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HRB 2023 - Amtsgericht Friedberg
Sitz der Gesellschaft Friedberg
Geschäftsführer Dr. Bernhard Hoffmann
Volker Sieg

CONFIDENTIAL
ONLY FOR PRESENTATION AT THE COMPETENT AUTHORITY

19.09.2025

CERTIFICATE OF QUALITY

ZeroTVMI K

We herewith confirm that the product "ZeroTVMI K" is produced in a company which has established a Quality Management System (ISO 9001-2015) certified by TÜV Süd.

The ISO-certification ensures safety to metaX in giving guarantee for a consistently high quality. Workflow and quality checks are regulated in a manual.

metaX Institut für Diätetik GmbH



Angélique Gebbing
Director Regulatory Affairs
State certified food chemist

	Analysenzertifikat		Blatt 1	von 1
	Abteilung: Qualitätssicherung	Prozessverantwortlicher: PL	Erstellt 02.07.2020	Version 5

Analysenzertifikat / Certificate of Analysis

1. Produktdaten/product data				
Produkt/product	Zero TVMI K			
Charge/batch	TVMI/4319-K			
Mindesthaltbarkeitsdatum/best before	15.11.2026			
Herstelldatum/date of manufacture	18.11.2024			

2. Verpackung/ packaging	interne Spezifikation/ internal specification		korrekter Einsatz/ correctly usage	
	Bezeichnung/name	Art.-Nr.	Ja/Yes	Nein/No
Packstoff/repository	Weißblechdose 99/119	49-008-80100	X	
Umverpackung/overpack	-	-	-	
Messlöffel/measuring spoon	Nr. 3 PP transparent	49-008-50011	X	
Füllmenge/content	500 g		X	
Schutzgas/protective gas	-		-	

3. physikalische Parameter/ physical properties	Ein- heit	Ist/actual value	Soll/nominal value
Restfeuchte/residual moisture	%	1,0	< 2
Schüttdichte/powder density	g/100ml	71,7	64,0 – 75,0
Messlöffel/measuring spoon	g	11,5	11,4 – 11,5
pH Wert/pH value	-	7,89	7,0 – 7,9
Viskosität/viscosity	mPa*s	-	k. A.
Osmolalität/osmolality	mOsmol/ kg	731	690 - 770
Sensorik/sensory analysis (Degustationsprotokoll QS FB)	Note:	1,0	< 4
entspricht interner Spezifikation/ confirms internal specification			
		Ja/Yes	Nein/No
Siebanalyse/sieve analysis		-	

4. biologische Parameter/ biological properties	entspricht interner Spezifikation/ confirms internal specification		Labor/ laboratory	Befundnr./ resultnr.
	Ja/Yes	Nein/No		
mikrobiologische Analyse/ microbiological analysis	X		BAV	24787981-90/982756 24787979-80/982755

5. chemische Parameter/ chemical properties	entspricht interner Spezifikation/ confirms internal specification		Labor/ laboratory	Befundnr./ resultnr.
	Ja/Yes	Nein/No		
Aminosäurenspektrum/ amino acid analysis	-		Intern	-
Mineralstoff- und Spurenelementanalytik/ mineral and trace elements analysis	-			
Fett- Kohlenhydrat- und Eiweißanalytik/ fat, carbohydrate and protein analysis	-			

6. Freigabe/approval	
Datum/Date	Unterschrift/signature
09.12.2024	



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM 3. Juni 2009

AKTENZEICHEN BVL-101-3132-20/0151(2009)-318579
(bitte bei Antwort angeben)

DATUM 21. September 2010

Anzeige von diätetischen Lebensmitteln (bilanzierte Diäten) nach § 4a Abs. 1 der Verordnung über diätetische Lebensmittel (DiätV)
Produkt „Zero TVMI K“

Sehr geehrte Damen und Herren,

hiermit bestätige ich den Eingang Ihrer Anzeige nach § 4a Abs. 1 DiätV vom 3. Juni 2009 für das Produkt „Zero TVMI K“. Bei der vorliegenden Anzeige handelt es sich um eine Erstanzeige.

