Public Summary

Summary for ARTG Entry:	273097 SUNSATIONAL EVERYDAY USE CLEAR SUNSCREEN SPF50+
ARTG entry for	Medicine Listed
Sponsor	Sunsational Body Care
Postal Address	PO Box 119, KENSINGTON, NSW, 1465 Australia
ARTG Start Date	18/03/2016
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.

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):
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 EVERYDAY USE CLEAR SUNSCREEN SPF50+

Product Type Single Medicine Product **Effective Date** 25/05/2018

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

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 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

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]

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Contains phenoxyethanol (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Lotion
Route of Administration	Topical
Visual Identification	

Active Ingredients

4-methylbenzylidene camphor	**40 mg/g**
bemotrizinol	**5 mg/g**
butyl methoxydibenzoylmethane	**50 mg/g**
octocrylene	**20 mg/g**

Other Ingredients (Excipients)

1,3-butylene glycol
acrylates/C10-30 alkyl acrylate crosspolymer
alkyl (C12-15) benzoate
butylated hydroxytoluene
cetyl dimeticone
cocoglycerides
dipropylene glycol dibenzoate
disodium edetate
dl-alpha-tocopheryl acetate
ethyl hydroxybenzoate
isopropyl palmitate
methyl hydroxybenzoate
PEG-15 cocamine
PEG-40 stearate
phenoxyethanol
PPG-15 stearyl ether benzoate
propyl hydroxybenzoate
purified water
trolamine
white beeswax

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