



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371280	Pure Children's Essentials
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	19/07/2021	
Product Category	Medicine	
Status	Active	
Approval Area	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 . Pure Children's Essentials

Product Type	Single Medicine Product	Effective Date	19/07/2021
--------------	-------------------------	----------------	------------

Permitted Indications

- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support healthy growth and development
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children
- Aids/assists teeth development
- Aids/assists teeth development in children
- Maintain/support healthy teeth
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building
- Maintain/support (state mineral) absorption in bones
- Maintain/support bone strength
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support immune system health
- Maintain/support healthy immune system function in children



Australian Government
Department of Health
 Therapeutic Goods Administration

- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support muscle health
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support cognitive development
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development
- Maintain/support brain/central nervous system development in children
- Maintain/support nervous system function
- Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

Indication Requirements

If product is indicated for supplementation, 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).

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

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 serious immunological diseases.

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

Product presentation must not imply or refer to any thyroid related diseases.

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).

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 chronic fatigue syndrome.

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Biotin	5 microgram/g
calcium ascorbate dihydrate Equivalent: ascorbic acid	12.11 mg/g 10 mg/g
calcium citrate Equivalent: calcium	207.31 mg/g 50 mg/g
calcium folinate Equivalent: folic acid	43 microgram/g 40 microgram/g
calcium hydrogen phosphate dihydrate Equivalent: calcium	10.96 mg/g 2.55 mg/g
calcium pantothenate Equivalent: pantothenic acid	3.27 mg/g 3 mg/g
choline bitartrate	30 mg/g
chromium nicotinate Equivalent: chromium	24.11 microgram/g 3 microgram/g
colecalfiferol	.002 mg/g
glycine	400 mg/g
hydroxocobalamin	3.01 microgram/g
iron (II) glycinate Equivalent: iron	3.56 mg/g .8 mg/g
lysine hydrochloride Equivalent: lysine	3 mg/g 2.4 mg/g
magnesium ascorbate monohydrate Equivalent: ascorbic acid	11.15 mg/g 10 mg/g
magnesium citrate Equivalent: magnesium	160.5 mg/g 26 mg/g
manganese amino acid chelate Equivalent: manganese	500 microgram/g 50 microgram/g
menaquinone 7	1.001 microgram/g
molybdenum trioxide Equivalent: molybdenum	6.75 microgram/g 4.5 microgram/g
nicotinamide	3 mg/g
palm tocotrienols complex	.504 mg/g
phytomenadione	6.005 microgram/g
potassium citrate Equivalent: potassium	5.53 mg/g 2 mg/g
potassium iodide Equivalent: iodine	23.54 microgram/g 18 microgram/g
pyridoxal 5-phosphate monohydrate Equivalent: pyridoxine	.31 mg/g .2 mg/g
pyridoxine hydrochloride Equivalent: pyridoxine	.9 mg/g .74 mg/g
retinol acetate Equivalent: vitamin A	.0943 mg/g .0799 mg/g
riboflavin sodium phosphate Equivalent: riboflavin	1 mg/g .73 mg/g
selenomethionine Equivalent: selenium	15.01 microgram/g 6 microgram/g
thiamine hydrochloride Equivalent: thiamine	1 mg/g .78 mg/g
zinc citrate dihydrate	3.73 mg/g



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: zinc

1.2 mg/g

Other Ingredients (Excipients)

Acacia
Beta vulgaris
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
dl-alpha-tocopherol
Flavour
fractionated coconut oil
liquid glucose
maize starch
malic acid
maltodextrin
Palm Fruit Oil
silicon dioxide
sodium ascorbate
sodium bicarbonate
spray-dried glucose syrup
starch sodium octenyl succinate
Stevia rebaudiana
sucrose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary