



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

## Public Summary

<b>Summary for ARTG Entry:</b>	363493	Advanced Synbiotic Powder
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Gutbiome Aust Pty Ltd	
<b>Postal Address</b>	12A Whitehall Avenue, Birkdale, QLD, 4159 Australia	
<b>ARTG Start Date</b>	28/04/2021	
<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 . Advanced Synbiotic Powder

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/04/2021
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### Permitted Indications

Maintain/support general health and wellbeing  
Decrease/reduce/relieve diarrhoea in children  
Helps reduce occurrence of symptoms of traveller's diarrhoea  
Maintain/support healthy bowel/colon function  
Maintain/support small intestine health  
Maintain/support intestinal health  
Maintain/support healthy digestive system function  
Maintain/support digestion/assimilation of nutrients  
Maintain/support digestive system health  
Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa  
Maintain/support intestinal good/beneficial/friendly flora  
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use  
Help restore good/beneficial/friendly gut flora after antibiotic use  
Helps restore good/beneficial/friendly intestinal/gut/bowel flora  
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth  
Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth  
Maintain/support small intestine good/beneficial/friendly flora  
Maintain/support gastrointestinal system health  
Helps enhance/promote gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Maintain/support gastrointestinal mucosal membrane health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support healthy gastrointestinal immune function  
Helps reduce occurrence of symptoms of upper respiratory tract infections in healthy individuals

### Indication Requirements



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Product presentation must not imply or refer to serious immunological diseases.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

**Additional Product information**

**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>Actinidia chinensis fruit Powder</b>	<b>185 mg/g</b>
<b>Bifidobacterium animalis ssp lactis</b>	<b>666.7 million CFU/g</b>
<b>Bifidobacterium bifidum</b>	<b>66.7 million CFU/g</b>
<b>Bifidobacterium breve</b>	<b>66.7 million CFU/g</b>
<b>Bifidobacterium infantis</b>	<b>100 million CFU/g</b>
<b>Bifidobacterium lactis</b>	<b>666.7 million CFU/g</b>
<b>Bifidobacterium longum</b>	<b>66.7 million CFU/g</b>
<b>Lactobacillus acidophilus</b>	<b>333.3 million CFU/g</b>
<b>Lactobacillus brevis</b>	<b>66.7 million CFU/g</b>
<b>Lactobacillus casei</b>	<b>300 million CFU/g</b>
<b>Lactobacillus delbrueckii ssp bulgaricus</b>	<b>66.7 million CFU/g</b>
<b>Lactobacillus gasseri</b>	<b>33.3 million CFU/g</b>
<b>Lactobacillus paracasei</b>	<b>333.3 million CFU/g</b>
<b>Lactobacillus plantarum</b>	<b>500 million CFU/g</b>
<b>Lactobacillus reuteri</b>	<b>33.3 million CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>3.333 billion CFU/g</b>
<b>Lactobacillus salivarius ssp salivarius</b>	<b>66.7 million CFU/g</b>
<b>Saccharomyces cerevisiae (Boulandii)</b>	<b>833.3 million CFU/g</b>
<b>Streptococcus thermophilus</b>	<b>200 million CFU/g</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
 glycine  
 microcrystalline cellulose  
 silicon dioxide



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