

**SPA NIACINAMIDE AND VITAMIN E HAND CREAM BROAD SPECTRUM SPF 15-
avobenzone, homosalate, octisalate, octocrylene cream
Jafra Cosmetics International Inc**

Active ingredients

Avobenzone 3%
Homosalate 5%
Octisalate 5%
Octocrylene 7%

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.

Warning

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.

Stop use and ask a doctor if rash occurs

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

Direction

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months of age: 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 your time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients

Water, Glycerin, Polyester-8, Butyrospermum Parkii (Shea) Butter, Dimethicone,

Styrene/Acrylates Copolymer, Ethylhexylglycerin, Benzyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Arachidyl Alcohol, Saccharide Isomerate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Behenyl Alcohol, Isohexadecane, Niacinamide, Hydroxyethyl Urea, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Arginine, Chlorphenesin, Arachidyl Glucoside, Disodium EDTA, Panthenol, Persea Gratissima (Avocado) Oil, Phytosterols, Sorbitan Isostearate, Polysorbate 60, Olea Europaea (Olive) Fruit Oil, Fragrance

Other information

Protect this product from excessive heat and direct sun

Product label

SPAN-165

JAFRA

LABEL JAFRA SPA
NIAC & VITE HAND
CREAM SPF US
09.NOV.23

MPVG

FINAL ARTWORK



**SPAN-142 REV.1 WITH OTC
OVERLABEL IS SPAN-165**

**PMS Only for reference
(Match against physical sample)**



BLACK



DO NOT PRINT

WHITE LABEL

40 mm

40 mm

40 mm

39.25 mm

143 mm

39.5 mm

Drug Facts

Active Ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 5%	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

Warnings

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

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Directions

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- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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, Glycerin, Polyester-8, Butyloxyperium Pankol (Shea) Butter, Dimethicone, Styrene/Acrylates Copolymer, Ethylhexylglycerin, Benzyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Arachidyl Alcohol, Saccharide Isomerate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Behenyl Alcohol, Isohexadecane, Niacinamide, Hydroxyethyl Urea, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Arginine, Chlorphenesin, Arachidyl Glucoside, Disodium EDTA, Panthenol, Persea Gratissima (Avocado) Oil, Phytosterols, Sorbitan Isostearate, Polyorbate 60, Olea Europaea (Olive) Fruit Oil, Fragrance

Other information

- protect this product from excessive heat and direct sun

JAFRA
spa

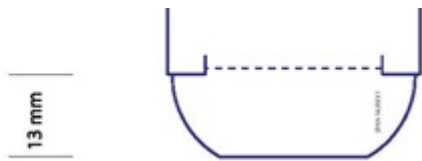
NIACINAMIDE & VITAMIN E
HAND CREAM
BROAD SPECTRUM SPF 15
SUNSCREEN



75 mL 2.5 FL OZ

Made in Mexico for:
JAFRA Cosmetics International, Inc.
Westlake Village, CA 91362
Distributed in EU: JAFRA Cosmetics
D-80026 Munich
www.JAFRA.com
Hecho en México para:
Distribuidora Comercial JAFRA, S.A. de C.V.
Bvd. Adolfo López Mateos 201, C.P. 00710,
Ciudad de México, México.
JAFRA y JAFRA SPA son
Marcas Registradas en México.
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LOS ANGELES - ZÜRICH - MÜNCHEN
MEXICO CITY - JAKARTA

**LABEL
PLACEMENT**



SPA NIACINAMIDE AND VITAMIN E HAND CREAM BROAD SPECTRUM SPF 15

avobenzene, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-003
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	5 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)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
DOCOSANOL (UNII: 9G1OE216XY)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
NIACINAMIDE (UNII: 25X5118RD4)	
HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ARGININE (UNII: 94ZLA3W45F)	
CHLORPHENESIN (UNII: I670DAL4S2)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J0OJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

PANTHENOL (UNII: WW9CM0067Z)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-003-01	1 in 1 CARTON	06/01/2022	
1		75 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68828-003-02	1 in 1 CARTON	06/01/2022	
2		7 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2022	

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-003)

Revised: 12/2023

Jafra Cosmetics International Inc