

**SUNNYLIFE SPF 50 SUNSCREEN FRAGRANCE FREE- avobenzone, homosalate, octisalate, octocrylene lotion**  
**OUTLIVING 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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**SUNNYLIFE SPF 50+ SUNSCREEN FRAGRANCE FREE LOTION JNR**

**DRUG FACTS**

**ACTIVE INGREDIENTS:**

Avobenzone 3%, Homosalate 10%

Octisalate 5% Octocrylene 8%

**PURPOSE**

Sunscreen

**Uses:**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer & early skin aging caused by the sun.

**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 doctor**

if rash occurs.

**Keep out of reach of children.**

If product is swallowed, get medical help contact Poison Control Center right away.

**DIRECTION:**

- For sunscreen use
- Apply generously 15 minutes before sun exposure. Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours. **Skin Protection Measures.** Spending time in the sun increases your risk of skin cancer & early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher & other sun protection measures including:

- Limit time in the sun, especially from 10am-2pm
- Wear long-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months: ask a doctor.

**OTHER INFORMATION:**

Protect this product from excessive heat and direct sun.

**INACTIVE INGREDIENTS:**

Water, Cera Alba, C12-15 Alkyl Benzoate, Silica, PEG-15 Cocamine, PEG-40 Stearate, Carbomer, Hydroxyethylcellulose, Caprylhydroxamic Acid, Caprylyl Glycol, Glycerin, Triethanolamine, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Citric Acid.

**QUESTIONS OR COMMENTS?**

+1 323.591.0219

**Package Labeling:**

**SUNNYLIFE®**

**SPF 50<sup>+</sup>**  
**Sunscreen**

**UVA/UVB**

**Broad Spectrum Protection**

**Water Resistant (80 minutes)**

**Fragrance Free Lotion**

# Jnr

6.8 fl oz (200mL)

## DRUG FACTS

|  |                             |
|--|-----------------------------|
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|--|-----------------------------|

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**Distributed by:** Sunnlyfe USA  
(Sunnlyfe LLC) 300 N. Crescent Heights Blvd, Los Angeles, CA 90048, USA

**Made in Australia**

**To report a serious adverse event, contact (323) 591-0219**

Product not tested on animals

S99CSLXX  
Coconut Suncream  
30 200 ml



## SUNNYLIFE SPF 50 SUNSCREEN FRAGRANCE FREE

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72566-050 |
| <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>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 100 mg in 1 mL |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 50 mg in 1 mL  |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 80 mg in 1 mL  |

### Inactive Ingredients

| Ingredient Name                                   | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0K00R)                   |          |
| <b>WHITE WAX</b> (UNII: 7G1J5DA97F)               |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ) |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)         |          |
| <b>PEG-15 COCAMINE</b> (UNII: 8L6LB12TSJ)         |          |
| <b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)         |          |
| <b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MMB07FC)    |          |
| <b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)   |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)         |          |

|  |  |
|--|--|
| GLYCERIN (UNII: PDC6A3C0OX)                |  |
| TROLAMINE (UNII: 9O3K93S3TK)               |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)          |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72566-050-06 | 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/06/2019           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 01/06/2019           |                    |

**Labeler** - OUTLIVING PTY LTD (745474788)

### Establishment

| Name                          | Address | ID/FEI    | Business Operations    |
|-------------------------------|---------|-----------|------------------------|
| Baxter Laboratories Pty. Ltd. |         | 740537709 | manufacture(72566-050) |

Revised: 11/2018

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