



Certificate GB16/871493

The Food Safety Management System of

SHS International Ltd

100 Wavertree Boulevard, Wavertree Technology Park,
Liverpool, L7 9PT, UK

has been assessed and determined to comply with the requirements of

Food Safety System Certification FSSC 22000

Certification scheme for food safety management systems consisting of the following elements:
ISO 22000:2018, ISO/TS22002-1:2009 and Additional FSSC 22000 requirement (version 5).

This certificate is applicable for the scope of:

**Blending and packing of foods for special medical purposes (FSMPs)
for the management of inborn errors of metabolism
and other specific disorders.**

Food Category: CIV - Processing of ambient stable products

This certificate is valid from 25 May 2021 until 25 May 2024
and remains valid subject to satisfactory surveillance audits.

Date of Certification decision 25 May 2021

Issue Date: 16 April 2021

Re-certification audit due 60 days prior to expiry date

Issue 6. Certified since 22 November 2010

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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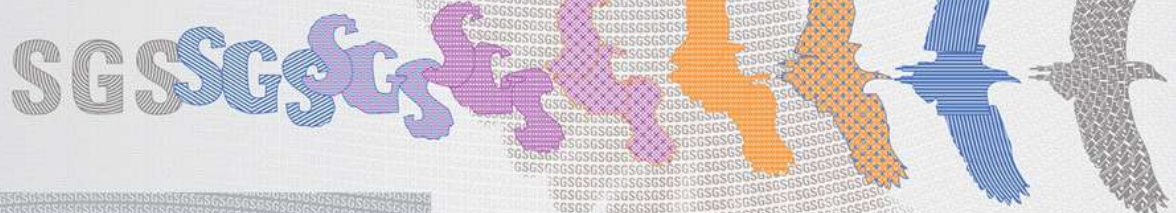
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Page 1 of 1

Validity of this certificate can be verified in the FSSC 22000 database of certified organizations available on www.fssc22000.com



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Concentrated

Unflavoured

500 g e





Food for special medical purposes. For the dietary management of **phenylketonuria (PKU) and hyperphenylalaninaemia (HPA)** in children over 1 year of age. A phenylalanine-free powdered mixture of amino acids with carbohydrate, vitamins, minerals and trace elements.

Important notice: For enteral use only. Not for parenteral use. Must be used under medical supervision. Not suitable as a sole source of nutrition. Suitable for children over 1 year of age. **Only to be used by individuals with PKU/HPA.**

Precautions: Diets with this product must contain adequate amounts of energy, essential fatty acids and phenylalanine to meet daily requirements.

Suggested intake: Should be determined by a clinician or dietitian only, and is dependent on age, bodyweight, and medical condition of the patient. The daily amount should be adjusted regularly under medical supervision.

Preparation and Administration: The suggested intake should be divided into 3 to 5 equal portions distributed throughout the day. The product should be taken mixed with calculated amounts of other food or drinks e.g. water, fruit juice, fruit puree.

Use only the scoop provided in the packaging. One level scoop provides 6.7 g = 4.0 g PE.

Storage: Store in a cool, dry place (<25°C). Always replace container lid after use. Once opened, use within 4 weeks.

Ingredients: Maltodextrin, L-lysine L-glutamate, L-glutamic acid, L-leucine, L-proline, calcium phosphate tri basic, L-valine, magnesium L-aspartate, L-isoleucine, L-tyrosine, L-serine, L-aspartic acid, L-threonine, L-alanine, potassium phosphate dibasic, L-arginine, tri sodium citrate, choline bitartrate, calcium chloride, L-methionine, glycine, L-cystine, L-histidine, L-tryptophan, inositol, L-ascorbic acid, L-carnitine, calcium carbonate, ferrous sulphate, zinc sulphate, flavouring (vanillin), DL- α -tocopheryl acetate, nicotinamide, calcium D-pantothenate, manganese sulphate, copper sulphate, sodium fluoride, thiamin mononitrate, pyridoxine hydrochloride, riboflavin, vitamin A acetate, chromium chloride, potassium iodide, folic acid, ammonium molybdate, sodium selenite, D-biotin, vitamin K₁, vitamin D₃, cyanocobalamin.

Best before: See base of can.

Nutrition information per		100 g		
Energy	1239 kJ 292 kcal		L-Valine L-Alanine L-Arginine L-Aspartic acid L-Glutamic acid Glycine L-Proline L-Serine	4.7 g 2.7 g 2.3 g 6.6 g 14.0 g 1.5 g 6.2 g 3.5 g
Fat	0 g		Salt	1.4 g
of which			Vitamins	
- Saturates	0 g		Vit. A	1800 µg
Carbohydrate	12.9 g		Vit. D	42.0 µg
of which			Vit. E	19.2 mg (α-TE/ET)
- Sugars	0.42 g		Vit. K	51.1 µg
Fibre	0 g		Thiamin	2.3 mg
Protein equivalent	60.0 g		Riboflavin	2.4 mg
of which			Vit. B ₆	2.1 mg
L-Cystine	1.5 g		Niacin	22.8 mg (43.6 mg NE/EN)
L-Histidine	1.5 g		Folic acid	230 µg
L-Isoleucine	3.9 g		Biotin	60.0 µg
L-Leucine	6.6 g		Vit. B ₁₂	4.5 µg
L-Lysine	4.7 g		Pantothenic acid	11.4 mg
L-Methionine	1.5 g		Vit. C	90.0 mg
-	-			
L-Phenylalanine	-			
L-Threonine	3.1 g			
L-Tryptophan	1.3 g			
L-Tyrosine	3.9 g			

Produced by: SHS International Ltd.,
100 Wavertree Boulevard, Liverpool L7 9PT,
United Kingdom.

