

**MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY
THE SECRETARIAT FOR CONSIDERATION BY THE
COMMITTEE**

**14.03 AMINO ACID FORMULA WITH VITAMINS AND
MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**
oral liquid, 87 mL, 30 (MSUD Cooler 10);
oral liquid, 130 mL, 30 (MSUD Cooler 15);
oral liquid, 174 mL, 30 (MSUD Cooler 20);
MSUD Cooler® 10, MSUD Cooler® 15, MSUD Cooler® 20

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS
WITHOUT PHENYALANINE AND TYROSINE**
oral liquid, 87 mL, 30 (TYR Cooler 10);
oral liquid, 130 mL, 30 (TYR Cooler 15);
oral liquid, 174 mL, 30 (TYR Cooler 20);
TYR Cooler® 10, TYR Cooler® 15, TYR Cooler® 20

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS
WITHOUT METHIONINE**
oral liquid, 87 mL, 30 (HCU Cooler 10);
oral liquid, 130 mL, 30 (HCU Cooler 15);
oral liquid, 174 mL, 30 (HCU Cooler 20);
HCU Cooler® 10, HCU Cooler® 15, HCU Cooler® 20,
Vitaflo Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested changes to the Restricted Benefit listing of MSUD, TYR and HCU Coolers including nutritional content.

2 Requested Listing:

- 2.1 The submission did not request changes to existing listings.
- 2.2 The purpose of the submission was to amend the nutritional profile of the currently listed product. The changes are summarised in the table below:

Table 1: Difference in nutritional contents for current and new Coolers formulations

Nutrient per 100ml	MSUD, TYR, and HCU Coolers (Current)	MSUD, TYR, and HCU Coolers (New)	PKU cooler
Energy kJ	302	316	316
kcal	71	75	75
Carbohydrate g	5.4	5.1	5.1
Of which (O/W) sugars	4.5	3.4	3.4
Fat g	0.4	0.9	0.9
O/W saturates g	0.1	0.2	0.2
O/W DHA mg/EPA mg	77/18	77/0	77/0
Osmolality mOsm/kg	1900	1550	1550
Vitamins			
Vitamin A mcg RE	160	150	150
Vitamin K mcg	19	14	14
Niacin mg	4.8	2.0	2.0
Folic Acid mcg	77	58	58
Biotin mcg	36	7.5	7.5
Pantothenic Acid mg	1.5	1.1	1.1
Minerals			
Sodium mg	98	60	60
Potassium mg	181	140	140
Chloride mg	140	80	80
Magnesium mg	72	63	63

Source: Coolers submission, updated table provided by sponsor

- 2.3 The sponsor stated that the source of docosahexaenoic acid (DHA) has changed, which has led to an insignificant amount of eicosapentaenoic acid (EPA). The sponsor has therefore removed EPA from the nutritional label, while the DHA content remains unchanged.
- 2.4 The key difference between the current and new formulation is a general decrease in vitamins, minerals, and trace elements, but the amino acid profile remains unchanged.

3 Background

- 3.1 The sponsor also advised that these changes were consistent with the request for PKU Cooler®, which was previously advised by the NPWP as clinically appropriate and in line with international nutritional recommendations. PKU Cooler was recommended by the PBAC at the March 2017 meeting.

4 Pricing considerations

- 4.1 There are no pricing considerations for this item as the key amino acid properties of these products have not changed.

5 NPWP Consideration

- 4.2 The Nutritional Products Working Party (NPWP) remained somewhat concerned that the reduced levels of folate and manganese in the revised formulations would not meet the nutritional requirements of patients. However, the NPWP noted that the patients are likely to get these micronutrients from other dietary intakes or supplements, especially in the case of pregnant women.
- 4.3 The NPWP supported the request to change the nutritional content of these products.

5 PBAC Outcome

- 5.1 The PBAC noted the change to the listings processed by the secretariat.

Outcome:

Recommended

6 Recommended listing

- 6.1 No change to the existing listing

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.