



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	385330	ACTIVATED PROBIOTICS BIOME BABY
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biome Australia Limited	
<b>Postal Address</b>	16 Dover Street, Cremorne, VIC, 3121 Australia	
<b>ARTG Start Date</b>	9/03/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 BABY

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/03/2022
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#### Permitted Indications

Decrease/reduce/relieve colic (wind/gas pain)  
Helps decrease/reduce/relieve symptoms of infant colic  
Maintain/support healthy digestive system function  
Maintain/support digestive system health  
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth  
Relieve digestive discomfort  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support healthy gastrointestinal immune function

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to serious immunological diseases.  
Label statement: If symptoms persist or worsen talk to your medical practitioner.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	Not recorded	Not recorded	Neither child resistant	Not recorded



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closure nor restricted  
flow insert

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium breve</b>	<b>.8 billion CFU/g</b>
<b>fructooligosaccharides</b>	<b>1.585 g/g</b>
<b>Lactobacillus rhamnosus</b>	<b>1 billion CFU/g</b>

**Other Ingredients (Excipients)**

glyceryl palmito-stearate

silicon dioxide

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