Distributed by:
Nutricia Middle East & Africa,
Jumeirah Lakes Towers, Cluster W,
Build JBC 5, Unit 3701,
Dubai, United Arab Emirates.







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118712



500 g e

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Job Name	ZCSH902625_RE.ap		
DSN Code	ZCSH902625		
Description	180140_CM_LVP_(FD) 618712 Nutri concentrate 2 Unflavoured 500g EN		
Account	SHS INTERNATIONAL LTD		
Account Executive Mail			
Pack Code	10342435		
Previous Pack Code	10284322		
Corporate Code	118712		
Artwork Loop	2		
Repro Loop	1		
Packtype	TIN		
Printer	SPRINGFIELD SOLUTIONS LTD	Material Code	***
Technical Plan	LVP003_Tin label M_v01		
Unwind Direction	***		
Printing Process	Offset		
Date	22-03-2018	First Barcode Number	501653365
Time	11:01	2D Code Number	10342435
Height (mm)	+109.	Barcode BWR (µm)	15,00
Width (mm)	+318.		
Ink Coverage (%)	300%		
Profile Number	PR0021038		
Proof Profile	SPRINGFIELD SOLUTIONS LTD PAPER CMYK 09JAN2014		

Material Code ***

First Barcode Number	5016533650754
2D Code Number	10342435
Barcode BWR (µm)	15,00

PR0021038
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Questions? We are at your service.

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Nutrition information per		100 g		
Energy	1239 kJ 292 kcal	L-Valine L-Alanine L-Arginine L-Aspartic acid L-Glutamic acid Glycine L-Proline L-Serine	4.7 g 2.7 g 2.3 g 6.6 g 14.0 g 1.5 g 6.2 g 3.5 g	Minerals and trace elements Na (23.5 mmol) 541 mg K (30.7 mmol) 1200 mg Ca (57.3 mmol) 2299 mg Mg (13.0 mmol) 315 mg P (44.5 mmol PO ₄) 1380 mg Cl (25.4 mmol) 902 mg Fe 27.0 mg Zn 19.8 mg Cu 2.1 mg I 323 µg Mn 3.6 mg Cr 90.0 µg F 1.53 mg Mo 94.8 µg Se 54.0 µg
Fat	0 g			
of which				
- Saturates	0 g			
Carbohydrate	12.9 g			
of which				
- Sugars	0.42 g			
Fibre	0 g	Salt	1.4 g	
Protein equivalent	60.0 g	Vitamins		
of which		Vit. A	1800 µg	
L-Cystine		Vit. D	42.0 µg	
L-Histidine	1.5 g	Vit. E	19.2 mg (α-TE/EI)	
L-Isoleucine	3.9 g	Vit. K	51.1 µg	
L-Leucine	6.6 g	Thiamin	2.3 mg	
L-Lysine	4.7 g	Riboflavin	2.4 mg	
L-Methionine	1.5 g	Vit. B6	2.1 mg	
L-Phenylalanine	-	Niacin	22.8 mg	
L-Threonine	3.1 g	Folic acid	230 µg	
L-Tryptophan	1.3 g	Biotin	60.0 µg	
L-Tyrosine	3.9 g	Vit. B12	4.5 µg	
		Pantothenic acid	11.4 mg	
		Vit. C	90.0 mg	

PROTEIN STATEMENT**Product Name: PKU Nutri 2 Concentrated B3228**

SHS International Ltd herewith confirms that the above-mentioned product is a food for special medical purposes

- **Protein content: 60g/100g of product**
- **Phenylalanine: <5mg/100g product**
- **Our products have been extensively analysed by QC601 and QC602 (method for low levels of Phenylalanine)**

Amino Acid	Label (g/100g)
L-Alanine	2.7
L-Arginine	2.32
L-Aspartic Acid	6.56
L-Cystine	1.54
L-Glutamic Acid	14
L-Glutamine	0
Glycine	1.54
L-Histidine	1.54
L-Isoleucine	3.93
L-Leucine	6.56
L-Lysine	4.73
L-Methionine	1.54
L-Proline	6.18
L-Phenylalanine	0
L-Serine	3.47
L-Threonine	3.1
L-Tryptophan	1.25
L-Tyrosine	3.86
L-Valine	4.73
Total Amino Acids	69.55



Diane Sheldon
Registration Officer

Date : 17/09/2021

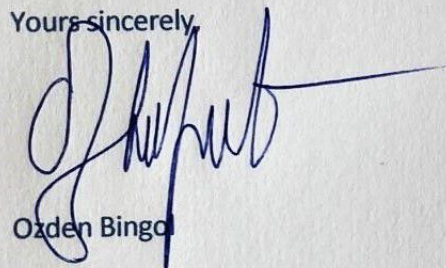
www.nutricia.com

Amsterdam, September 6th, 2021

To whom it may concern,

We herewith confirm that PKU NUTRI 2 CONCENTRATED (60g/100g) is registered and lawfully sold in the countries listed in the table below.

