consultare un medico
prima di utilizzare il prodotto su bambini di
età inferiore ai 6 mesi. Tenere fuori dalla
portata dei bambini.

125 ml e 4.2 FL OZ (US)

FACE AND BODY SUNSCREEN SPRAY SPF 35

homosalate, oxybenzone, octinoxate, octisalate, octocrylene lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-092 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 10 mL in 100 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 3 mL in 100 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 6 mL in 100 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5 mL in 100 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 2.79 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |
| MORINGA OLEIFERA BARK (UNII: 1X2218R709) | |
| WITHANIA SOMNIFERA ROOT (UNII: V038D626IF) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |

| | |
|---|--|
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| EDETATE TRISODIUM (UNII: 420IP921MB) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SHEANUT OIL (UNII: O88E196QRF) | |
| GINGER (UNII: C5529G5JPQ) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:68828-092-01 | 1 in 1 BOX | | |
| 1 | | 125 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 06/05/2012 | |

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|---------------------|
| Jafra Manufacturing, S.A. de C.V. | | 814732061 | manufacture |