



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	216395	Soleil Defence SPF 50+
ARTG entry for	Medicine Listed	
Sponsor	Amarco Enterprises Pty Ltd	
Postal Address	9 Waltham Street, Artarmon, NSW, 2064 Australia	
ARTG Start Date	23/10/2013	
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):

- 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 . Soleil Defence SPF 50+

Product Type	Single Medicine Product	Effective Date	10/05/2023
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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 for use in sunscreen products only.
- Indication can only be used for sunscreen products with an SPF rating of 30 or higher.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Cream

Route of Administration Topical

Visual Identification

Active Ingredients

bemotrizinol	50 mg/g
diethylamino hydroxybenzoyl hexyl benzoate	50 mg/g
ethylhexyl triazone	20 mg/g
methylene bis-benzotriazolyl tetramethylbutylphenol	60 mg/g
octyl methoxycinnamate	50 mg/g
phenylbenzimidazole sulfonic acid	10 mg/g

Other Ingredients (Excipients)

butylated hydroxytoluene
cetostearyl alcohol
decyl glucoside
ethylhexylglycerin
Fragrance (perfume)
medium chain triglycerides
neopentyl glycol diheptanoate
nicotinamide
phenoxyethanol
phenyl trimethicone
piroctone olamine
potassium cetyl phosphate
propylene glycol dibenzoate
propylene glycol
purified water
sodium stearyl glutamate
triacontanyl PVP
xanthan gum

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