

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


Water/Aqual, Styrene/Acrylate Copolymer, Glyceryl Stearate, PEG-100 Stearate, Aluminum Starch Octenylsuccinate, Lauroyl Lysine, Arachidyl Alcohol, Behenyl Alcohol, Arachidyl Glucoside, Ethylhexylglycerin, Benzyl Alcohol, Bisabolol, Royal Jelly, Cyclopentasiloxane, Acrylates/Dimethicon Copolymer, Cocos Nucifera, Moringa Oleifera, Fragrance/Parfum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Allantoin, Arginine, Chlorphenesin, Cichorium Intybus (Chicory) Root Extract, Kappaphycus Alvarezii Extract, Glycerin, Polygonum Aviculare Extract, Sodium Ascorbyl Phosphate, Benzyl Salicylate, Limonene, Hydroxycitronellal, Butylphenyl Methylpropional (Lillial), Linalool

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Royal Jelly

Solar Protection Fluid
 Broad Spectrum SPF 50
 50 ml 1.7 FL OZ (US)

Foil Stamp

 For all skin types

Drug Facts

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Avobenzene 3%.....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
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Drug Facts (continued)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Benzyl Alcohol, Benzyl Salicylate, Bisabolol, Butylphenyl Methylpropional (Lilial), Butyrospermum Parkii (Shea) Butter, Chlorphenesin, Cyclopentasiloxane, Dipropylene Glycol, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Hydrogenated Lecithin, Hydroxycitronellal, Lauroyl Lysine, Lecithin, Limonene, Linalool, Maltodextrin, PEG-100 Stearate, Phenethyl Alcohol, Polygonum Aviculare Extract, Royal Jelly, Sodium Ascorbyl Phosphate, Styrene/Acrylates Copolymer, Tetrapeptide-45, Water/Aqua

Other information

- protect this product from excessive heat and direct sun


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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. Blvd. 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

avobenzene, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-240
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
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
LAUROYL LYSINE (UNII: 113171Q70B)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
ROYAL JELLY (UNII: L497I37F0C)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
MORINGA OLEIFERA WHOLE (UNII: 5JH60A416W)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALLANTOIN (UNII: 344S277G0Z)	
ARGININE (UNII: 94ZLA3W45F)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CHICORY ROOT (UNII: 090CTY533N)	
KAPPAPHYCUS ALVAREZII (UNII: T479H08K2O)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJK51DR)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-240-02	1 in 1 BOX	08/10/2015	
1	NDC:68828-240-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68828-240-03	1 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/02/2018	

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(68828-240)

Revised: 2/2018

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