

**14.03(h) TRIGLYCERIDES MEDIUM CHAIN FORMULA,  
Oral powder 400 g,  
Monogen<sup>®</sup>,  
Nutricia Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The Committee Secretariat Submission requested a change to the formulation of the triglyceride medium chain formula, Monogen<sup>®</sup>, in order to comply with new European compositional standards.

**2 Background**

- 2.1 Monogen was first listed on the PBS in 2001.
- 2.2 The submission requested a change to the formulation of Monogen 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]. 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. Further information on the compositional changes are presented in Section 4.

**3 Requested listing**

- 3.1 The submission did not request changes to the current listing of Monogen (PBS item 10152H and 8478F).

## 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.

### *Nutritional profile changes*

4.3 The main changes to the nutritional profile proposed in the submission include an increase in polysaccharides, vitamin A and folate, and a decrease in glucose, maltose, potassium and chloride. These changes as well as other changes are presented in Table 1.

**Table 1: Nutritional composition changes to Monogen**

Parameter (units of measurement per 100g)	Old formulation	New formulation
Energy value (kJ)	1871	1859
Energy value (kcal)	444	441
Saturates (g)	11.2	11.3
Carbohydrates (g)	69.1	68.6
Sugars (g)	13.4	11.8
Protein (g)	12.9	12.8
Salt (g)	0.53	0.52
Glucose (g)	1.3	0.69
Lactose (g)	7.8	7.85
Maltose (g)	4.3	3.3
Polysaccharides (g)	55.1	56.2
Starch (g)	-	0.01
Organic acids (g)	0.59	0.62
Animal fat (g)	0.2	0.13
Milk fat (g)	0.2	0.13
Medium chain triglycerides (MCT) (g)	10.8	10.9
Long chain triglycerides (LCT) (g)		2.0
Monounsaturates (g)	0.4	0.34
Sodium (Na) (mg)	213	210
Potassium (K) (mg)	413	397
Chloride (Cl) (mg)	315	301
Calcium (Ca) (mg)	357	365
Phosphorus (P) (mg)	220	214
Iron (Fe) (mg)	6.7	6.63
Zinc (Zn) (mg)	4.5	4.56
Manganese (Mn) (mg)	0.36	0.031
Molybdenum (Mo) (µg)	20.9	24.0
Selenium (µg)	11.5	17.4
Chromium (µg)	10.6	9.93
Iodine (I) (µg)	80.3	88.5
Calcium/Phosphorus ratio	1.7	1.66
Vitamin A (µg Retinol equivalent)	325	386

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Parameter (units of measurement per 100g)	Old formulation	New formulation
Vitamin E (mg a-Tocopherol equivalent)	4.9	4.92
a-Tocopherol (mg)	6.6	6.64
Vitamin B2 (mg)	0.49	0.52
Niacin incl. Tryptophan (mg Niacin equivalent)	7.8	7.47
Panthenic acid (mg)	2.2	2.21
Folic acid (µg)	67.8	70.2
Folate (µg)		117
Vitamin B12 (µg)	0.67	0.63
Biotin (µg)	14.2	15.5
Vitamin C (mg)	60.1	59.9
L-Carnitine (mg)	10.1	10.7
Inositol (mg)	88.7	87.4
Taurine (mg)	30	29.9
MCT (gFattyAcid/100gFattyAcid)	84.0	84.4
LCT (gFattyAcid/100gFattyAcid)	16.0	15.6

Source: Monogen Minor Submission, Table 1 pg. 3-4

## 5 NPWP Consideration

- 5.1 The Nutritional Products Working Party (NPWP) noted the requested change to the formulation for Monogen to meet international guidelines and standards for nutritional content of supplementary products for infants.
- 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 noted the revised formulation had included a range of changes to the nutritional profile, including the vitamin, mineral and micronutrient profile. 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 listing of triglycerides medium chain formula, Monogen, for the dietary management of conditions requiring

a source of medium chain triglycerides, following its 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.