

AGE AND POLLUTION PROTECTOR BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene 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.

Royal Jelly Defy Age and pollution protector Broad Spectrum SPF 50

Active Ingredients Purpose

Avobenzone 3% Sunscreen

Homosalate 10% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 10% 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 generously and evenly 15 minutes before sun exposure

Use a water-resistant sunscreen if swimming or sweating

Reapply at least every 2 hours.

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 your time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses •

Children under 6 months of age: ask a doctor.

Inactive ingredients

Alumina, Butylene Glycol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceramide 3, Cerium Oxide, Dipropylene Glycol, Ethylhexyl Methoxycrylene, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Glycine Soja (Soybean) Seed Extract, Hexylene Glycol, Hydrogenated Lecithin, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyltaurate Copolymer, Lecithin, Maltodextrin, Olea Europaea (Olive) Fruit Oil, PEG-100 Stearate, Persea Gratissima (Avocado) Oil, Phenethyl Alcohol, Phenoxyethanol, Phytosterols, Polyester-8, Polymethyl Methacrylate, Polysorbate 60, Potassium Sorbate, Royal Jelly Powder, Royal

Jelly, Sodium Benzoate, Sodium Hyaluronate, Sodium PCA, Squalane, Styrene/Acrylates Copolymer, Sucrose Stearate, Tetrapeptide-45, Theobroma Cacao (Cocoa) Seed Extract, Tocopherol, Tocopheryl Acetate, Tuber Magnatum Extract, VP/Eicosene Copolymer, Water/Aqua, Xanthan Gum

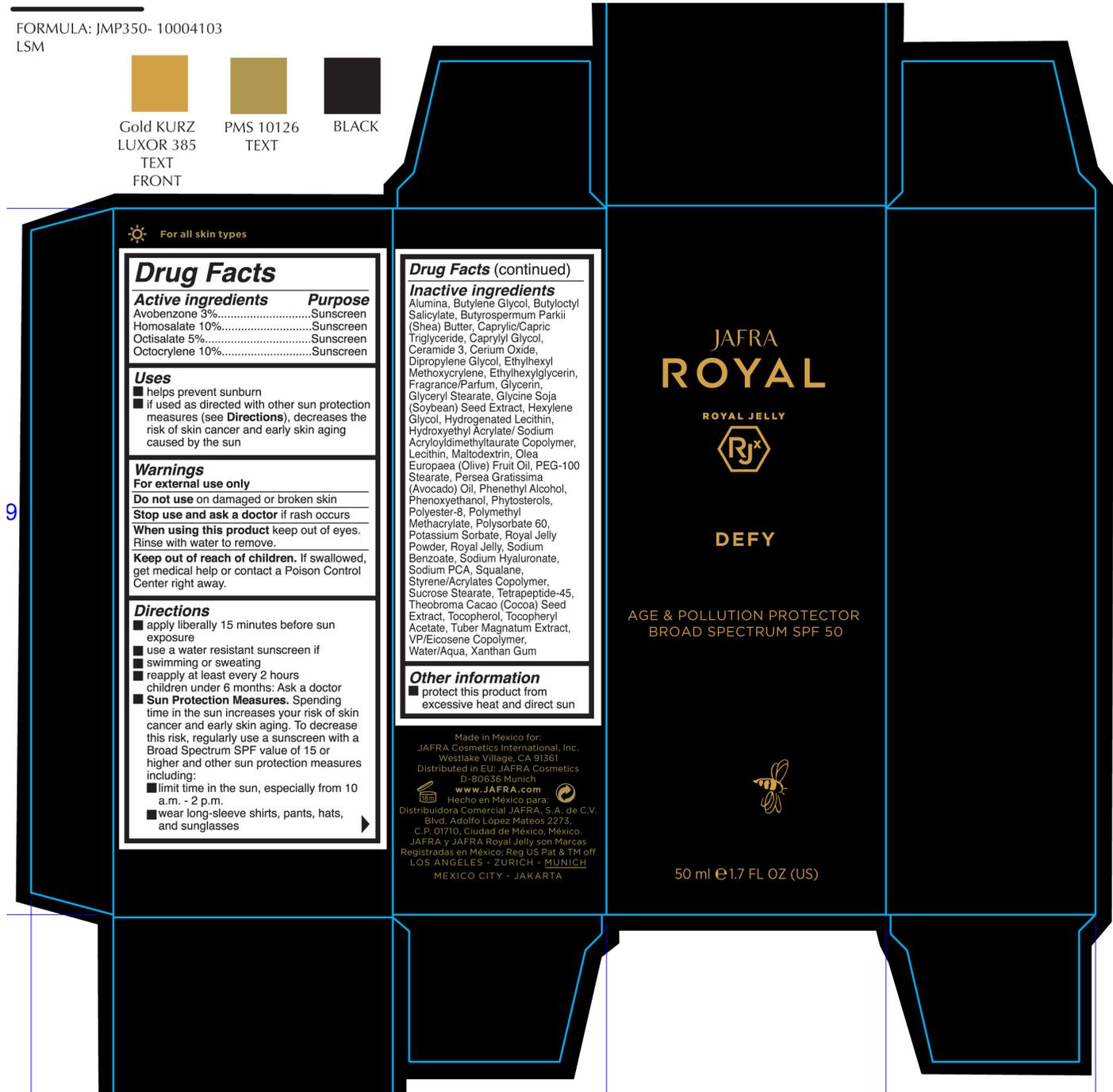
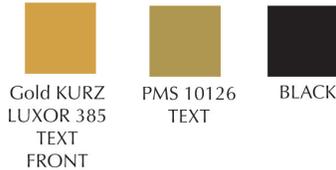
Jafra Royal Jelly

