

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 IVORY- homosalate, octisalate, zinc oxide 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.

Always Foundation Makeup Broad Spectrum SPF 15 Ivory

Active Ingredients

Homosalate 4.25% Purpose Sunscreen

Octisalate 4.75% Purpose Sunscreen

Zinc Oxide 7.0% Purpose 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 product is 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

Stop use and ask a doctor if rash occurs

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 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

C12-15 Alkyl Benzoate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethicone Crosspolymer, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcocoate PEG-8 Dimethicone, Iron Oxides/CI 77491/CI 77492/CI 77499, Kaolin, Lecithin, Methicone, Phenoxyethanol, Phenyl Trimethicone, Propylene carbonate, Silica, Silica Dimethyl Silylate, Sodium Chloride, Stoddard solvent, Titanium Dioxide/CI 77891, Triethoxycaprylsilane, Water/Aqua

Protect this product from excessive heat and direct sun

JAFRA beauty

Always

Foundation Makeup

Broad Spectrum SPF 15

30 ML e 1 FL OZ (US)

COLR-599 REV.1 FINAL ART

JAFRA

ONLY USA

UNIT CARTON - JAFRA BEAUTY ALWAYS
FOUNDATION MAKEUP SPF 15
19.JUN.2020 (13. AUG.2020 LSM)

FORMULA: JMB1029-1043
LSM

JMB1033 10004952 Soft Ivory
JMB1034 10004953 Natural Tan
JMB1035 10004954 Golden Tan
JMB1036 10004976 Cocoa
JMB1037 10004977 Shell
JMB1038 10004978 Buff
JMB1039 10004979 Natural
JMB1040 10004990 Ivory
JMB1041 10004991 Bisque
JMB1042 10004992 Honey

| | | | |
|---|------------------|---|-------------|
| + | NATURAL LG14 | + | BISQUE MDN4 |
| + | SOFT IVORY LP16 | + | BUFF MDP6 |
| + | IVORY LN18 | + | HONEY DG18 |
| + | NATURAL TAN MG16 | + | COCOA DN20 |
| + | SHELL MP18 | | |
| + | GOLDEN TAN MG20 | | |

12 mm

36 mm

36 mm

36 mm

5.45 mm

14 mm



BLACK

match colors according to the approved samples

35.75 mm

SHADE NAME

placement shade name listed

105 mm

Drug Facts

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Octisalate 4.75%.....Sunscreen
Zinc Oxide 7.0%.....Sunscreen

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Drug Facts (continued)

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 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

C12-15 Alkyl Benzoate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethicone Crosspolymer, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcocoate PEG-8 Dimethicone, Iron Oxides/CI 77491/CI 77492/CI 77499, Kaolin, Lecithin, Methicone, Phenoxyethanol, Phenyl Trimethicone, Propylene carbonate, Silica, Silica Dimethyl Silylate, Sodium Chloride, Stoddard solvent, Titanium Dioxide/CI 77891, Triethoxycaprylsilane, Water/Aqua

Other information

■ protect this product from excessive heat and direct sun

JAFRAbeauty
always

FOUNDATION
MAKEUP
BROAD SPECTRUM
SPF 15

30 ml e 1 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. 0710, Ciudad de México, México.
JAFRA es Marca Registrada
LOS ANGELES - ZURICH
MUNICH - MEXICO CITY - JAKARTA

35.75 mm

13 mm

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 IVORY

homosalate, octisalate, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-424 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 4.75 g in 100 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 7 g in 100 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 4.25 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| METHICONE (20 CST) (UNII: 6777U11MKT) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| PROPYLENE CARBONATE (UNII: 8D08K3S51E) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| WHITE SPIRIT TYPE 1 (UNII: 37LNI116R) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| WATER (UNII: 059QF0K00R) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| KAOLIN (UNII: 24H4NWX5CO) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68828-424-01 | 30 mL in 1 TUBE; Type 0: Not a Combination Product | 08/20/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 08/20/2020 | |

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Jafra Manufacturing, S.A. de C.V. | | 814732061 | manufacture(68828-424) |

Revised: 8/2020

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