



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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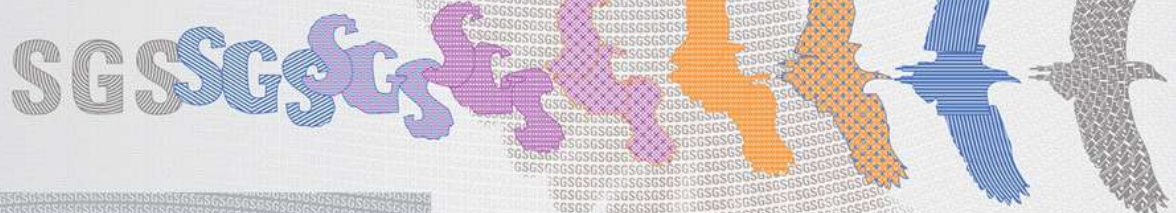
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Page 1 of 1

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



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

Important notice: For enteral use only. Must be used under medical supervision. Not suitable as a sole source of nutrition. Suitable for infants. Only intended for use by patients with PKU/HPA.

Precautions: This product must be supplemented with adequate amounts of energy, essential fatty acids and phenylalanine to meet daily requirements. If used as part of modular feed, ensure fluid intakes are adequate 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.
1 scoop (4.4 g approx.) = approx. 2.2 g protein equivalent.

Preparation: The product should be taken mixed with calculated amounts of other food or drinks e.g., water, infant formula, fruit puree. The suggested intake should be given in conjunction with a natural protein source and divided into equal portions distributed throughout the day. If used as part of modular feed, use cooled, previously boiled water and ensure that the product is at the correct temperature before feeding by placing a few drops on the wrist. Once reconstituted, use within 1 hour. If added to infant formula or used in a modular feed, always discard unfinished feeds and do not rewarm prepared product during feed.

Important: Product is not sterile. Use clean utensils to prepare feed. Prepare immediately prior to feeding.

Dental health warning: Good dental hygiene is important for infants and children, as prolonged or frequent contact of drinks and feeds with teeth increases the risk of tooth decay. Make sure their teeth are cleaned after the last feed at night. Ask your Health or Dental Professional for advice.

Storage: Store in a cool, dry place. Always replace container lid after use. Once opened, use within 4 weeks.

Ingredients: maltodextrin, L-lysine, L-glutamate, L-glutamic acid, L-leucine, potassium citrate, L-proline, calcium hydrogen phosphate, L-valine, L-isoleucine, L-tyrosine, magnesium L-aspartate, L-serine, L-aspartic acid, L-threonine, L-alanine, choline bitartrate, L-arginine, sodium chloride, glycine, L-cystine, L-histidine, L-methionine, calcium carbonate, L-tryptophan, potassium chloride, inositol, taurine, L-ascorbic acid, L-carnitine-L-tartrate, ferrous sulphate, zinc sulphate, DL-α-tocopherol acetate, nicotinamide, calcium D-pantothenate, copper sulphate, thiamin hydrochloride, retinyl acetate, riboflavin, pyridoxine hydrochloride, sodium fluoride, manganese sulphate, potassium iodide, chromium chloride, pteroylmonglutamic acid, sodium molybdate, sodium selenite, D-biotin, cholecalciferol, phytomenadione, cyanocobalamin.