Yours sincerely,



Ozden Bingol

Global Market Access Director

Danone Specialized Nutrition

Brand Name	Marketed	Country Name With Currency	Reimbursement Status
PKU NUTRI 2 CONC UPGRADE 2X500G EN	YES	Croatia (Hrk)	YES
PKU NUTRI 2 CONC UPGRADE 2X500G EN	YES	Russia (₽)	YES
PKU NUTRI 2 CONC UPGRADE 2X500G EN	YES	Serbia (€)	NO
PKU NUTRI 2 CONC UPGRADE 2X500G EN	YES	Ukraine (Hry)	YES



REPUBLIKA HRVATSKA
MINISTARSTVO ZDRAVSTVA

KLASA: 541-02/16-07/48
URBROJ: 534 -07-1-1-3/1-17-3
Zagreb, 13. veljače 2017.

Ministar zdravstva u predmetu izdavanja potvrde o notifikaciji hrane za posebne prehrambene potrebe po zahtjevu trgovačkog društva G-M Pharma Zagreb d.o.o., Zagreb, Velika Cesta 74, od 05. listopada 2016. na temelju članka 13. stavak 1. Zakona o hrani za posebne prehrambene potrebe ("Narodne novine" br. 39/13), izdaje

P O T V R D U
o notifikaciji hrane za posebne prehrambene potrebe

Hrana za posebne medicinske potrebe pod nazivom:

1. „PKU Nutri 1“, proizvođača SHS International Ltd., Wavertree Boulevard, Liverpool, L79PT, Velika Britanija, namijenjena za dijetalnu prehranu dojenčadi oboljele od fenilketonurije i hiperfenilalaninemije;
2. „PKU Nutri 2“, proizvođača SHS International Ltd., Wavertree Boulevard, Liverpool, L79PT, Velika Britanija, namijenjena za dijetalnu prehranu djece iznad 1 godine starosti oboljele od fenilketonurije i hiperfenilalaninemije;
3. „PKU Nutri 3“, proizvođača SHS International Ltd., Wavertree Boulevard, Liverpool, L79PT, Velika Britanija, namijenjena za dijetalnu prehranu djece iznad 8 godina, adolescenata i odraslih oboljelih od fenilketonurije i hiperfenilalaninemije;

upisana je u Registar hrane za posebne prehrambene potrebe Ministarstva zdravlja sukladno članku 13. stavak 2. Zakona o hrani za posebne prehrambene potrebe ("Narodne novine" br. 39/13).

Upravna pristojba naplaćena je temeljem Zakona o upravnim pristojbama ("Narodne novine" br. 8/96, 77/96, 95/97, 131/97, 68/98, 66/99, 145/99, 30/00, 116/00, 163/03, 17/04, 110/04, 141/04, 150/05, 153/05, 129/06, 117/07, 25/08, 60/08, 20/10, 69/10, 126/11, 112/12, 19/13, 80/13).



MINISTAR

prof. dr. sc. Milan Kujundžić, dr. med.

DOSTAVITI:

1. G-M Pharma Zagreb d.o.o.,
Zagreb, Velika Cesta 74
2. Evidencija, ovdje
3. Pismohrana, ovdje





Product Documentation Sheet

Version: 1
Date: 01/08/2014

Page: 1 of 8

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

This declaration involves the following claims:
Phenylalanine free

This declaration takes into consideration the following directives and recommendations:
FSMP-Directive

Remarks/Reason for change:

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

composition	1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	1 portion (100 g)	content per 1 g protein	100 kJ ready to feed product
protein equivalent	g					60	6	21.4	6	1	5
amino acids	g					72					
vegetable protein	g										
animal protein	g										
fat	g										
vegetable fat	g										
animal fat	g										
MCT	g										
digest. carbohydrates	g					10	1	3.6	1	0.2	0.8
dietary fiber	g										
salt equivalent	g					1.35	0.14	0.5	0.1	0.02	0.1
minerals	g					6.8	0.7	2.4	0.7	0.1	0.6
water (calculated)	g					11.2	91.1	325.4	91.1	0.2	76.6
energy	kJ					1190	119	-	119		-
	kcal					280	28	-	28		-
vitamins											
A	µg					1200	120	429	120	20	101
D3	µg					18	1.8	6.4	1.8	0.3	1.5
E	mg					21	2.1	7.5	2.1	0.4	1.8
K1	µg					57	5.7	20.4	5.7	1	4.8
thiamin (B1)	mg					1.8	0.2	0.64	0.2	0.03	0.2
riboflavin (B2)	mg					2.4	0.2	0.86	0.2	0.04	0.2
B6	mg					2.7	0.3	0.96	0.3	0.05	0.2
niacin	mg					12.6	1.3	4.5	1.3	0.2	1
niacin equivalents	mg					33.6	3.4	12	3.4	0.6	2.8
biotin	µg					90	9	32	9	2	7.6
folic acid	µg					288	29	103	29	5	24
B12	µg					3.6	0.4	1.3	0.4	0.06	0.3
pantothenic acid	mg					11.4	1.1	4.1	1.1	0.2	1
C	mg					180	18	64	18	3	15
nutrient relation (energy %)											
protein	%					86	86		86		
fat	%					0	0		0		
carbohydrates	%					14	14		14		

