

6.11 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Oral gel 85 g, 30 (PKU squeeze), PKU squeeze®, Vitaflo Australia Pty Limited

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested that amino acid formula with vitamins and minerals without phenylalanine (PKU squeeze®) with new source of Vitamin A continue to be listed on the Pharmaceutical Benefits Scheme (PBS) under the existing conditions.

2 Background

- 2.1 PKU squeeze was recommended by the PBAC at its November 2010 meeting and is currently listed on the PBS as a restricted benefit listing for phenylketonuria (PKU).
- 2.2 With regard to change in the source of Vitamin A, the submission claimed PKU squeeze continues to meet the requirements for foods that have special medical purposes as set out under The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes.

3 Requested listing

- 3.1 The submission requested no changes to the existing listing of PKU squeeze, including no change to the price of currently listed PKU squeeze.

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

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

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

Nutritional profile

- 4.3 The submission stated that the source of Vitamin A has changed from retinyl acetate to retinyl palmitate to optimise the stability of Vitamin A in PKU squeeze.

Table 1: Nutritional profile comparison of PKU squeezeie.

Nutrient per 100g Consumable product	PKU squeezeie	
	2010 ^a	2022 ^b
Energy kJ	689	668
kcal	164	157
Protein Equivalent g	12	12
Carbohydrate g	28	26
O/W sugars g	Not stated	16
Fat g	0.6	0.6
O/W saturates g	Not stated	0.18
Docosahexaenoic acid mg	74	74
Arachidonic acid mg	148	148
Amino acid equivalent	14	~13 (sum of amino acid profile) ^c
Vitamins		
Vitamin A RE mcg	169	170
Vitamin D3 mcg	3.4	4.1
Vitamin E mg	2.6	2.6
Vitamin C mg	17.6	18
Vitamin K mcg	11.5	12
Thiamin mg	0.28	0.28
Riboflavin mg	0.34	0.34
Niacin mg (mg NE)	4 (not stated)	4.0 (8.5)
Vitamin B6 mg	0.3	0.3
Folic Acid mcg	59	59
Vitamin B12 mcg	0.56	0.56
Biotin mcg	7	7.1
Pantothenic Acid mg	1.4	1.4
Choline mg	78.8	79
Minerals		
Sodium mg	107	107
Potassium mg	264	260
Chloride mg	164	164
Calcium mg	306	310
Phosphorus mg	234	230
Magnesium mg	47	47
Trace Elements		
Iron mg	4	4
Copper mg	0.22	0.22
Zinc mg	2.94	3.1
Manganese mg	0.41	0.48
Iodine mcg	39	39
Molybdenum mcg	14.1	14
Selenium mcg	9.88	10
Chromium mcg	20	20

Source: ^a Appendix 1 from PKU squeezeie minor PBAC submission Nov 2010; ^b Appendix 1 from current PKU squeezeie committee secretariat submission Nov 2022; ^c PKU squeezeie data card May 2022

Estimated PBS utilisation and financial implications

- 4.4 The submission considered that there would be no change to the market utilisation due to the change in Vitamin A source of PKU squeeze. It is expected that the change in the source of Vitamin A in PKU squeeze will not have a financial impact.

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

5 NPWP Consideration

- 5.1 The Nutritional Products Working Party (NPWP) supported the continued PBS listing of PKU squeeze, with new source of Vitamin A, under the existing conditions.
- 5.2 The NPWP considered that the change in Vitamin A source to retinyl palmitate was safe and appropriate.

6 PBAC Outcome

- 6.1 The PBAC recommended that PKU squeeze continue to be listed on the PBS under the same conditions as currently listed.
- 6.2 The PBAC agreed with the NPWP advice that the new source of vitamin A is safe and appropriate.
- 6.3 The PBAC noted that the sponsor requested no changes to the current pricing arrangement, and that this recommendation will result in a nil cost to Government.
- 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 change to the existing listing

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 10 Sponsor's Comment

The sponsor had no comment.