

**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.*

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**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

### Active ingredients

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

### Purpose

### 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

### Warnings

**For external use only**

**Do not use** on damaged or broken skin

**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)

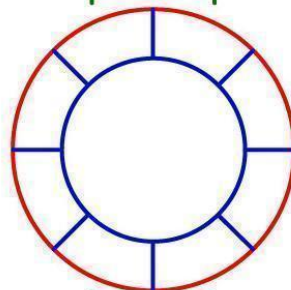
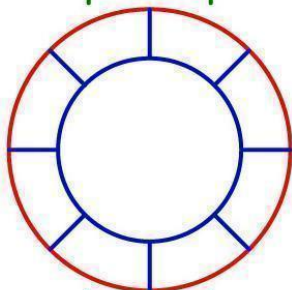
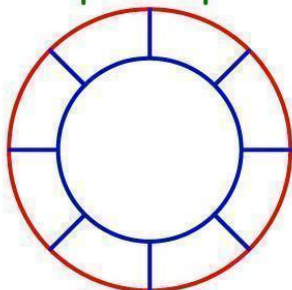
### Inactive ingredients

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

avobenzene, 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       |
|----------------------------------------------------------------|-------------------|----------------|
| AVOBENZENE (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)   | AVOBENZENE        | 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: 6JVVW35JOOJ)             |          |
| 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: 059QF0KO0R)                     |          |
| INGR            | DECYL GLUCOSIDE (UNII: Z17H97EA6Y)           |          |
| INGR            | COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)    |          |
| INGR            | PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)    |          |
| INGR            | COCO GLUCOSIDE (UNII: ICS790225B)            |          |
| INGR            | SODIUM LAURYL SARCOSINATE (UNII: 5PGH842FAU) |          |
| INGR            | ROYAL JELLY (UNII: L497I37F0C)               |          |
| INGR            | SODIUM HYDROXIDE (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 | <b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)   |  |
| INGR | <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)     |  |
| INGR | <b>BENZYL SALICYLATE</b> (UNII: WAO5MNK9TU)           |  |
| INGR | <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)              |  |
| INGR | <b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)          |  |
| INGR | <b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69) |  |
| INGR | <b>LINALOOL, (+)-</b> (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            | <b>WATER</b> (UNII: 059QF0KO0R)                                                                               |          |
| INGR            | <b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4) |          |
| INGR            | <b>SQUALANE</b> (UNII: GW89575KF9)                                                                            |          |
| INGR            | <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)                                                                      |          |
| INGR            | <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                                                          |          |
| INGR            | <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)                                                                    |          |
| INGR            | <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)                                                             |          |
| INGR            | <b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)                                                       |          |
| INGR            | <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                                                            |          |
| INGR            | <b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)                                                                 |          |
| INGR            | <b>ROYAL JELLY</b> (UNII: L497I37F0C)                                                                         |          |
| INGR            | <b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)                                                                |          |
| INGR            | <b>CHICORY ROOT</b> (UNII: 090CTY533N)                                                                        |          |
| INGR            | <b>HELIANTHUS ANNUUS SPROUT</b> (UNII: 4P26HG1S5W)                                                            |          |
| INGR            | <b>PALMITOYL GLYCINE</b> (UNII: M6V3RIU5KI)                                                                   |          |
| INGR            | <b>ETHYLHEXYLGLYCERIN</b> (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: AYF4VM3N1Z)               |  |
| 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: 6/2019

JAFRA COSMETICS INTERNATIONAL