1 = required declaration according to EEC-directive 90/496/EEC Labelling Directive

2 = required declaration according to EEC-directive 99/21/EEC FSMP Directive

3 = required declaration according to EEC-directive 91/321/EEC Infant Formula Directive

4 = required declaration according to EEC-directive 96/5/EEC Weaning Food Directive

5 =

* reference value = EC-Weaning/Infant Food Directive

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

composition	1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	1 portion (100 g)	content per 1 g protein	100 kJ ready to feed product
minerals	g					6.8	0.7	2.4	0.7	0.1	0.6
sodium	mg					540	54	193	54	9	45
	mmol					23.5	2.3	8.4	2.3	0.4	2
potassium	mg					1200	120	429	120	20	101
	mmol					30.7	3.1	11	3.1	0.5	2.6
calcium	mg					2300	230	821	230	38	193
	mmol					57.4	5.7	20.5	5.7	1	4.8
magnesium	mg					300	30	107	30	5	25
	mmol					12.3	1.2	4.4	1.2	0.2	1
phosphorus	mg					1380	138	493	138	23	116
	mmol					44.6	4.5	15.9	4.5	0.7	3.7
chloride	mg					900	90	321	90	15	76
	mmol					25.4	2.5	9.1	2.5	0.4	2.1
iron	mg					30	3	10.7	3	0.5	2.5
	mmol					0.5	0.05	0.19	0.05	0.01	0.05
Na+K+Cl	mmol/l					0.8	0.08	0.28	0.08	0.01	0.07
Ca/P						1.7	1.7	1.7	1.7	1.7	1.7
trace elements											
zinc	mg					30	3	10.7	3	0.5	2.5
copper	mg					2.1	0.2	0.8	0.2	0.04	0.2
iodide	µg					340	34	121	34	6	29
manganese	mg					3.6	0.4	1.3	0.4	0.06	0.3
chromium	µg					120	12	43	12	2	10
fluoride	mg					1.8	0.18	0.6	0.18	0.03	0.2
molybdenum	µg					95	9.5	34	9.5	1.6	8
selenium	µg					50	5	18	5	0.8	4
choline	mg					780	78	279	78	13	66
inositol	mg					265	27	95	27	4.4	22

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4 = required declaration according to EEC-directive 96/5/EEC Weaning Food Directive

5 =

* reference value = EC-Weaning/Infant Food Directive

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

composition	1	2	3	4	5	100 g dry product	100 g (ml) ready to feed product	100 kcal ready to feed product	1 portion (100 g)	content per 1 g protein	100 kJ ready to feed product
protein	g					60	6	21.4	6	1	5
amino acids	g					72				1.2	
essential amino acids											
cystine	g					1.6	0.16	0.58	0.16	0.027	0.14
histidine	g					1.6	0.16	0.58	0.16	0.027	0.14
isoleucine	g					4	0.4	1.4	0.4	0.067	0.34
leucine	g					6.8	0.68	2.4	0.68	0.114	0.57
lysine	g					4.9	0.49	1.74	0.49	0.081	0.41
methionine	g					1.6	0.16	0.58	0.16	0.027	0.14
phenylalanine	g										
threonine	g					3.2	0.32	1.16	0.32	0.054	0.27
tryptophan	g					1.3	0.13	0.45	0.13	0.021	0.11
tyrosine	g					4	0.4	1.4	0.4	0.067	0.34
valine	g					4.9	0.49	1.74	0.49	0.081	0.41
sum of ess. amino acids	g					34	3.4	12.1	3.4	0.566	2.85
sum of branched chain amino acids	g					15.7	1.57	5.61	1.57	0.26	1.3
non ess. amino acids											
alanine	g					2.8	0.28	1	0.28	0.047	0.24
arginine	g					2.4	0.24	0.9	0.24	0.04	0.2
aspartic acid	g					6.8	0.68	2.4	0.68	0.114	0.57
glutamic acid	g					14.4	1.44	5.14	1.44	0.24	1.2
glycine	g					1.6	0.16	0.58	0.16	0.027	0.14
proline	g					6.4	0.64	2.27	0.64	0.106	0.53
serine	g					3.6	0.36	1.29	0.36	0.06	0.3
sum of non-ess. amino acids	g					38	3.8	13.59	3.8	0.634	3.2
taurine	mg										
carnitine	mg					150	15	53.6	15	3	12.6
chemical score* method						0					

