



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338588	Sunbutter Tinted Sunscreen SPF50
ARTG entry for	Medicine Listed	
Sponsor	Mamani Pty Ltd	
Postal Address	28 Bass Street, McCrae, VIC, 3938 Australia	
ARTG Start Date	29/06/2020	
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 . Sunbutter Tinted Sunscreen SPF50

Product Type	Single Medicine Product	Effective Date	17/02/2021
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Permitted Indications

SPF 50 Broad spectrum high protection sunscreen

Indication Requirements

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 contact with eyes (or words to that effect).

Wear protective clothing, hats and eyewear when exposed to the sun.[Or words to this 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
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Route of Administration	Topical
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Visual Identification



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Active Ingredients

zinc oxide 227 mg/g

Other Ingredients (Excipients)

Candelilla Wax
Castor Oil
coco-caprylate
Coconut Oil
d-alpha-tocopheryl acetate
iron oxide black
iron oxide red
iron oxide yellow
isostearic acid
medium chain triglycerides
polyglyceryl-3 polyricinoleate
Theobroma Oil

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