



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	374479	DetoxClear
<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>	10/09/2021	
<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 . DetoxClear**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/09/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support body mucous membrane health
- Maintain/support body tissue repair/regeneration
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support digestive system health after exercise
- Maintain/support gastrointestinal system health after exercise
- Maintain/support gastrointestinal mucosal membrane health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow
- Traditionally used in Western herbal medicine to helps enhance/promote healthy liver function
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
- Maintain/support healthy liver function
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Maintain/support immune system health after exercise
- Maintain/support immune system health
- Maintain/support immune system health
- Maintain/support healthy immune system function

**Indication Requirements**

- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to drugs/alcohol.

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

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Adults only.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Powder

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Arthrospira platensis</b>	<b>222.22 mg/g</b>
<b>Brassica oleracea var. italica seed Extract dry concentrate</b>	<b>5.5575 mg/g</b>
Equivalent: Brassica oleracea var. italica (Dry)	85.5 mg/g
<b>Camellia sinensis leaf Extract dry concentrate</b>	<b>22.22 mg/g</b>
Equivalent: Camellia sinensis (Dry)	666.66 mg/g
<b>Chlorella vulgaris whole plant Powder</b>	<b>222.22 mg/g</b>
<b>glutamine</b>	<b>185.19 mg/g</b>
<b>glycine</b>	<b>37.04 mg/g</b>
<b>levomefolate glucosamine</b>	<b>32.957 microgram/g</b>
Equivalent: levomefolic acid	18.5185 microgram/g
<b>mecobalamin (co-methylcobalamin)</b>	<b>37.04 microgram/g</b>
<b>Punica granatum fruit hull Extract dry concentrate</b>	<b>1.85 mg/g</b>
Equivalent: Punica granatum (Dry)	37 mg/g
<b>pyridoxal 5-phosphate monohydrate</b>	<b>1.3587 mg/g</b>
Equivalent: pyridoxine	930 microgram/g
<b>quercetin dihydrate</b>	<b>11.1411 mg/g</b>
<b>retinol palmitate</b>	<b>30.525 microgram/g</b>
Equivalent: vitamin A	16.65 microgram/g
<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>18.52 mg/g</b>
Equivalent: Silybum marianum (Dry)	555.6 mg/g

**Other Ingredients (Excipients)**

- aluminium sodium silicate
- aluminium starch octenylsuccinate
- butylated hydroxytoluene
- citric acid
- colloidal anhydrous silica
- dl-alpha-tocopheryl acetate
- ethoxylated hydrogenated castor oil
- Flavour

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**fractionated coconut oil**  
**Gelatin**  
**Guar Gum**  
**lecithin**  
**maltodextrin**  
**mono- and di- glycerides**  
**Oryza sativa**  
**potable water**  
**silicon dioxide**  
**Siraitia grosvenorii**  
**Steviol glycosides**  
**sucrose**

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