1 = required declaration according to EEC-directive 90/496/EEC Labelling Directive

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4 = required declaration according to EEC-directive 96/5/EEC Weaning Food Directive

5 =

* reference protein = casein

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

composition	1	2	3	4	5	100 g fat (dry product)	100 g dry product	100 g (ml) ready to feed product	100 kcal ready to feed product	1 portion (100 g)	content per 1 g protein
fat	g										
fatty acids spectrum											
- butyric acid C4	g										
- caproic acid C6	g										
- caprylic acid C8	g										
- capric acid C10	g										
- lauric acid C12	g										
- myristic acid C14	g										
- myristolic acid C14:1w9	g										
- pentadecanoic a. C15	g										
- palmitic acid C16	g										
- palmitolic acid C16:1w7	g										
- margaric acid C17	g										
- stearic acid C18	g										
- elaidic acid C18:1tw9	g										
- oleic acid C18:1w9	g										
- vaccenic acid C18:1tw11	g										
- c-t linoleic acid C18:2ctw6	g										
- linoleic acid C18:2w6	g										
- gamma-linolenic a. C18:3w6	g										
- alpha-linolenic a. C18:3w3	g										
- arachidic acid C20	g										
- eicoseic acid C20:1w9	g										
- eicosadienoic acid C20:2w6	g										
- homo-g-linolenic a. C20:3w6	g										
- arachidonic acid C20:4w6	g										
- eicosapentanoic a. C20:5w3	g										
- behenic acid C22	g										
- erucic acid C22:1w9	g										
- docosatetranoic a. C22:4w6	g										
- docosapentanoic a. C22:5w3	g										
- docosahexanoic a. C22:6w3	g										
- lignoceric acid C24	g										
- non identified fa	g										
fatty acids characteristics											
trans fatty acids	g										
saturated fatty acids	g										
unsaturated fatty acids	g										
mono unsaturated fatty acids	g										
poly unsaturated fatty acids	g										
essential fatty acids *	g										
w3 LCP	g										
w6 LCP	g										
w6/w3 fatty acids	g										
linoleic / alpha-linolenic acid	g										
poly. unsat./saturated fatty acids											
= P/S quotient											
cholesterol	mg										

1 = required declaration according to EEC-directive 90/496/EEC Labelling Directive

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5 =

* = Linoleic + alpha-Linolenic acid

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

composition	1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	1 portion (100 g)	% of carbohydrates ready to feed p.	content per 1 g protein
digest. carbohydrates	g					10	1	3.6	1.0	100	0.2
carbohydrates											
sugars	g					0.4	0.04	0.13	0.04	4	0.006
- glucose	g					0.1	0.01	0.04	0.01	1	0.002
- fructose	g										
- lactose	g										
- sucrose	g										
- maltose	g					0.3	0.03	0.09	0.03	3	0.004
- galactose	g										
polysacch., digest.	g					9.6	1	3.4	1	96	0.16
dietary fiber (AOAC)	g										
- soluble	g										
- insoluble	g										
starch	g										
polyols	g										
- sorbitol	g										
bread unit						1	0.1		0.1		

1 = required declaration according to EEC-directive 90/496/EEC Labelling Directive

2 = required declaration according to EEC-directive 99/21/EEC FSMP Directive

3 = required declaration according to EEC-directive 91/321/EEC Infant Formula Directive

4 = required declaration according to EEC-directive 96/5/EEC Weaning Food Directive

5 =

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

Further details:

osmolarity: mosmol/l

osmolality: mosmol/kg H₂O

renal solute load:

pH-value (Standard dilution):

1. Standard dilution: 10 g powder + 90 mL water = 100 g/mL ready to feed product

Serving size: 10 g powder + 90 mL water = 1 portion / meal

g powder +	mL water	= 1 portion / meal
g powder +	mL whole milk (3,5% fat)	= 1 portion / meal
g powder +	mL fat reduced milk (1,5% fat)	= 1 portion / meal
g powder +	mL whole milk (3,5% fat) + mL water	= 1 portion/meal

10 g powder/portion = 0 scoops/portion

Scoop weight:	1. scoop =	g	Identification:
	2. scoop =	g	
	3. scoop =	g	

Shelf life: 24 months

Packing material: 500g can

Product: PKU Nutri 2 Concentrated

PD Recipe No.: 12/03/04

SP Recipe No.: B3042

List of ingredients according to the labelling council directive 79/112 EEC:

