



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	396977	BiomeClear
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	5/10/2022	
<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 . BiomeClear

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/10/2022
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Antioxidant/Reduce free radicals formed in the body  
Maintain/support natural body cleansing/detoxification processes  
Aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut  
Aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut  
Maintain/support body waste elimination  
Maintain/support healthy eye function  
Maintain/support eye health in aging individuals  
Maintain/support eye health  
Helps maintain/support eye macula health  
Helps enhance/promote general health and wellbeing  
Maintain/support general health and wellbeing  
Maintain/support healthy bowel/colon function  
Reduce occurrence of excess intestinal wind/gas  
Decrease/reduce/relieve excess intestinal gas  
Maintain/support small intestine health  
Maintain/support intestinal transit time  
Helps enhance/promote healthy digestive system function  
Helps enhance/promote healthy digestive system function  
Maintain/support healthy digestive system function  
Maintain/support healthy digestive system function  
Maintain/support healthy digestion  
Helps enhance/promote gastrointestinal system mucosa health  
Helps decrease/reduce dietary fat absorption in digestive system  
Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa  
Maintain/support intestinal good/beneficial/friendly flora  
Helps restore good/beneficial/friendly intestinal/gut/bowel flora

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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 healthy digestive system flora/good bacteria growth  
Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth  
Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth  
Nourish good/beneficial/friendly intestinal flora  
Maintain/support small intestine good/beneficial/friendly flora  
Helps enhance/promote gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Aids/assists repair of gastrointestinal/gut wall lining  
Decrease/reduce/relieve abdominal bloating/distention  
Helps reduce occurrence of abdominal bloating  
Helps reduce occurrence of abdominal bloating  
Helps decrease/reduce/relieve mild gastrointestinal tract inflammation  
Decrease/reduce/relieve digestive spasms  
Helps enhance/promote healthy liver function  
Hepatoprotectant/protect the liver  
Maintain/support liver health  
Maintain/support liver health  
Enhance/improve/promote/increase nutrient uptake  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support skin health

#### Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.  
Product presentation must only refer to detoxification in relation to natural body processes.  
  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.  
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.  
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to drugs/alcohol.  
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.  
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.  
Do not take while on warfarin therapy without medical advice.

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

##### Visual Identification



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**Active Ingredients**

<b>Arthrospira platensis</b>	<b>125 mg</b>
<b>Bifidobacterium breve</b>	<b>.5 CFU</b>
<b>Chlorella vulgaris cell Powder</b>	<b>25 mg</b>
<b>Cynara scolymus leaf Powder</b>	<b>50 mg</b>
<b>Dunaliella salina whole plant Dry</b>	<b>50 mg</b>
<b>Grifola frondosa fruiting body Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Grifola frondosa (Fresh)	275 mg
<b>high selenium yeast</b>	<b>25 mg</b>
Equivalent: selenium	.05 mg
<b>Lactobacillus acidophilus</b>	<b>1 billion CFU</b>
<b>Lactobacillus casei</b>	<b>.5 billion CFU</b>
<b>Lactobacillus fermentum</b>	<b>.5 CFU</b>
<b>Lactobacillus plantarum</b>	<b>1.25 billion CFU</b>
<b>Lactobacillus reuteri</b>	<b>.5 billion CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>2.5 billion CFU</b>
<b>lutein</b>	<b>2.5 mg</b>
<b>Polyporus umbellatus mushroom Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Polyporus umbellatus (Fresh)	250 mg
<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>87.5 mg</b>
Equivalent: Silybum marianum (Fresh)	3.0625 g
<b>Tremella fuciformis fruiting body Extract dry concentrate</b>	<b>12.5 mg</b>
Equivalent: Tremella fuciformis (Fresh)	100 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
disodium edetate  
dl-alpha-tocopherol  
gellan gum  
hypromellose  
liquid glucose  
magnesium stearate  
maize starch  
maltodextrin  
microcrystalline cellulose  
potable water  
potassium acetate  
sodium ascorbate  
soluble maize starch

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