Im Rahmen dieses Anzeigeverfahrens werden von mir die eingereichten Unterlagen ausschließlich formal auf ihre Vollständigkeit hin geprüft. Eine weitergehende inhaltliche Prüfung findet nicht statt. Der Inverkehrbringer ist von der selbstverantwortlichen Einhaltung der lebensmittelrechtlichen Vorschriften nicht freigestellt.

Bei Änderung des Produktes (z.B. Produktname, Zusammensetzung usw.) ist eine Änderungsanzeige erforderlich. Ich bitte auch um Mitteilung, falls Sie das o.g. Produkt vom Markt nehmen sollten (mit Angabe des Datums).

Dieses Anzeigeverfahren ist derzeit gebührenfrei. Die Gebührenverordnung wird zurzeit überarbeitet, so dass ich Sie darauf hinweisen möchte, dass ggf. zukünftig eine Gebühr erhoben werden kann.

Mit freundlichen Grüßen

Im Auftrag

A handwritten signature in black ink, appearing to read 'E. Breitweg-Lehmann', with a stylized flourish at the end.

Dr. Evelyn Breitweg-Lehmann

Referatsleiterin

IMPORTANT NOTICE Must only be used under medical supervision. Not suitable as a sole source of nutrition. For enteral use only. Only for people with proven Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA). Suitable from 4 months to 6 years of age.

DEFINITION AND INDICATION ZeroTVMI K is a mixture of pure L-amino acids free of Threonine, Valine, Methionine and Isoleucine (TVMI), enriched with vitamins, minerals and trace elements in adequate amounts. ZeroTVMI K is a highly concentrated protein supplement – low in energy, without carbohydrate and fat. ZeroTVMI K is a food for special medical purposes for use in the dietary management of Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA). Suitable from 4 months to 6 years of age.

DOSAGE AND DIRECTIONS FOR USE The daily total amount of amino acid mixture depends on age, body weight and individual medical condition and should be re-examined and adjusted in accordance with the results of regular monitoring.

The daily dosage should, at best, be divided into 3–5 single portions and always be taken along with calculated amounts of regular food according to individual protein tolerance. The daily dosage of amino acid mixture can consist either exclusively of ZeroTVMI K or of several products suitable for use in the dietary management of Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA).

The diet must be supplemented with energy, natural protein and other nutrients in prescribed quantities.

PREPARATION For standard dilution fill 50 ml still water into a shaker. Add 6,9 g ZeroTVMI K (≈ 5 g protein equivalent). Shake – ready to drink! Can also be prepared with more or less amount of water, as desired. The enclosed scoop measures approx. 10 g powder. At best always weigh the amount of ZeroTVMI K needed. Always consider the individually prescribed daily amount. Always prepare freshly.

STORAGE Store in a cool, dry place. Tin should be sealed properly after use. Once opened content should be used up within 6 weeks.



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23/03/02 d21/12/22



For Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA)
– from 4 months to 6 years of age –
FOOD FOR SPECIAL MEDICAL PURPOSES

Food for Special Medical Purposes. Protein supplement free of Threonine, Valine, Methionine and Isoleucine (TVMI) for use in the dietary management of Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA). Suitable from 4 months to 6 years of age.

NUTRITION DECLARATION

ZeroTVMI K	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	0,18

Vitamins

Vitamin A	µg 1013	70
Vitamin D3	µg 36	2,5
Vitamin E	mg 25	1,8
Vitamin K1	µg 93	6
Vitamin C	mg 94	6
Thiamin (Vitamin B1)	mg 2,5	0,17
Riboflavin (Vitamin B2)	mg 3	0,2
Niacin	mg 30	2
Vitamin B6	mg 1,8	0,12
Folic acid	µg 181	12
Vitamin B12	µg 7	0,5
Biotin	µg 36	2,5
Pantothenic acid	mg 7	0,5