L-lysine-L-glutamate
maltodextrin
L-glutamic acid
L-leucine
L-proline
L-valine
L-isoleucine
L-tyrosine
magnesium-L-aspartate
calcium orthophosphate
L-serine
L-aspartic acid
L-threonine
L-alanine
potassium orthophosphate
L-arginine
sodium bicarbonate
choline bitartrate
calcium chloride
L-histidine
L-methionine
L-cystine
glycine
calcium carbonate
L-tryptophane
inositol
L-ascorbic acid
L-carnitine
ferrous sulphate
zinc sulphate
vanillin
DL-alpha-tocopheryl acetate
calcium-D-pantothenate
niacinamide
manganous sulphate
cupric sulphate
sodium fluoride
pyridoxine hydrochloride
riboflavin
thiamin mononitrate
retinyl acetate
chromium (III) chloride
potassium iodide
pteroylmonoglutamic acid
ammonium molybdate
sodium selenite
D-biotin
phyloquinone
cholecalciferol
cyanocobalamin



OGYÉI
Országos Gyógyszerészeti
és Élelmezés-egészségügyi Intézet

Országos Élelmezés- és Táplálkozástudományi Intézet Főigazgatóság

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Tel: (1) 8869-300, Fax: (1) 8869-460

E-mail: ogyei@ogyei.gov.hu

Web: www.ogyei.gov.hu

Iktatószám: 1097/2015. OÉTI

Budapest, 2015. június 04.

Zimai Veronika

Notifikációs szám: T/1977/2015.

Numil Kft.

Melléklet: a bejelentett termék
pótcímke szövegterve (1 old) és angol
nyelvű címketerve (1 lap)

1134 Budapest

Róbert Károly krt. 82-84.

Ügyfélszolgálat: (+36) 1 476 64 40

ugyfelszolgalat@oeti.antsz.hu

**Válaszlevelében kérjük, hivatkozzon az OÉTI
iktatószámra.**

Igazolás speciális – gyógyászati célra szánt – tápszer bejelentéséről

1. Bejelentő adatai

Név: Numil Kft.

Cím: 1134 Budapest, Róbert Károly krt. 82-84.

Telephely: 1134 Budapest, Róbert Károly krt. 82-84.

Elérhetőség: Tel: 06 1 452-7872

Forgalmazó: Numil Kft., 1134 Budapest, Róbert Károly krt. 82-84.

2. Termék eredete

Ország: Egyesült Királyság

Előállító neve: SHS International Ltd.

Előállító címe: 100 Wavertree Boulevard Liverpool L7 9PT, United Kingdom

Előállítás helye: Egyesült Királyság

Előállító elérhetősége: -

3. Termék megnevezése:

PKU Nutri 2 Concentrated

Ízesítés nélküli speciális - gyógyászati célra szánt - tápszer fenilketonúriás (PKU) és
hiperfenilalaninémiás (HPA) 1 éves kornál idősebb gyermekek számára.

4. Termék besorolása:

Speciális – gyógyászati célra szánt – tápszer

1097/2015 OÉTI

Notifikációs szám: T/1977/2015

5. Termék összetevői csökkenő mennyiségi sorrendben:

L-lizin-L-glutamát, maltodextrin, L-glutaminsav, L-leucin, L-prolin, L-valin, L-izoleucin, L-tirozin, kálium-citrát, magnézium-L-aszpartát, kalcium-ortofoszfát, L-szerin, L-aszparaginsav, L-treonin, L-alanin, kálium-ortofoszfát, L-arginin, nátrium-bikarbonát, kolin-bitartarát, kalcium-klorid, L-hisztidin, L-metionin, L-cisztin, glicin, kalcium-karbonát, L-triptofán, inozitol, L-aszkorbinsav, taurin, L-karnitin, vas-szulfát, cink-szulfát, aroma (vanillin), DL-alfa-tokoferil-acetát, kalcium-D-pantotenát, niacinamid, mangán-szulfát, réz-szulfát, nátrium-fluorid, piridoxin-hidroklorid, riboflavin, tiamin-mononitrát, retinil-acetát, króm(III)-klorid, kálium-jodid, pteroil-monoglutaminsav, ammónium-molibdát, nátrium-szelenit, D-biotin, fillokinon, kolekalciferol, cianokobalamin.

6. Érzékszervi tulajdonságok:

Semleges ízű, illatú por.

7. Csomagolás, mennyiségi jellemzők:

fémdoboz, 500 g

8. Jelölés:

A bejelentett termék pótcímke szövegterve (1 old) és angol nyelvű címketerve (1 lap)) mellékelve.

9. Felhasználási terület:

PKU Nutri 2 Concentrated, ízesítés nélküli speciális - gyógyászati célra szánt - tápszer fenilketonúriás (PKU) és hiperfenilalaninémiás (HPA) 1 éves kornál idősebb gyermekek számára. Egy fenilalaninmentes aminosav porkeverék szénhidráttal, vitaminokkal, ásványi anyagokkal és nyomelemekkel.

Csak enterális táplálásra alkalmas, parenterálisan nem adható.

Kizárólagos táplálásra nem alkalmas.

A terméket tartalmazó diétának tartalmaznia kell a napi szükségletnek megfelelő mennyiségű energiát, esszenciális zsírsavakat és fenilalanint.

10. Fontos figyelmeztetés:

Csak 1 évnél idősebb fenilketonúriás vagy hiperfenilalaninémiás gyermekek részére.

