6.11 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE
Oral gel 85 g, 30 (PKU squeezie),
PKU squeezie®,
Vitaflo Australia Pty Limited

1. Purpose of Submission
	1. The Committee Secretariat submission requested that amino acid formula with vitamins and minerals without phenylalanine (PKU squeezie®) with new source of Vitamin A continue to be listed on the Pharmaceutical Benefits Scheme (PBS) under the existing conditions.
2. Background
	1. PKU squeezie 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. With regard to change in the source of Vitamin A, the submission claimed PKU squeezie 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
	1. The submission requested no changes to the existing listing of PKU squeezie, including no change to the price of currently listed PKU squeezie.

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

# Consideration of the evidence

Sponsor hearing

* 1. There was no hearing for this item.

Consumer comments

* 1. The PBAC noted that no consumer comments were received for this item.

Nutritional profile

* 1. 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 squeezie*.*

Table 1: Nutritional profile comparison of PKU squeezie.

| Nutrient per 100gConsumable product | PKU squeezie |
| --- | --- |
| 2010a | 2022b |
| Energy kJ kcal | 689164 | 668157 |
| Protein Equivalent g | 12 | 12 |
| Carbohydrate gO/W sugars g | 28Not stated | 2616 |
| Fat gO/W saturates g | 0.6Not stated | 0.60.18 |
| 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 squeezie minor PBAC submission Nov 2010; b Appendix 1 from current PKU squeezie committee secretariat submission Nov 2022; c PKU squeezie data card May 2022

Estimated PBS utilisation and financial implications

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

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

# NPWP Consideration

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

# PBAC Outcome

* 1. The PBAC recommended that PKU squeezie continue to be listed on the PBS under the same conditions as currently listed.
	2. The PBAC agreed with the NPWP advice that the new source of vitamin A is safe and appropriate.
	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.
	4. The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

# Recommended listing

* 1. No change to the existing listing

# 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.

# 10 Sponsor’s Comment

The sponsor had no comment.