Public Summary

Summary for ARTG Entry: 294245  Sticky Zinc SPF 50+ Medium Tint

ARTG entry for  Medicine Listed
Sponsor  Feel Good and Co Pty Ltd
Postal Address  4/42 Faure Lane, Dunsborough, WA, 6281 Australia
ARTG Start Date  22/09/2017
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. Sticky Zinc SPF 50+ Medium Tint

Product Type  Single Medicine Product  Effective Date  4/04/2023

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]
Avoid prolonged exposure in the sun.[or words to that effect]

Additional Product information

Container information

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Life Time</th>
<th>Temperature</th>
<th>Closure</th>
<th>Conditions</th>
</tr>
</thead>
</table>

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Visit www.tga.gov.au for contact information
## Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
</table>

## Components

### 1. Formulation 1

#### Dosage Form
- Lotion

#### Route of Administration
- Topical

#### Visual Identification

#### Active Ingredients

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>bemotrizinol</td>
<td>30 mg/g</td>
</tr>
<tr>
<td>diethylamino hydroxybenzoyl hexyl benzoate</td>
<td>40 mg/g</td>
</tr>
<tr>
<td>octocrylene</td>
<td>20 mg/g</td>
</tr>
<tr>
<td>zinc oxide</td>
<td>200 mg/g</td>
</tr>
</tbody>
</table>

#### Other Ingredients (Excipients)

- alkyl (C12-15) benzoate
- allantoin
- Aloe vera
- butylated hydroxytoluene
- calcium stearate
- caprylyl glycol
- Carnauba Wax
- cyclomethicone
- dexamethasone
- disodium edetate
- dl-alpha-tocopheryl acetate
- glycerol
- glyceryl monooleate
- iron oxide black
- iron oxide red
- iron oxide yellow
- isopropyl palmitate
- magnesium sulfate heptahydrate
- nicotinamide
- octanohydroxamic acid
- PEG-30 dipolyhydroxystearate
- purified water
- triacontanyl PVP
- white beeswax
- white soft paraffin

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