Minerals

Sodium	mg 1050	72
Potassium	mg 1857	128
Chloride	mg 1620	112
Calcium	mg 2265	156
Phosphorus	mg 962	66
Magnesium	mg 456	31

Trace elements

Iron	mg 32	2
Zinc	mg 26	1,8
Copper	mg 3	0,2
Manganese	mg 7	0,5
Fluoride	µg 1,1	0,1
Selenium	µg 87	6
Chromium	µg 72	5
Molybdenum	µg 159	11
Iodine	µg 362	25

FURTHER NUTRITION INFORMATION

	100 g	6,9 g
L-Carnitine	mg 65	4,5
Choline	mg 181	12
myo-Inositol	mg 340	24
Taurine	mg 72	5
Amino acids	g 87	6
(*1 g protein = 1,2 g amino acids)		
L-Alanine	g 5,9	0,41
L-Arginine	g 5,1	0,36
L-Aspartic acid	g 12,2	0,84
L-Cystine	g 3,3	0,23
L-Glutamine	g 4,9	0,34
L-Glutamic acid	g 7,8	0,54
Glycine	g 4,9	0,34
L-Histidine	g 1,9	0,13
L-Isoleucine	g –	–
L-Leucine	g 8,4	0,58
L-Lysine	g 5,6	0,39
L-Methionine	g –	–
L-Phenylalanine	g 3,7	0,26
L-Proline	g 10,5	0,73
L-Serine	g 6,5	0,45
L-Threonine	g –	–
L-Tryptophan	g 1,0	0,13
L-Tyrosine	g 4,3	0,30
L-Valine	g –	–

This tin contains approx. 72 servings à 6,9 g.

INGREDIENTS

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, calcium carbonate, 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.



BEST BEFORE
see bottom stamp

500g e

Product Information

– for professionals only –



ZeroTVMI K, J, A

In Short

- ZeroTVMI is a Food for Special Medical Purposes (FSMP) for use in the dietary management of Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA)
- for 3 age groups (K, J, A):
 - > ZeroTVMI K: 4 months to 6 years of age
 - > ZeroTVMI J: 7 to 14 years of age
 - > ZeroTVMI A: from 15 years of age onwards
- highly concentrated powdered protein supplements free of Threonine, Valine, Methionine and Isoleucine (TVMI)
- no additional calories: no carbohydrate – no fat
- neutral or rather characteristic taste
- highly purified L-amino acids
- micronutrients in balanced, age-based amounts
- in 500 g tin or in convenient portion sachets at 5 g (K) or 10 g (J,A) protein equivalent

Product Profile

ZeroTVMI is a highly concentrated powdered mixture of highly purified L-amino acids free of Threonine, Valine, Methionine and Isoleucine (TVMI).

ZeroTVMI contains neither carbohydrate nor fat and therefore no additional calories. All 3 products have a neutral or rather characteristic taste.

The 3 products are enriched with vitamins, minerals and trace elements in balanced, age-based amounts.

ZeroTVMI for 3 age groups

- > ZeroTVMI K from 4 months to 6 years
- > ZeroTVMI J from 7 to 14 years
- > ZeroTVMI A from 15 years onwards

Administration

Each of the 3 products should always be taken along with calculated quantities of other foods.

Preparation

For preparation

- > fill 100 – 150 ml still water into a shaker – for ZeroTVMI K 50 ml might be sufficient,
- > add 1 sachet and shake. Ready!

Can also be prepared with more or less amount of water, as desired.

Always prepare freshly!

Function ZeroTVMI substitutes that part of the protein in the diet which may not be taken up from natural food sources.

Indication ZeroTVMI is a food for special medical purposes and as protein supplement suitable for the dietary management of Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA).

Dosage The daily total amount of amino acid mixture depends on age, body weight and individual medical condition/ protein tolerance and should be re-examined and adjusted in accordance with the results of regular monitoring.

The daily dosage of amino acid mixture should at best be divided into 3 – 5 single portions.

