

**14.03(b) AMINO ACID FORMULA WITH VITAMINS,
MINERALS AND LONG CHAIN POLYUNSATURATED
FATTY ACIDS WITHOUT PHENYLALANINE,**

Oral powder 400 g

PKU Anamix Infant®

Nutricia Australia Pty Ltd

**AMINO ACID FORMULA WITH VITAMINS AND
MINERALS WITHOUT PHENYLALANINE AND
TYROSINE,**

Oral powder 400 g

TYR Anamix Infant®

Nutricia Australia Pty Ltd

**AMINO ACID FORMULA WITH VITAMINS AND
MINERALS WITHOUT LYSINE AND LOW IN
TRYPTOPHAN,**

Oral powder 400 g

GA1 Anamix Infant®

Nutricia Australia Pty Ltd

**AMINO ACID FORMULA WITH VITAMINS AND
MINERALS WITHOUT METHIONINE, THREONINE AND
VALINE AND LOW IN ISOLEUCINE**

Oral powder 400 g

MMA/PA Anamix Infant®

Nutricia Australia Pty Ltd

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Oral powder 400 g

HCU Anamix Infant®

Nutricia Australia Pty Ltd

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Oral powder 400 g

MSUD Anamix Infant®

Nutricia Australia Pty Ltd

1 Purpose of Application

1.1 The Committee Secretariat submission requested a change to the formulation of the following products based on new European compositional standards:

- PKU Anamix Infant® (PBS Code 8479G)
- TYR Anamix Infant® (PBS Code 8445L)
- GA1 Anamix Infant® (PBS Code 2650L)
- MMA/PA Anamix Infant® (PBS Code 8058D)
- HCU Anamix Infant® (PBS Code 8417B)
- MSUD Anamix Infant® (PBS Code 2380G)

2 Background

2.1 PKU Anamix Infant® (PBS Code 8479G) is PBS listed for the dietary management of proven Phenylketonuria (PKU). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.

2.2 TYR Anamix Infant® (PBS Code 8445L) is PBS listed for the dietary management of proven Tyrosinaemia (TYR). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.

2.3 GA1 Anamix Infant® (PBS Code 2650L) is PBS listed for the dietary management of proven Glutaric Aciduria Type 1 (GA1). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.

- 2.4 MMA/PA Anamix Infant® (PBS Code 8058D) is PBS listed for the dietary management of proven Methylmalonic acidaemia and Propionic acidaemia (MMA/PA). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.
- 2.5 HCU Anamix Infant® (PBS Code 8417B) is PBS listed for the dietary management of proven Pyridoxine non-responsive homocystinuria (HCU). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.
- 2.6 MSUD Anamix Infant® (PBS Code 2380G) Infant is PBS listed for the dietary management of proven Maple syrup urine disease (MSUD). The product is intended for use from birth to 12 months of age and as a supplementary feed up to 3 years of age.
- 2.7 The submission requested a change to the formulation of the above six products to meet new European Commission Delegated Regulations on Infant and Follow-on Formulae [Commission Delegated Regulation (EU) 2016/127] and Food for Special Medical Purposes (FSMP) [Commission Delegated Regulation (EU) 2016/128] intended to satisfy the nutritional requirements of infants. Regulation 2016/128 sets out new maximum and minimum levels of vitamin and mineral substances for products that will provide a sole source of nutrition, and new maximum levels of vitamins and minerals for products that are not a sole source of nutrition. This regulation also requires additional nutrient declarations on the packaging with the intent to guarantee appropriate use of the product.

3 Requested listing

- 3.1 The submission did not request changes to the current listings of PKU Anamix Infant® (PBS Code 8479G), TYR Anamix Infant® (PBS Code 8445L), GA1 Anamix Infant® (PBS Code 2650L), MMA/PA Anamix Infant® (PBS Code 8058D), HCU Anamix Infant® (PBS Code 8417B), MSUD Anamix Infant® (PBS Code 2380G).

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a Committee Secretariat submission.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 4.3 As a Committee Secretariat submission, no clinical trials were presented in the submission.

Other relevant matters

4.4 Key changes to the nutritional profile are presented in Table 1.

Table 1: Comparison of the current and new composition profile for all Anamix infant products (PKU Anamix Infant®, TYR Anamix Infant®, GA1 Anamix Infant®, MMA/PA Anamix Infant®, HCU Anamix Infant®, MSUD Anamix Infant®)

Nutrient	Unit per 100g	Old formulation	New formulation
Carbohydrate	g	49.8	50.1
Sugars	g	7.3	7.5
Lactose	g	1.6	1.7
Galactose	g	0.06	0.08
Potassium	mg	501	505
Iron	mg	8.1	7.92
Copper	mg	0.43	0.42
Zinc	mg	5.7	5.59
Manganese	mg	0.43	0.029
Molybdenum	µg	12	12.1
Magnesium	mg	58	58.3
Selenium	µg	15.5	17.7
Chromium	µg	13.3	14
Iodine	µg	83	97.9
Vitamin A	µg RE	392	408
Vitamin E	mg	7.4	9.06
Vitamin D	µg	8.7	11.2
Vitamin E	mgαT	4.6	11.5
Vitamin C	mg	49	48.9
Vitamin K	µg	37.2	37.3
Thiamine	mg	0.5	0.51
Riboflavin	mg	0.5	0.51
Niacin	mg	2.2	2.33
Vitamin B6	mg	0.5	0.51
Vitamin B12	µg	1.2	1.21
Pantothenic acid	mg	2.8	2.81
Inositol	mg	98	97.9
Potential Renal Solute Load	mOsmol/l	173	179
Carnitine	mg	6.9	30.2

Source: Table 1, pg 4 of the submission

5 NPWP Consideration

- 5.1 The Nutritional Products Working Party (NPWP) noted the requested changes to Anamix Infant products to meet international guidelines and standards for nutritional content of supplementary products for infants. The NPWP noted the revised formulation included a range of changes to the nutritional profile, including vitamin, mineral and micronutrient profile.
- 5.2 The NPWP noted that the manganese levels were lower than that of the Australian adequate intake (AI) levels. However, the NPWP considered this was not a concern as adequate levels of manganese could be reached with the consumption of drinking water, vegetables and cereals.

- 5.3 The NPWP considered that the nutritional values spreadsheets and comparison with appropriate FSANZ and EU Food standards included in the submission were informative and agreed it would be useful for submissions to continue to present information in this format.
- 5.4 The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients and supported the request to change the formulation.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended continuing the Restricted Benefit listings of: PKU Anamix Infant® for the dietary management of Phenylketonuria; TYR Anamix Infant® for the dietary management of Tyrosinaemia; GA1 Anamix Infant® for the dietary management of proven Glutaric Aciduria Type 1; MMA/PA Anamix Infant® for the dietary management of proven Methylmalonic acidaemia and Propionic acidaemia; HCU Anamix Infant® for the dietary management of proven Pyridoxine non-responsive homocystinuria; and MSUD Anamix Infant® for the dietary management of proven Maple syrup urine disease, following their reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted that the NPWP was not concerned with the manganese levels being lower than the Australian AI levels, as adequate levels could be reached with the consumption of drinking water, vegetables and cereals.
- 6.3 The PBAC noted the NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 No changes to the existing listing.

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not

necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.