

**FACE PROTECTOR SPF 40- octinoxate oxybenzone octisalate octocrylene titanium dioxide 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.*

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**FACE PROTECTOR SPF 40**

SUNSCREEN ACTIVE INGREDIENT (SPF 40):

OCTINOXATE/ETHYLHEXYL METHOXYCINNAMATE, OXYBENZONE/BENZOPHENONE-3, OCTISALATE/ETHYLHEXYL SALICYLATE, OCTOCRYLENE, TITANIUM DIOXIDE/CI 77891.

PURPOSE: SUNSCREEN

OTHER INGREDIENTS: WATER/AQUA, C12-15 ALKYL BENZOATE, ALUMINA, DIMETHICONE, ETHYLHEXYL ETHYLHEXANOATE, SODIUM DIHYDROXYCETYL PHOSPHATE, BUTYLENE GLYCOL, GLYCERYL STEARATE SE, ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER, PANTHENOL, TOCOPHERYL ACETATE, AVENA SATIVA (OAT) KERNEL EXTRACT, PVP/EICOSENE COPOLYMER, CETYL ALCOHOL, XANTHAN GUM, BEESWAX/CERA ALBA, FRAGRANCE/PARFUM, IRON OXIDES/CI 77491/CI 77492/CI 77499, PEG-4 LAURATE, IODOPROPYNYL BUTYLCARBAMATE, DMDM HYDANTOIN, TRISODIUM EDTA.

FACE PROTECTOR SPF 40

TO USE: APPLY SUNSCREEN PRODUCT 20 MINUTES BEFORE EXPOSURE. RE-APPLY FREQUENTLY TO MAINTAIN PROTECTION, ESPECIALLY AFTER PERSPIRING, SWIMMING OR TOWELING.

DISCONTINUE USE IF IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN.

JAFRA SUN

FACE PROTECTOR SPF 40

JAFRA  
SUN

40

Face Protector SPF 40

Crema Bloqueadora Facial FPS 40

50 ml e 1.7 FL OZ (US)

**Intensiver Sonnenschutz für das Gesicht SPF 40**  
**Protezione Solare per il Viso Alta SPF 40**

**To use:** Apply sunscreen product 20 minutes before exposure. Re-apply frequently to maintain protection, especially after perspiring, swimming or towel-drying.

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

**Instrucciones de uso:** Aplicar uniformemente 20 minutos antes de exponerse al sol. Para mantener la protección, repita la aplicación después de exposición prolongada al agua o transpiración excesiva.

**Precaución:** Solo para uso externo. Evite el contacto con los ojos. Descontinúe su uso si hubiere irritación o sarpullido. 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.

**Warnhinweis:** Vor dem Sonnenaufenthalt großzügig auftragen. Regelmäßig erneuern, speziell nach dem Baden und Abtrocknen. Bleiben Sie nicht zu lange in der Sonne - auch nicht mit Sonnenschutzmitteln. Babys & Kleinkinder nicht direkter Sonne aussetzen. Mittagssonne und übermäßige Sonnenbestrahlung meiden. Fragen Sie einen Arzt, bevor Sie das Produkt für Kinder unter 6 Monaten verwenden. Von Kindern fernhalten. Sonnenschutzprodukte bieten keinen 100%-igen Schutz.

**Avvertenze:** Non rimanere al sole troppo a lungo. Un'esposizione eccessiva al sole costituisce un grave rischio per la salute. Tenere i bambini ed i neonati lontano dalla luce diretta del sole. Solo per uso esterno. Evitare il contatto con gli occhi. Evitare l'uso in caso d'irritazione. Consultare un medico prima di utilizzare il prodotto su bambini di età inferiore ai 6 mesi. Tenere fuori dalla portata dei bambini.

**SUNSCREEN ACTIVE INGREDIENTS (SPF 40):** Octinoxate/Ethylhexyl Methoxycinnamate, Oxybenzone/Benzophenone-3, Octisalate/Ethylhexyl Salicylate, Octocrylene, Titanium Dioxide/CI 77891. **OTHER INGREDIENTS:** Water/Aqua, C12-15 Alkyl Benzoate, Alumina, Dimethicone, Ethylhexyl Ethylhexanoate, Sodium Dihydroxyethyl Phosphate, Butylene Glycol, Glyceryl Stearate SE, Adipic Acid/Diethylene Glycol/Glycerin Crosspolymer, Panthenol, Tocopherol Acetate, Avena Sativa (Oat) Kernel Extract, PVP/Eicosene Copolymer, Cetyl Alcohol, Xanthan Gum, Beeswax/Cera Alba, Fragrance/Parfum, Iron Oxides/CI 77491/CI 77492/CI 77499, PEG-4 Laurate, Iodepropynyl Butylcarbamate, DMDM Hydantoin, Trisodium EDTA.

**INGREDIENTES:** Agua, Metoxicinamato de Octilo, C12-15 Alquil Benzoato, Dióxido de Titanio, Alúmina, Dimeticona, Benzofenona-3, Salicilato de Octilo, Octilenoato de Octilo, Dihidroxietilfosfato de Sodio, Butilenglicol, SE Estearato de Glicerilo, Copolímero de Glicerina/Acido Adípico/Dietilenglicol, Octocrieno, Extracto de Semilla de Avena (Avena Sativa), Copolímero PVP/eoseno, Alcohol Cetílico, Goma Xantán, Cera de Abeja, Fragancia, Hidantoina DMDM, Pantenol, Acetato de Tocoferol, Óxidos de Hierro, PEG-4 Laurato, Yodopropinil Butilcarbamato, EDTA Trisódico.

Contains: Oxybenzone / Contiene: Oxybenzone / Enthält Oxybenzon / Contiene: Oxybenzone

Made in Mexico for: JAFRA Cosmetics International, Inc.  
Westlake Village, CA 91361

Distributed in EU: JAFRA Cosmetics D-80636 Munich

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Hecho en México para:

Distribuidora Comercial JAFRA, S.A. de C.V.  
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CAUTION: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.

**FACE PROTECTOR SPF 40**

octinoxate oxybenzone octisalate octocrylene titanium dioxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-054
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL ETHYLHEXANOATE (UNII: 430RJA6715)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
DIETHYLENE GLYCOL ADIPATE (UNII: 6KE5V549E0)	
OAT (UNII: Z6J799EAJK)	
POVIDONE K30 (UNII: U725QWY32X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-054-13	50 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
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture