

	Product specification	doku- no.: version: page:	1-31411-B- 20170126-external B 1 of 5
---	------------------------------	------------------------------------	--

Product:	ZeroTVMI K		GB
-----------------	-------------------	--	-----------

1. Product description

Name : **ZeroTVMI K**

Extended name: **Zero TVMI K**

Food for special medical purposes. Protein supplement free of Threonine, Valine, Methionine and Isoleucine for the dietary management of Methylmalonic Aciduria or Propionic Aciduria. For infants/ children from 4 months to 6 years of age.

Sales denomination: Food for special medical purposes

2. Specific requirements according to food law

The product is intended as a dietary food for special medical purposes (balanced diet) according to Regulation (EC) No 609/2013.

The product complies with the relevant German, as well as European, provisions of the food law, especially the provisions of the Food, Consumer Goods and Feed Code (LFGB) and Regulation (EC) No 178/2002.

The product is produced in a factory that has a certified quality system (ISO 9001-2000).

The raw materials for the product correspond to the purity requirements obtainable according to the generally recognized rules of technology and are fully suitable for human consumption.

Packaging which can directly or indirectly influence the quality of the food must be suitable for use in foodstuffs. Packaging and transport containers are designed to protect the product against external influences. The packing materials and transport containers in contact with the raw material must not impair the quality of the raw material. The packaging materials used comply with the legal requirements of Regulation (EC) No 1935/2004 and Regulation (EC) No 10/2011 on materials and articles (made of plastic) intended to come into contact with foodstuffs. There is no odor, taste or other impairment of the delivered goods from the packaging material.

3. Product properties

3.1. Ingredients

Date: 27.01.2014

L-lysine-L-aspartate, L-proline, potassium-L-glutamate, L-arginine-L-aspartate, L-leucine, L-serine, L alanine, calcium phosphate, glycine, L-glutamine, L-tyrosine, magnesium-L-aspartate, L phenylalanine, L-cystine, sodium chloride, L-histidine, L-tryptophan, choline, L-carnitine, vitamin E, vitamin A, sodium molybdate, folic acid, inositol, niacin, ferrous sulphate, sodium selenite, vitamin C, zinc sulphate, pantothenic acid, taurine, vitamin K, sodium fluoride, manganese sulphate, chromium (III) chloride, vitamin B2, vitamin B1, vitamin B6, potassium iodide, cupric sulphate, biotin, vitamin D, vitamin B12.

Created 26.01.2017	Checked 26.01.2017	Released : 26.01.2017	
Katja Gaude	Angélique Gebbing	Angélique Gebbing	

Product:
ZeroTVMI K
GB

3. 2. Nutrition information

		100 g	6,9 g	
Energy	kJ	1231	85	
	kcal	290	20	
Fat	g	0	0	
of which saturates	g	0	0	
Carbohydrate	g	0	0	
of which sugars	g	0	0	
Protein eqv.	g	72	5	
Salt	g	2,6	0,2	
		100 g	6,9 g	per g protein
Vitamins				
Vitamin A	µg	1100	76	15
Vitamin D	µg	30	2	0,4
Vitamin E	mg	26	1,8	0,36
Vitamin K1	µg	67	5	1
Vitamin C	mg	130	9	1,8
Thiamin (Vit. B1)	mg	2,6	0,18	0,036
Riboflavin (Vit. B2)	mg	3	0,23	0,05
Niacin	mg	33	2,3	0,5
Vitamin B6	mg	3	0,23	0,05
Folic acid	µg	557	38	8
Vitamin B12	µg	7	0,5	0,1
Biotin	µg	59	4	0,8
Pantothenic acid	mg	15	1	0,2
Minerals				
Potassium	mg	1857	128	26
Chloride	mg	637	44	9
Calcium	mg	2228	154	31
Phosphorus	mg	1188	82	16
Magnesium	mg	334	23	5
Trace elements				
Iron	mg	33	2,3	0,5
Zinc	mg	27	2	0,4
Copper	mg	3	0,2	0,04
Manganese	mg	6	0,4	0,08
Fluoride	mg	1,1	0,1	0,015
Selenium	µg	54	4	0,7
Chromium	µg	156	11	2
Molybdenum	µg	117	8	1,6
Iodine	µg	386	27	5

Product:	ZeroTVMI K		GB
-----------------	-------------------	--	-----------

FURTHER NUTRITION INFORMATION				
Sodium	mg	1050	72	14
L-Carnitine	mg	67	5	1
Choline	mg	297	20	4
myo-Inositol	mg	349	24	5
Taurine	mg	74	5	1
Amino acids	g	87	6	1,2
L-Alanine	g	5,9	0,40	0,08
L-Arginine	g	5,1	0,36	0,07
L-Aspartic acid	g	12,2	0,80	0,17
L-Cystine	g	3,3	0,22	0,05
L-Glutamine	g	4,9	0,34	0,07
L-Glutamic acid	g	7,8	0,50	0,11
Glycine	g	4,9	0,34	0,07
L-Histidine	g	1,9	0,13	0,03
L-Isoleucine	g	-	-	-
L-Leucine	g	8,4	0,60	0,12
L-Lysine	g	5,6	0,40	0,08
L-Methionine	g	-	-	-
L-Phenylalanine	g	3,7	0,26	0,05
L-Proline	g	10,5	0,70	0,15
L-Serine	g	6,5	0,45	0,09
L-Threonine	g	-	-	-
L-Tryptophan	g	1,9	0,13	0,03
L-Tyrosine	g	4,3	0,30	0,06
L-Valine	g	-	-	-

4. Quality parameters and reference values

4.1. Sensoric properties

appearance: white powder

consistency: fine powder

odour: characteristical

taste: characteristical

Product:
ZeroTVMI K
GB

4.2. Potential allergens

Potential allergen	present (Y/N)	Cross-contamination possible (Y/N)
Cereals containing gluten and products thereof	N	N
Crustaceans and products thereof	N	N
Eggs and products thereof	N	N
Fish and products thereof	N	N
Peanuts and products thereof	N	N
Soybeans and products thereof	N	N
Milk and products thereof (including lactose)	N	N
Nuts and products thereof	N	N
Celery and products thereof	N	N
Mustard and products thereof	N	N
Sesame seeds and products thereof	N	N
Sulphur dioxide at concentration > 10mg/kg (SO ₂)	N	N
Lupin and products thereof	N	N
Molluscs and products thereof	N	N

4.3. Statement on GMO

Neither genetically modified raw materials, nor genetic engineering methods are used in the production of the above-mentioned product. The product is therefore not subject to the requirements of Regulation (EC) No 1829/2003 on genetically modified food and feed and is not subject to labeling requirements in accordance with Regulation (EC) No 1830/2003 on the traceability and labeling of genetically modified organisms..

4.4. Microbiological requirements

	Unit	Guide value	Warn value
TAMC	CFU/g	5×10^2	5×10^3
Cronobacter spp.	CFU/g	-	n.n. in 25 g
Enterobacteriaceae	CFU/g	-	n.n. 10 g
Yeast and moulds	CFU/g	5×10^1	5×10^2
Spores of sulfite-reducing Clostridia	CFU/g		1×10^1
presumptive B. cereus	CFU/g	5×10^1	5×10^2
Salmonella spec.	CFU/g	-	n.n. in 125 g
coagulase positive Staphylococci	CFU/g	-	n.n. in 1 g
L. monocytogenes	CFU/g	-	n.n. in 250 g

Product:
ZeroTVMI K
GB

4.5. Chemical and physical properties

	Average values	Solution
pH-value	6,7-7,8	10 g / 100 ml water
Humidity	< 2%	powder
Osmolality	730-760 mosmol/kg	10 g / 100 ml water
Bulk density	0,64-0,73 g/cm ³	powder

5. Form of delivery

Packaging:

Tin can - 500 g

Folding box -172,50 g

6. Shelf life

24 months after production date

7. Storage

Cool and dry

8. Traceability

The traceability is guaranteed by the best before date and by the batch number.