



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

## Public Summary

<b>Summary for ARTG Entry:</b>	299671	METAGENICS THERMOPHASE DETOX ESSENTIALS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	15/02/2018	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . METAGENICS THERMOPHASE DETOX ESSENTIALS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/05/2020
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Chinese medicine to maintain/support natural liver cleansing/detoxification processes
- Aids/assists excretion of metabolic waste products
- Maintain/support body waste elimination
- Maintain/support general health and wellbeing
- Maintain/support healthy digestive system function
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal mucosal membrane health
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow
- Traditionally used in Chinese medicine to helps enhance/improve/promote/increase bile secretion/flow
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
- Traditionally used in Western herbal medicine to maintain/support healthy liver regeneration
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Maintain/support liver health

### Indication Requirements

- 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.
- Product presentation must not imply or refer to drugs/alcohol.



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

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

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.

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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Adults only.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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.

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

**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>ascorbic acid</b>	<b>13.16 mg/g</b>
<b>calcium pantothenate</b>	<b>2.89 mg/g</b>
<b>Camellia sinensis leaf Extract dry concentrate</b>	<b>10.95 mg/g</b>
Equivalent: Camellia sinensis (Dry)	273.75 mg/g
<b>cysteine</b>	<b>2.63 mg/g</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>1.68 mg/g</b>
Equivalent: d-alpha-tocopherol	1.32 mg/g
<b>Dunaliella salina</b>	<b>5.68 mg/g</b>
<b>Gardenia jasminoides fruit Extract dry concentrate</b>	<b>7.89 mg/g</b>
Equivalent: Gardenia jasminoides (Dry)	78.9 mg/g
<b>glutamine</b>	<b>78.95 mg/g</b>
<b>Larix arabinogalactan</b>	<b>52.63 mg/g</b>
<b>magnesium amino acid chelate</b>	<b>52.63 mg/g</b>
Equivalent: magnesium	5.26 mg/g
<b>mecobalamin (co-methylcobalamin)</b>	<b>10.53 microgram/g</b>
<b>nicotinamide</b>	<b>2.63 mg/g</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>2.63 mg/g</b>
Equivalent: pyridoxine	1.68 mg/g
<b>riboflavin sodium phosphate</b>	<b>736.84 microgram/g</b>
Equivalent: riboflavin	526.32 microgram/g
<b>selenomethionine</b>	<b>9.79 microgram/g</b>
Equivalent: selenium	3.94 microgram/g

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<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>4.51 mg/g</b>
Equivalent: Silybum marianum (Dry)	315.7 mg/g
<b>taurine</b>	<b>18.42 mg/g</b>
<b>thiamine hydrochloride</b>	<b>1.32 mg/g</b>
<b>zinc amino acid chelate</b>	<b>3.95 mg/g</b>
Equivalent: zinc	790 microgram/g

**Other Ingredients (Excipients)**

Acacia  
ascorbic acid  
ascorbyl palmitate  
citric acid  
colloidal anhydrous silica  
d-alpha-tocopherol  
Flavour  
maltodextrin  
Olive Oil  
Pisum sativum  
purified water  
silicon dioxide  
Steviol glycosides  
xanthan gum

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