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Notifikációs szám: T/1977/2015

11. Adagolás:

Az adagot csak orvos és dietetikus határozhatja meg. Az adag függ az életkortól, a testsúlytól és az egyén egészségi állapotától. A javasolt napi bevitelt rendszeres orvosi ellenőrzés alatt kell tartani.

Elkészítés: A javasolt adag elosztandó 3-5 egyenlő részre a nap folyamán és előre kiszámított mennyiségű más étellel, itallal (pl. vízzel, gyümölcslével, gyümölcspürével) együtt fogyasztandó.

A fenti termék a 24/2003. (V.9.) ESZCSM rendelet 5. § alapján bejelentettnek tekintendő.

Felhívjuk szíves figyelmét, hogy jelen visszaigazolás kizárólag azt igazolja, hogy a bejelentő eleget tett a bejelentési kötelezettségének, nem gyártási, illetve forgalomba hozatali engedély, továbbá nem tanúsítja a termék és a jelölés/címke megfelelőségét.

A termék összetételében, jelölésében, címkeszövegében bekövetkezett bármilyen változás új bejelentési eljárást von maga után.



PKU Nutri 2 Concentrated

Ízesítés nélküli speciális – gyógyászati célra szánt – tápszer fenilketonúriás (PKU) és hiperfenilalaninémiás (HPA) 1 éves kornál idősebb gyermekek számára. Egy fenilalaninmentes aminosav porkeverék szénhidráttal, vitaminokkal, ásványi anyagokkal és nyomelemekkel.

Fontos figyelmeztetés: Csak enterális táplálásra alkalmas, parenterálisan nem adható. Csak orvosi felügyelet mellett alkalmazható. Kizárólagos táplálásra nem alkalmas. Csak 1 évnél idősebb fenilketonúriás vagy hiperfenilalaninémiás gyermekek részére. A terméket tartalmazó diétának tartalmaznia kell a napi szükségletnek megfelelő mennyiségű energiát, esszenciális zsírsavakat és fenilalanint. **Javasolt adagolás:** az adagot csak orvos és dietetikus határozhatja meg. Az adag függ az életkortól, a testsúlytól és az egyén egészségi állapotától. A javasolt napi bevitt rendszeres orvosi ellenőrzés alatt kell tartani. **Elkészítés:** A javasolt adag elosztandó 3-5 egyenlő részre a nap folyamán és előre kiszámított mennyiségű más étellel, itallal (pl. vízzel, gyümölcslével, gyümölcspürével) együtt fogyasztandó. **Tárolás:** Tárolja hűvös, száraz helyen (<25°C). Használat után mindig zárja vissza a doboz tetejét. Felbontás után használja fel 4 héten belül. Védőgázcsomagolásban.

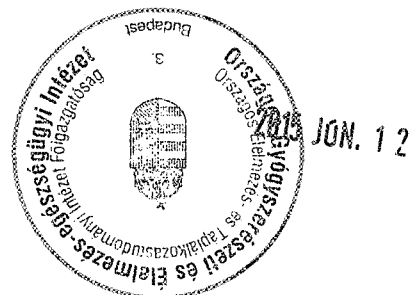
Összetevők: L-lizin L-glutamát, maltodextrin, L-glutaminsav, L-leucin, L-prolin, L-valin, L-izoleucin, L-tirozin, kálium-citrát, magnézium L-aszpartát, kalcium ortofoszfát, L-szerin, L-aszparaginsav, L-treonin, L-alanin, kálium-ortofoszfát, L-arginin, nátrium-bikarbonát, kolin-bitartarát, kalcium-klorid, L-hisztidin, L-metionin, L-cisztin, glicin, kalcium-karbonát, L-triptofán, inozitol, L-aszkorbinsav, taurin, L-karnitin, vas-szulfát, cink-szulfát, aroma (vanillin), DL-alfa-tokoferil acetát, kalcium D –pantotenát, niacinamid, mangán-szulfát, réz-szulfát, nátrium-fluorid, piridoxin-hidroklorid, riboflavin, tiamin-mononitrát, retinil-acetát, króm(III)-klorid, kálium-jodid, pteroilmonoglutaminsav, ammónium-molibdát, nátrium-szelenit, D-biotin, fillokinon, kolekalciferol, cianokobalamin.