Defy

Age & Pollution Protector Broad Spectrum SFP 50

50 ml 1.7 Fl Oz

FORMULA: JMP350- 10004103
LSM



For all skin types

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	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

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

Alumina, Butylene Glycol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceramide 3, Cerium Oxide, Dipropylene Glycol, Ethylhexyl Methoxycrylene, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Glycine Soja (Soybean) Seed Extract, Hexylene Glycol, Hydrogenated Lecithin, Hydroxyethyl Acrylate/ Sodium Acryloyldimethylaurate Copolymer, Lecithin, Maltodextrin, Olea Europaea (Olive) Fruit Oil, PEG-100 Stearate, Persea Gratissima (Avocado) Oil, Phenethyl Alcohol, Phenoxyethanol, Phytosterols, Polyester-8, Polymethyl Methacrylate, Polysorbate 60, Potassium Sorbate, Royal Jelly Powder, Royal Jelly, Sodium Benzoate, Sodium Hyaluronate, Sodium PCA, Squalane, Styrene/Acrylates Copolymer, Sucrose Stearate, Tetrapeptide-45, Theobroma Cacao (Cocoa) Seed Extract, Tocopherol, Tocopheryl Acetate, Tuber Magnatum Extract, VP/Eicosene Copolymer, Water/Aqua, Xanthan Gum

Other information

- protect this product from excessive heat and direct sun

Made in Mexico for
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Distributed in EU: JAFRA Cosmetics
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Hecho en México para:
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JAFRA y JAFRA Royal Jelly son Marcas
Registradas en México; Reg US Pat & TM off
LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - JAKARTA

JAFRA
ROYAL
ROYAL JELLY

DEFY
AGE & POLLUTION PROTECTOR
BROAD SPECTRUM SPF 50

50 ml e 1.7 FL OZ (US)

AGE AND POLLUTION PROTECTOR BROAD SPECTRUM SPF 50
avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-409
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SOYBEAN (UNII: L7HT8F1ZOD)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (10000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SQUALANE (UNII: GW89575KF9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCOA (UNII: D9108TZ9KG)	
CERIC OXIDE (UNII: 619G5K328Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ROYAL JELLY (UNII: L497I37F0C)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
CERAMIDE NP (UNII: 4370DF050B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-409-01	7.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2019	
2	NDC:68828-409-02	14 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2019	
3	NDC:68828-409-03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/09/2019	

Labeler - Jafra cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-409)

Revised: 7/2019

Jafra cosmetics International