

# **JURLIQUE SPF40 HIGH PROTECTION SUNSCREEN- avobenzone, octinoxate, and octocrylene cream**

## **Jurlique 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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## **Jurlique SPF40 High Protection Sunscreen**

### ***Drug Facts***

#### **Active ingredients**

Avobenzone, 3.0%

Octinoxate, 7.5 %

Octocrylene, 2.75%

#### **Purpose**

Sunscreen

#### **Use**

- help prevent sunburn

#### **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.

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.** If product is 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-sleeved shirts, pants, hats and sunglasses

#### **Other information**

- protect this product from excessive heat and direct sun
- Store below 30°C/86°F

- product may cause discolouration in contact with some fabric
- patch testing on skin recommended before use, discontinue use if signs of irritation occur
- you may report a serious adverse reaction to Report Reaction, LLC PO Box 22, Plainsboro, NJ 08536-022

### **Inactive ingredients**

Water, Phenoxyethyl Caprylate, Acrylates/Vinyl Neodecanoate Crosspolymer, Glycerin, Ethylhexyl Methoxycrylene, Diethylhexyl Syringylidenemalonate, Glyceryl Stearate, VP/Eicosene Copolymer, Cetearyl Alcohol, Myristyl Myristate, Sodium Stearoyl Glutamate, Plukenetia volubilis Seed Oil, Butyrospermum parkii (Shea) Butter, Palmaria palmata Extract, Ascophyllum nodosum Extract, Fucus vesiculosus Extract, Porphyra umbilicalis Extract, Corandrum sativum (Coriander) Extract, Chamomilla recutita (Matricaria) Flower Extract, Rosa gallica Flower Extract, Glycyrrhiza glabra (Licorice) Extract, Viola odorata Extract, Viola tricolor Extract, Sambucus nigra Flower Extract, Camellia sinensis Leaf Extract, Cucumis sativus (Cucumber) Fruit Extract, Tasmannia lanceolata Fruit Extract, Syzygium leuhmanii Extract, Kunzea pomifera Fruit Extract, Fragrance/Parfum<sup>1</sup>, Silica, Acrylates/Beheneth-25 methacrylate Copolymer, Xanthan Gum, Sodium Stearoyl Lactylate, Tocopherol, SD Alcohol 40-A (Alcohol Denat.), Sodium Phytate, Caprylic/Capric Triglyceride, Phenoxyethanol, Ethylhexylglycerin, Chlorphenesin, Sodium Dehydroacetate, Benzyl Alcohol, Sodium PCA, Sodium Hydroxide, Limonene<sup>1</sup>, Linalool<sup>1</sup>, Citronellol<sup>1</sup>, Geraniol<sup>1</sup>, Farnesol<sup>1</sup>, Citral<sup>1</sup>.

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<sup>1</sup> From Essential Oil

### **PRINCIPAL DISPLAY PANEL - 100 mL Tube Carton**

#### **Jurlique**

#### **Sun Specialist**

with Superberry Complex

#### **SPF40**

#### **High Protection Cream**

#### **PA+++**

Protective broad spectrum  
sunscreen for face and body

100mL 3.3 fl. oz.



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This innovative high protection UVA and UVB sunscreen for face and body is enriched with powerful Superberry Complex and Inca Inchi Oil to protect and hydrate skin, while defending against environmental aggressors.

### Product and benefits

High protection, UVA and UVB filters, skin conditioning. This rich cream combines UVA and UVB sunscreen ingredient technology with new Superberry Complex, a fruit extract blend that delivers essential vitamins, minerals and amino acids to condition and protect the skin from the effects of environmental aggressors. Inca Inchi Oil is rich in essential fatty acids and a special blend of natural emollients and Shea Butter help to maintain optimum skin moisturisation during sun exposure for skin that looks and feels protected, hydrated and smooth.

### Free from

Titanium Dioxide (TiO<sub>2</sub>), Oxybenzone, PABA, Petrochemical, Parabens, PEGs, Silicone, Formaldehyde donors, Colorants.

### About Jurlique

Jurlique has been the leader in natural skin care science for over 25 years. We apply advanced technologies to organic ingredients from our Australian farm to create high performance, potent skin care. The result: healthy, beautiful skin.

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Made in USA for Jurlique,  
Jurlique, 52-54 Oborn Rd.,  
Mt. Barker, SA 5251, Australia.

[www.jurlique.com](http://www.jurlique.com)



This carton is manufactured from recycled and sustainably sourced fibre. Please recycle.

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# JURLIQUE SPF40 HIGH PROTECTION SUNSCREEN

avobenzone, octinoxate, and octocrylene cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68105-006
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>Phenoxyethyl Caprylate</b> (UNII: GM5AN7T8U)	
<b>ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER</b> (UNII: EPA1872R1N)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Ethylhexyl Methoxycrylene</b> (UNII: S3KFG6Q5X8)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Copovidone K25-31</b> (UNII: D9C330MD8B)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Myristyl Myristate</b> (UNII: 4042ZC00DY)	
<b>Sodium Stearoyl Glutamate</b> (UNII: 65A9F4P024)	
<b>Ascophyllum nodosum</b> (UNII: 168S4EO8YJ)	
<b>Fucus vesiculosus</b> (UNII: 535G2ABX9M)	
<b>Porphyra Umbilicalis</b> (UNII: 14AN0J70WO)	
<b>Coriander</b> (UNII: 1OV56052IK)	
<b>Chamomile</b> (UNII: FGL3685T2X)	
<b>Rosa Gallica Flower</b> (UNII: X8W61WUV70)	
<b>Glycyrrhiza Glabra</b> (UNII: 2788Z9758H)	
<b>Viola Odorata</b> (UNII: AET12U8B74)	
<b>Viola tricolor</b> (UNII: 9Q24RAI43V)	
<b>European Elderberry</b> (UNII: BQY1UBX046)	
<b>Bancha Tea Leaf/Twig</b> (UNII: EWI42IEH1C)	
<b>Cucumber</b> (UNII: YY7C30VXJT)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Sodium Stearoyl Lactylate</b> (UNII: IN99IT31LN)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>Alcohol</b> (UNII: 3K9958V90M)	

<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Sodium Dehydroacetate</b> (UNII: 8W46YN971G)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>Phytate Sodium</b> (UNII: 88496G1ERL)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68105-006-01	1 in 1 CARTON	01/01/2015	
1		100 mL in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2015	

**Labeler** - Jurlique International (752025791)

**Registrant** - Cosmetic Laboratories of America (013696501)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Cosmetic Laboratories of America		013696501	MANUFACTURE(68105-006)