Átlagos tápérték/100 g termék: **Energia** 1190 kJ/280 kcal, **Zsír** 0g, amelyből Telített zsírsavak 0 g, **Szénhidrát:** 10 g, amelyből cukrok: 0,4g, **Rost** 0g, **Fehérje ekvivalens:** 60g, **Só** 1,35 g, **Aminosavak:** 72 g, L-cisztin 1,6 g, L-hisztidin: 1,6g, L-izoleucin 4g, L-leucin 6,8g, L-lizin 4,9g, L-metionin 1,6 g, L-fenilalanin 0g, L-treonin 3,2 g, L-triptofan 1,3g, L-tirozin 4g, L-valin 4,9g, L-alanin 2,8g, L-arginin 2,4g, L-aszparaginsav 6,8g, L-glutaminsav 14,4g, Glicin 1,6g, L-prolin 6,4g, L-szerin 3,6g. **Ásványi anyagok:** Nátrium 540mg, Kálium 1200 mg, Kalcium 2300 mg, Magnézium 300 mg, Foszfor 1380 mg, Klorid 900 mg, **Nyomelemek:** Vas 30 mg, Cink 30 mg, Réz 2,1 mg, Jód 340 mcg, Mangán 3,6 mg, Króm 120 mcg, Fluor 1,8 mg, Molibdén 95 mcg, Szelén 50 mcg, **Vitaminok:** A-vitamin 1200 mcg RE, D- vitamin 18 mcg, E- vitamin 21 mg TE, K- vitamin 57 mcg, Tiamin 1,8 mg, Riboflavin 2,4 mg, B6- vitamin 2,7 mg, Niacin 33,6 mg NE, 12,6 mg, Folsav 288 mcg, Biotin 90 mcg, B12- vitamin 3,6 mcg, Pantoténsav 11,4 mg, C- vitamin 180 mg, Egyéb: L-karnitin 150 mg, kolin 780 mg, Inozitol 265 mg.

Minőségét megőrzi: doboz alján látható időpontig

Gyártja: SHS International Ltd., 100 Wavertree Boulevard, Liverpool L79PT, Egyesült Királyság.

Forgalmazza: Numil Kft. 1134 Budapest, Róbert Károly krt. 82-84. www.nutricia.hu Diétás tanácsadás: 06 40/223-223





Food for special medical purposes. For the dietary management of phenylketonuria (PKU) and hyperphenylalaninaemia (HPA) in children over 1 year of age. A phenylalanine-free powdered mixture of amino acids with carbohydrate, vitamins, minerals and trace elements.

Important notice: For enteral use only. Not for parenteral use. Must be used under medical supervision. Not suitable as a sole source of nutrition. Suitable for children over 1 year of age. **Only to be used by individuals with PKU/HPA.**

Precautions: Diets with this product must contain adequate amounts of energy, essential fatty acids and phenylalanine to meet daily requirements.

Suggested intake: Should be determined by a clinician or dietician only, and is dependent on age, bodyweight, and medical condition of the patient. The daily amount should be adjusted regularly under medical supervision.

Preparation and Administration: The suggested intake should be divided into 3 to 5 equal portions distributed throughout the day. The product should be taken mixed with calculated amounts of other food or drinks e.g. water, fruit juice, fruit puree.

Storage: Store in a cool, dry place (<25°C). Always replace container lid after use. Once opened, use within 4 weeks. Packaged in a protective atmosphere.

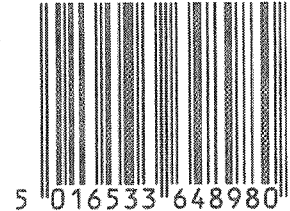
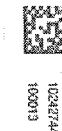
Ingredients: L-lysine L-glutamate, maltodextrin, L-glutamic acid, L-leucine, L-proline, L-valine, L-isoleucine, L-tyrosine, magnesium L-aspartate, calcium orthophosphate, L-serine, L-aspartic acid, L-threonine, L-alanine, potassium orthophosphate, L-arginine, sodium bicarbonate, choline bitartrate, calcium chloride, L-histidine, L-methionine, L-cystine, glycine, calcium carbonate, L-tryptophan, inositol, L-ascorbic acid, L-carnitine, ferrous sulphate, zinc sulphate, flavouring (vanillin), DL-α-tocopheryl acetate, calcium D-pantothenate, niacinamide, manganese sulphate, cupric sulphate, sodium fluoride, pyridoxine hydrochloride, riboflavin, thiamin mononitrate, retinyl acetate, chromium(III)chloride, potassium iodide, pteroylmonglutamic acid, ammonium molybdate, sodium selenite, D-biotin, phyloquinone, cholecalciferol, cyanocobalamin.

Best before: See base of can.

Produced by: SHS International Ltd, 100 Waverley Boulevard, Liverpool L7 9PT, United Kingdom.

Nutrition information:		per 100 g	
Energy	1190 kJ / 280 kcal	L-Threonine	3.2 g
		L-Tryptophan	1.3 g
Fat	0 g	L-Tyrosine	4 g
		L-Valine	4.9 g
Carbohydrate	10 g	L-Alanine	2.8 g
		L-Arginine	2.4 g
Fibre	0 g	L-Aspartic acid	6.8 g
		L-Glutamic acid	14.4 g
Protein equivalent	60 g	Glycine	1.6 g
		L-Proline	6.4 g
Salt	1.35 g	L-Serine	3.6 g
Amino Acids	72 g		
L-Cystine	1.6 g		
L-Histidine	1.6 g		
L-Isoleucine	4 g		
L-Leucine	6.8 g		
L-Lysine	4.9 g		
L-Methionine	1.6 g		
L-Phenylalanine	-		

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