



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

## Public Summary

<b>Summary for ARTG Entry:</b>	339190	Oriental Botanicals Kids' Nutrient Ninja
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	McPherson's Consumer Products Pty Ltd	
<b>Postal Address</b>	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
<b>ARTG Start Date</b>	8/07/2020	
<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 . Oriental Botanicals Kids' Nutrient Ninja

Product Type	Single Medicine Product	Effective Date	8/07/2020
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### Permitted Indications

- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish/fortify/invigorate spleen
- Maintain/support energy production
- Maintain/support healthy growth and development
- Maintain/support healthy growth and development in children up to 12 years of age
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite
- Maintain/support healthy appetite when dietary intake is inadequate
- Traditionally used in Chinese medicine to calms the mind
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- Maintain/support cognitive development
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support brain/central nervous system development

### Indication Requirements

Product presentation must not imply or refer to neurological conditions or developmental delays.

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If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to disease in any body organ.

**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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, chewable

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>30 mg</b>
<b>betacarotene</b>	<b>.3 mg</b>
<b>Biotin</b>	<b>25 microgram</b>
<b>calcium citrate tetrahydrate</b>	<b>23.98 mg</b>
Equivalent: calcium	5 mg
<b>calcium pantothenate</b>	<b>1.64 mg</b>
Equivalent: calcium	140 microgram
Equivalent: pantothenic acid	1.5 mg
<b>choline bitartrate</b>	<b>151.96 mg</b>
Equivalent: choline	62.5 mg
<b>Citrus bioflavonoids extract</b>	<b>500 microgram</b>
<b>colecalfiferol</b>	<b>.0025 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>4 mg</b>
Equivalent: d-alpha-tocopherol	4.84 IU
<b>ferrous fumarate</b>	<b>7.61 mg</b>
Equivalent: iron	2.5 mg
<b>folic acid</b>	<b>100 microgram</b>
<b>magnesium glycinate</b>	<b>111.11 mg</b>
Equivalent: magnesium	15 mg
<b>manganese (II) glycinate</b>	<b>2.84 mg</b>
Equivalent: manganese	650 microgram

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<b>mecobalamin (co-methylcobalamin)</b>	<b>2.4 microgram</b>
<b>menaquinone 7</b>	<b>10 microgram</b>
<b>nicotinamide</b>	<b>2.997 mg</b>
<b>potassium iodide</b>	<b>59 microgram</b>
Equivalent: iodine	45 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>784 microgram</b>
Equivalent: pyridoxine	500 microgram
<b>pyridoxine hydrochloride</b>	<b>.999 mg</b>
<b>retinol acetate</b>	<b>.2357 mg</b>
<b>riboflavin sodium phosphate</b>	<b>1.32 mg</b>
Equivalent: riboflavin	1 mg
<b>selenomethionine</b>	<b>18.8 microgram</b>
Equivalent: selenium	7.5 microgram
<b>Tagetes erecta flower Extract dry concentrate</b>	<b>5 mg</b>
Equivalent: Tagetes erecta (Dry)	200 mg
<b>thiamine nitrate</b>	<b>1.998 mg</b>
<b>zinc glycinate monohydrate</b>	<b>5.32 mg</b>
Equivalent: zinc	1.5 mg
<b>Ziziphus jujuba fruit Extract dry concentrate</b>	<b>217 mg</b>
Equivalent: Ziziphus jujuba (Dry)	3.255 g

**Other Ingredients (Excipients)**

Acacia  
beetroot  
citric acid  
colloidal anhydrous silica  
d-alpha-tocopherol  
dl-alpha-tocopherol  
Flavour  
hypromellose  
magnesium stearate  
maize starch  
maltodextrin  
medium chain triglycerides  
mono- and di- glycerides  
Pea Starch  
purified water  
rice starch  
silicon dioxide  
Siraitia grosvenorii  
sodium alginate  
sodium ascorbate  
sodium bicarbonate  
spray-dried glucose syrup  
thaumatin  
xylitol

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