ZeroTVMI can be combined with other products from the ZeroTVMI-system.

The diet must be supplemented with energy, natural protein and other nutrients in prescribed quantities.

Important Notice Must only be used under medical supervision. Not for use as a sole source of nutrition. For enteral use only. Only for people with proven Methylmalonic Aciduria (MMA) or Propionic Aciduria (PA). Suitable for the – for each of the three products – indicated age group.

Amino acids per 100 g powder

ZeroTVMI		K	J	A
L-Alanine	g	5,9	6,2	6,4
L-Arginine	g	5,1	5,3	5,5
L-Aspartic acid	g	12,2	11,8	13,4
L-Cystine	g	3,3	3,4	3,5
L-Glutamine	g	4,9	4,9	7,7
L-Glutamic acid	g	7,8	7,9	4,8
Glycine	g	4,9	5,1	7,2
L-Histidine	g	1,9	2,0	2,0
L-Isoleucine	g	–	–	–
L-Leucine	g	8,4	8,7	9,0
L-Lysine	g	5,6	5,8	6,0
L-Methionine	g	–	–	–
L-Phenylalanine	g	3,7	3,9	4,0
L-Proline	g	10,5	10,9	10,8
L-Serine	g	6,5	6,8	6,3
L-Threonine	g	–	–	–
L-Tryptophan	g	1,9	2,0	2,0
L-Tyrosine	g	4,3	4,5	4,5
L-Valine	g	–	–	–

Amino acids per 1 sachet

ZeroTVMI		K	J	A
L-Alanine	g	0,41	0,82	0,8
L-Arginine	g	0,36	0,71	0,7
L-Aspartic acid	g	0,84	1,57	1,7
L-Cystine	g	0,23	0,45	0,5
L-Glutamine	g	0,34	0,65	1,0
L-Glutamic acid	g	0,54	1,04	0,6
Glycine	g	0,34	0,68	0,9
L-Histidine	g	0,13	0,26	0,3
L-Isoleucine	g	–	–	–
L-Leucine	g	0,58	1,16	1,2
L-Lysine	g	0,39	0,77	0,8
L-Methionine	g	–	–	–
L-Phenylalanine	g	0,26	0,52	0,5
L-Proline	g	0,73	1,45	1,4
L-Serine	g	0,45	0,90	0,8
L-Threonine	g	–	–	–
L-Tryptophan	g	0,13	0,26	0,3
L-Tyrosine	g	0,30	0,60	0,6
L-Valine	g	–	–	–

INGREDIENTS

ZeroTVMI K

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, calcium carbonate, 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.

ZeroTVMI J

L-lysine-L-aspartate, L-proline, potassium-L-glutamate, L-arginine-L-aspartate, L-leucine, L-serine, L-alanine, glycine, L-glutamine, calcium phosphate, L-tyrosine, L-phenylalanine, magnesium-L-aspartate, L-cystine, L-histidine, L-tryptophan, calcium carbonate, 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.

ZeroTVMI A

L-lysine-L-aspartate, L-proline, L-arginine-L-aspartate, L-leucine, L-glutamine, glycine, L-alanine, L-serine, potassium-L-glutamate, magnesium-L-aspartate, L-tyrosine, L-phenylalanine, calcium phosphate, L-cystine, 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, vitamin K, manganese sulphate, chromium (III) chloride, vitamin B2, vitamin B1, vitamin B6, potassium iodide, cupric sulphate, biotin, vitamin D, vitamin B12.

Delivery Unit	ZeroTVMI K	tin 2 x 500 g = 1000 g	box, sachets (sa) 4 x 25 sa at 6,9 g = 690 g
Article Number		xx-001-31411	xx-001-31418
Delivery Unit	ZeroTVMI J	tin 2 x 500 g = 1000 g	box, sachets (sa) 4 x 25 sa at 13,3 g = 1330 g
Article Number		xx-001-31461	xx-001-31468
Delivery Unit	ZeroTVMI A	tin 2 x 500 g = 1000 g	box, sachets (sa) 4 x 25 sa at 12,8 g = 1280 g
Article Number		xx-001-31511	xx-001-31518
Delivery to	Pharmacies, clinics		
Storage	Store in a cool, dry place.		

