

**ROYAL JELLY KIT JAFRA- avobenzone, homosalate, octisalate, octocrylene
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.

Jafra Royal Jelly Kit

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalatate 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 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 value of 15 or higher and other sun protection measures including:

limit time in the sun, especially 10a.m. - 2 p.m.

wear long-sleeve shirts, pants, hats and sunglasses

Inactive ingredients

Water/Aqua, Styrene/Acrylates 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/Dimethicone 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

Jafra Royal Jelly

Total Content 30 ml 1 FL OZ

Solar Protection Fluid Broad Spectrum SPF 50

Drug Facts

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

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Warnings

For external use only

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Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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

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 value of 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

Drug Facts (continued)

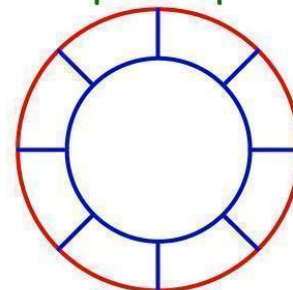
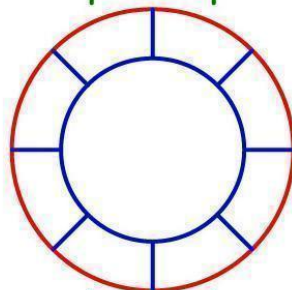
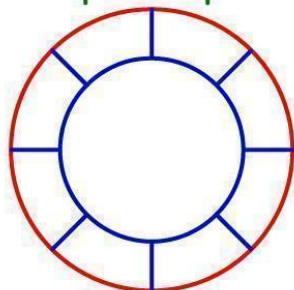
Inactive ingredients

Water/Aqua, Styrene/Acrylates 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/Dimethicone 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

Other information

- protect this product from excessive heat and direct sun

Tester - not for resale





ROYAL JELLY KIT JAFRA
 avobenzone, homosalate, octisalate, octocrylene kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-242

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-242-01	1 in 1 KIT; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	08/13/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL
Part 2	1 BOTTLE	7.5 mL
Part 3	1 BOTTLE	7.5 mL

Part 1 of 3

SOLAR PROTECTION FLUID BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Item Code (Source)	NDC:68828-243
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)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LEVOMENOL (UNII: 24WE03BX2T)	
ROYAL JELLY (UNII: L497I37F0C)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
COCONUT (UNII: 3RT3536DHY)	
MORINGA OLEIFERA LEAF (UNII: 4WET1AWO9B)	
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: 836SJG51DR)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
HYDROXYCITRONELLOL (UNII: R0B4U2I48W)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
LINALOOL, (+)- (UNII: F4VNO44C09)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-243-01	15 mL in 1 BOTTLE; 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	08/13/2015	

Part 2 of 3

GENTLE CLEANSING MILK

cleansing (cold creams, cleansing lotions, liquids, and pads)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
INGR	CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
INGR	PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
INGR	CO CO GLUCOSIDE (UNII: ICS790225B)	
INGR	SODIUM LAURYL SARCO SINATE (UNII: 5PGH842FAU)	
INGR	ROYAL JELLY (UNII: L497I37F0C)	
INGR	SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
INGR	GLYCOL STEARATE (UNII: 0324G66D0E)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	EDETATE SODIUM (UNII: MP1J8420LU)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	COCONUT (UNII: 3RT3536DHY)	
INGR	MORINGA OLEIFERA LEAF (UNII: 4WET1AWO9B)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

INGR	SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
INGR	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
INGR	LINALOOL, (+)- (UNII: F4VNO44C09)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 of 3

GLOBAL LONGEVITY BALM

cleansing (cold creams, cleansing lotions, liquids, and pads)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
INGR	SQUALANE (UNII: GW89575KF9)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
INGR	HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	ROYAL JELLY (UNII: L497I37F0C)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	CHICORY ROOT (UNII: 090CTY533N)	
INGR	HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
INGR	PALMITOYL GLYCINE (UNII: M6V3RIU5KI)	
INGR	ETHYLHEXYL GLYCERIN (UNII: 147D247K3P)	

INGR	MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
INGR	POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
INGR	C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
INGR	LAURETH-7 (UNII: Z95S6G8201)	
INGR	CYCLOMETHICONE (UNII: NMQ347994Z)	
INGR	DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
INGR	WITHANIA SOMNIFERA FLOWER (UNII: 2HZ95R7082)	
INGR	NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
INGR	LENTIL (UNII: 6O38V6B52O)	
INGR	EDETATE TRISODIUM (UNII: 420IP921MB)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	HONEY (UNII: Y9H1V576FH)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	ARGININE (UNII: 94ZLA3W45F)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	PEG-4 LAURATE (UNII: AYP4VM3N1Z)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
INGR	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
INGR	LINALOOL, (+)- (UNII: F4VNO44C09)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.5 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/13/2015	

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(68828-243, 68828-242)

Revised: 6/2020

JAFRA COSMETICS INTERNATIONAL