Public Summary

Summary for ARTG Entry:	355433 ACTIVATED PROBIOTICS BIOME ECZEMA
ARTG entry for	Medicine Listed
Sponsor	Biome Australia Limited
Postal Address	16 Dover Street, Cremorne, VIC, 3121 Australia
ARTG Start Date	23/02/2021
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

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.

Products

1 . ACTIVATED PROBIOTICS BIOME ECZEMA

Product Type Single Medicine Product **Effective Date** 23/02/2021

Permitted Indications

Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis

Decrease/reduce/relieve symptoms of mild eczema/dermatitis

Helps reduce occurrence of symptoms of eczema/dermatitis

Indication Requirements

Product presentation must only refer to mild eczema.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Lactobacillus salivarius ssp salivarius	**1 billion organisms/g**

Other Ingredients (Excipients)

maltodextrin
silicon dioxide
sorbitol
Vanilla Powder
xylitol

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