

SOLAR PROTECTION FLUID BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene cream
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.

Royal Jelly - Solar Protection Fluid Broad Spectrum SPF 50

Active Ingredients Purpose

Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen

Uses

- Helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Stop use and ask a doctor if rash occurs

Warnings

- **For external use only**
- **Do not use** on damaged or broken skin
- **when using this product** keep out of eyes. Rinse with water to remove.

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if
- swimming or sweating
- reapply at least every 2 hours children under 6 months: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Actinidia Chinensis (Kiwi) Fruit Water, Alcohol, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Benzyl Alcohol, Bisabolol, Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Chlorphenesin, Cocos Nucifera Fruit Extract, Cyclopentasiloxane, Dipropylene Glycol, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Hydrogenated Lecithin, Lauroyl Lysine, Lecithin, Maltodextrin, Moringa Oleifera Leaf Extract, PEG-100 Stearate, Phenethyl Alcohol, Polygonum Aviculare Extract, Royal Jelly, Sodium Ascorbyl Phosphate, Sophora Flavescens Root Extract, Styrene/Acrylate Copolymer, Tetrapeptide-45, Water/Aqua

JAFRA

Royal Jelly

Solar Protection Fluid

Broad Spectrum SPF 50

50 ml 1.7 FL OZ (US)



PMS 431 C



Match Gold Hot
Foil Stamp



BLACK

For all skin types

Drug Facts

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Avobenzone 3%.....	Sunscreen
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Drug Facts (continued)

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Other information

- protect this product from excessive heat and direct sun

JAFRA
ROYAL

ROYAL JELLY



REVITALIZE

SOLAR PROTECTION FLUID
BROAD SPECTRUM SPF 50



50 ml e 1.7 FL OZ (US)

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.
Bvd. Adolfo López Mateos 2273,
C.P. 01710, Ciudad de México, México.
JAFRA y JAFRA Royal Jelly son Marcas
Registradas en México; Reg US Pat & TM off
LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - MILAN - MOSCOW

SOLAR PROTECTION FLUID BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-282
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
KIWI FRUIT OIL (UNII: 66086CWP3Q)	
ALCOHOL (UNII: 3K9958V90M)	
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
ARGININE (UNII: 94ZLA3W45F)	
DOCOSANOL (UNII: 9G1OE216XY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
COCONUT (UNII: 3RT3536DHY)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LAUROYL LYSINE (UNII: 113171Q70B)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MORINGA OLEIFERA LEAF (UNII: 4WET1AWO9B)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
ROYAL JELLY (UNII: L497I37F0C)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-282-02	1 in 1 CARTON	08/10/2015	
1	NDC:68828-282-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/10/2015	

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(68828-282)

Revised: 2/2018

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