



**Australian Government**  
**Department of Health, Disability and Ageing**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 441791 SUNSATIONAL CLEAR FRAGRANCE FREE FAMILY SUNSCREEN SPF50+

**ARTG entry for** Medicine Listed  
**Sponsor** City-Country Sales and Distribution Pty Ltd  
**Postal Address** PO Box 6203, Alexandria, NSW, 2015  
Australia  
**ARTG Start Date** 21/02/2024  
**Product Category** Medicine  
**Status** Active  
**Approval Area** 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.

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):

- a) 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.
- b) 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. SUNSATIONAL CLEAR FRAGRANCE FREE FAMILY SUNSCREEN SPF50+

Product Type	Single Medicine Product	Effective Date	21/02/2024
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#### Permitted Indications

May assist in preventing some skin cancers (sunscreen)  
May reduce the risk of some skin cancers (sunscreen)  
SPF 50 PLUS Broad spectrum very 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.  
Indication for use in sunscreen products only.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Contains phenoxyethanol (or words to that effect).  
Avoid prolonged exposure in the sun.[or words to that effect]  
Wear protective clothing, hats and eyewear when exposed to the sun.[Or words to this effect]  
Avoid contact with eyes (or words to that effect).  
Contains benzoates  
Contains sorbates

#### Additional Product information