



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307115	Brauer Baby & Kids Ultra Pure DHA
ARTG entry for	Medicine Listed	
Sponsor	BNutrition Pty Ltd	
Postal Address	PO Box 234, Tanunda, SA, 5352 Australia	
ARTG Start Date	17/07/2018	
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 . Brauer Baby & Kids Ultra Pure DHA

Product Type	Single Medicine Product	Effective Date	7/05/2021
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Permitted Indications

Helps maintain/support healthy eye development
Maintain/support healthy eye function
Maintain/support eye health
Helps maintain/support eye retina health
Helps maintain/support healthy vision development
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing
Maintain/support brain function
Maintain/support brain/central nervous system development

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to neurological conditions or developmental delays.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft
Route of Administration Oral

Visual Identification

Active Ingredients

concentrated fish Omega-3 triglycerides	319.15 mg
Equivalent: docosahexaenoic acid	150 mg
Equivalent: eicosapentaenoic acid	31.91 mg

Other Ingredients (Excipients)

Gelatin
glycerol
Lemon Oil
Olive Oil
purified water

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