NUTRITION INFORMATION		ZeroTVMI K		ZeroTVMI J		ZeroTVMI A	
		100 g	6,9 g/ 1 sachet	100 g	13,3 g/ 1 sachet	100 g	12,8 g/ 1 sachet
Energy	kJ	1231	85	1281	170	1316	170
	kcal	290	20	301	40	310	40
Fat	g	0	0	0	0	0	0
of which saturates	g	0	0	0	0	0	0
Carbohydrate	g	0	0	0	0	0	0
of which sugars	g	0	0	0	0	0	0
Protein eqv.	g	72	5	75	10	77	10
Amino acids	g	87	6	90	12	93	12
Salt	g	2,6	0,18	0	0	0	0

Vitamins		g protein			g protein			g protein		
Vitamin A	µg	1013	70	14	1350	180	18	1200	155	16
Vitamin D3	µg	36	2,5	0,5	30	4	0,4	9	1,2	0,12
Vitamin E	mg	25	1,8	0,35	27	3,5	0,35	19	2,5	0,25
Vitamin K1	µg	93	6	1,3	97	13	1,3	85	11	1
Vitamin C	mg	94	6	1,3	157	21	2	100	13	1,3
Thiamin (Vit. B1)	mg	2,5	0,17	0,035	2,6	0,35	0,035	2	0,25	0,025
Riboflavin (Vit. B2)	mg	3	0,2	0,04	3	0,4	0,04	2	0,3	0,03
Niacin	mg	30	2	0,4	60	8	0,8	31	4	0,4
Vitamin B6	mg	1,8	0,12	0,025	2,4	0,3	0,03	2	0,3	0,03
Folic acid	µg	181	12	2,5	302	40	4	696	90	9
Vitamin B12	µg	7	0,5	0,1	5	0,6	0,06	7	0,9	0,09
Biotin	µg	36	2,5	0,5	60	8	0,8	193	25	2,5
Pantothenic acid	mg	7	0,5	0,1	10	1,3	0,13	12	1,6	0,16

Minerals		g protein			g protein			g protein		
Sodium	mg	1050	72	14	0	0	0	0	0	0
Potassium	mg	1857	128	26	1875	249	25	1160	150	15
Chloride	mg	1620	112	22	0	0	0	0	0	0
Calcium	mg	2265	156	31	2100	280	28	1190	154	15
Phosphorus	mg	962	66	13	1001	133	13	787	102	10
Magnesium	mg	456	31	6	405	54	5	387	50	5

Trace elements		g protein			g protein			g protein		
Iron	mg	32	2	0,4	27	3,6	0,36	23	3	0,3
Zinc	mg	26	1,8	0,36	27	3,6	0,36	20	2,6	0,26
Copper	mg	3	0,2	0,04	3	0,4	0,04	2	0,25	0,025
Manganese	mg	7	0,5	0,1	9	1,1	0,11	5	0,7	0,07
Fluoride	mg	1,1	0,1	0,015	1,1	0,15	0,015	0	0	0
Selenium	µg	87	6	1,2	109	15	1,5	56	7	0,7
Chromium	µg	72	5	1	150	20	2	77	10	1
Molybdenum	µg	159	11	2	128	17	1,7	116	15	1,5
Iodine	µg	362	25	5	338	45	4,5	271	35	3,5

FURTHER NUTRITION INFORMATION

L-Carnitine	mg	65	4,5	0,9	68	9	0,9	54	7	0,7
Choline	mg	181	12	2,5	677	90	9	193	25	2,5
myo-Inositol	mg	340	24	5	353	47	5	116	15	1,5
Taurine	mg	72	5	1	75	10	1	0	0	0