

**JURLIQUE SUN SUNSCREEN SPF 30- octinoxate, octisalate, oxybenzone, and titanium dioxide cream, augmented**

**Jurlique International Pty. Ltd.**

*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 Sun Lotion Sunscreen SPF 30**

***Drug Facts***

**Active ingredients**

Octinoxate 7.5%  
Octisalate 2.0%  
Oxybenzone 5.0%  
Titanium dioxide 2.1%

**Purpose**

Sunscreen

**Use**

Helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert**

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

**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

**Other information**

- protect this product from excessive heat and direct sunlight
- store below 25°C/77°F
- you may report a serious adverse reaction to Report Reaction, LLC PO Box 22, Plainsboro, NJ

08536-0222

**Inactive ingredients**

Water, Glycerin, Ethylhexyl Stearate, Caprylic/Capric Triglyceride, Potassium Cetyl Phosphate, Glyceryl Stearate, Persea Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Ethylhexyl Palmitate, Dimethicone, Trimethylsiloxysilicate, Hydrolyzed Wheat Protein, Tocopheryl Acetate, Sodium Hydroxymethylglycinate, Lactic Acid, Alumina, Stearic Acid, Xanthan Gum, Cetyl Alcohol, Lavandula Angustifolia (Lavender) Oil, Pinus Sylvestris (Pine) Leaf Oil, Cupressus Sempervirens (Cypress) Oil, Citrus Aurantium Amara (Bitter Orange) Oil, Linalool, Limonene.

**PRINCIPAL DISPLAY PANEL - 100mL Bottle Carton**

**Jurlique**

**Sun Lotion**

**SPF 30**

A protective sunscreen lotion

100mL 3.3 Fl. Oz.



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# Jurlique

Sun Lotion

SPF 30

A protective sunscreen lotion



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100mL 3.3 Fl.Oz.



A lightweight, high-performance sunscreen lotion to help reduce the appearance of dryness and protect against environmental aggressors.

**Product and benefits**  
Hydrating and protecting.

A silky lotion rich in Avocado and Jojoba Oils, with Hydrolyzed Wheat Protein, designed to deeply moisturise and restore smoothness, while providing sunscreen protection.

**How to use this product**  
Refer to Drug Facts Box.



**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.

Made in Australia by Jurlique,  
52-54 Oborn Rd., Mt. Barker, SA 5251.  
Jurlique, London, W1S 1HQ, U.K.

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



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



## JURLIQUE SUN SUNSCREEN SPF 30

octinoxate, octisalate, oxybenzone, and titanium dioxide cream, augmented

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68105-005
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	20 mg in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	50 mg in 1 mL
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	21 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Ethylhexyl Stearate</b> (UNII: EG3PA2K3K5)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>Potassium Cetyl Phosphate</b> (UNII: 03KCY6P7UT)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>Ethylhexyl Palmitate</b> (UNII: 2865993309)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW)</b> (UNII: J2S07SB0YL)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>Sodium Hydroxymethylglycinate</b> (UNII: DIG6BWZ9XT)	
<b>Lactic Acid</b> (UNII: 33X04XA5AT)	
<b>Aluminum Oxide</b> (UNII: LMI26O6933)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>PINE NEEDLE OIL (PINUS SYLVESTRIS)</b> (UNII: 5EXL5H740Y)	
<b>BITTER ORANGE OIL</b> (UNII: 9TLV70SV6I)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>LIMONENE, (+/-)-</b> (UNII: 9MC3I34447)	

## Product Characteristics

<b>Color</b>	WHITE (Off-White)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68105-005-03	1 in 1 CARTON		
1	NDC:68105-005-01	100 mL in 1 BOTTLE, PUMP		
2	NDC:68105-005-04	1 in 1 CARTON		
2	NDC:68105-005-02	30 mL in 1 BOTTLE, PUMP		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2013	

**Labeler** - Jurlique International Pty. Ltd. (752025791)

## Establishment

Name	Address	ID/FEI	Business Operations
Jurlique International Pty. Ltd.		752025791	MANUFACTURE(68105-005)

Revised: 11/2012

Jurlique International Pty. Ltd.