



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	322469	Soleo Organics Original Formula High Performance Coconut
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SE Operations Pty Ltd	
<b>Postal Address</b>	1242 Hay St, West Perth, WA, 6005 Australia	
<b>ARTG Start Date</b>	29/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

The following two conditions apply where testing conducted by AMA Laboratories Inc. is used to substantiate compliance of the product with the Australian and New Zealand Sunscreen Standard AS/NZS 2604 Sunscreen products - Evaluation and classification (the Sunscreen Standard):

- The sponsor is required to hold adequate supplementary in-vitro testing data and/or relevant testing data from an independent testing laboratory on a comparable formulation, or other justification acceptable to the TGA, to scientifically justify the validity and accuracy of the SPF, broad spectrum and water resistance claims for the product.
- The sponsor must provide the data, documentation or other justification to the TGA within 10 working days of a request by the TGA, or as deemed reasonable by the delegate upon request.

### Products

#### 1 . Soleo Organics Original Formula High Performance Coconut

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/08/2019
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#### Permitted Indications

- May assist in preventing some skin cancers (sunscreen)
- May reduce the risk of some skin cancers (sunscreen)
- SPF 30 Broad spectrum high protection sunscreen
- Can aid in the prevention of premature skin ageing (sunscreen)
- Can aid in the prevention of solar keratosis (sunscreen)
- Can aid in the prevention of sunspots (sunscreen)

#### Indication Requirements

- Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
- Label statement: Prolonged exposure to the sun should be avoided, it is important to wear protective clothing, hats and eyewear when exposed to the sun. Product should be kept out of the eyes.
- Indication for use in sunscreen products only.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record



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**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Cream  
**Route of Administration** Topical

**Visual Identification**

**Active Ingredients**

zinc oxide 223.5 mg/g

**Other Ingredients (Excipients)**

- Camellia sinensis
- Candelilla Wax
- Chamaemelum nobile
- Cucumis sativus
- d-alpha-tocopheryl acetate
- Fragrance (perfume)
- hydrogenated vegetable oil
- lecithin
- Macadamia integrifolia
- medium chain triglycerides
- Sunflower Oil
- Theobroma Oil
- vegetable oil
- Vitis vinifera
- white beeswax

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