Nutrition information per 100 g

Energy	1251 kJ 299 kcal	L-Proline L-Serine L-Threonine L-Tryptophan L-Tyrosine L-Valine	5.18 g 2.88 g 2.58 g 0.96 g 3.22 g 3.80 g	Minerals and trace elements	
Fat of which - Saturates	0 g 0 g	Salt	1.8 g		
Carbohydrate of which - Sugars	25.6 g 0.89 g	Vitamins		Mg Fe Zn Cu Mn F Mo Se Cr I	(30.4 mmol) 700 mg (57.5 mmol) 2250 mg (38.5 mmol) 1400 mg (48.0 mmol) 1925 mg (37.0 mmol PO ₄) 1146 mg (9.87 mmol) 240 mg 35.0 mg 16.5 mg 1.80 mg 0.27 mg 0.50 mg 100 µg 60.0 µg 80.0 µg 300 µg
Fibre	0 g	Vit. A Vit. D Vit. E Vit. K Thiamin Riboflavin Niacin Pantothenic acid Vit. B ₆ Folic acid Biotin Vit. C	1900 µg 42.5 µg 21.7 µg 35.0 µg 2.00 mg 2.25 mg 22.5 mg 15.0 mg 1.75 mg 250 µg 417 µg 4.25 µg 50.0 µg 100 mg	Others	
Protein equivalent of which L-Alanine L-Arginine L-Aspartic acid L-Cysteine L-Glutamic acid Glycine L-Histidine L-Isoleucine L-Leucine L-Lysine L-Methionine L-Phenylalanine	50.0 g 2.35 g 1.95 g 5.46 g 1.33 g 11.6 g 1.35 g 1.30 g 3.29 g 5.42 g 3.84 g 1.30 g		(16.0 mg TE/ET) 	L-Carnitine Choline Inositol Taurine *nil added	75.0 mg 700 mg 450 mg 235 mg

500 g e

149585 10393047

5 016533 655391

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

Nutricia Middle East & Africa,
Jumeirah Lakes Towers, Cluster W,
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Job Name	ZCSH903561_RE.ap		
DSN code	ZCSH903561		
Description	191513_UK_LVP_(SVDS)_PKU Nutri 1 Concentrated_EN_649585_Can/Tin_ 10393047		
Account	SHS INTERNATIONAL LTD		
Executive Mail			
Pack Code	10393047		
Previous Pack Code	10365453		
Corporate Code	649585		
Artwork Loop	1		
Repro Loop	1		
Packtype	TIN		
Printer	SPRINGFIELD SOLUTIONS LTD	Material Code	***
Technical Plan	LVP003_Tin label M_v01		
Unwind Direction	***		
Printing Process	Offset		
Date	19-01-2020	First Barcode Number	5016533655391
Time	12:23	2D Code Number	10393047
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	5016533655391
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Barcode BWR (μm)	15,00

APER CMYK 09JAN2014

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Nutrition information per 100 g			
Energy	1251 kJ 299 kcal	L-Proline L-Serine	5.18 g 2.88 g
Fat	0 g	L-Threonine L-Tryptophan	2.58 g 0.96 g
of which		L-Tyrosine L-Valine	3.22 g 3.80 g
- Saturates	0 g	Salt	1.8 g
Carbohydrate	25.6 g	Vitamins	
of which		Vit. A	1900 µg
- Sugars	0.89 g	Vit. D	42.5 µg
Fibre	0 g	Vit. E	(16.0 mg TE/ET) 21.7 mg
Protein equivalent	50.0 g	Vit. K	35.0 µg
of which		Thiamin	2.00 mg
L-Alanine	2.35 g	Riboflavin	2.25 mg
L-Arginine	1.95 g	Niacin	(38.5 mg NE/EN) 22.5 mg
L-Aspartic acid	5.46 g	Pantothenic acid	15.0 mg
L-Cystine	1.33 g	Vit. B ₆	1.75 mg
L-Glutamic acid	11.6 g	Folic acid	250 µg
Glycine	1.35 g	Folate	417 µg
L-Histidine	1.30 g	Vit. B ₁₂	4.25 µg
L-Isoleucine	3.29 g	Biotin	50.0 µg
L-Leucine	5.42 g	Vit. C	100 mg
L-Lysine	3.84 g		
L-Methionine	1.30 g		
L-Phenylalanine	-		
		Minerals and trace elements	
		Na	(30.4 mmol) 700 mg
		K	(57.5 mmol) 2250 mg
		Cl	(39.5 mmol) 1400 mg
		Ca	(48.0 mmol) 1925 mg
		P	(37.0 mmol PO ₄) 1146 mg
		Mg	(9.87 mmol) 240 mg
		Fe	35.0 mg
		Zn	16.5 mg
		Cu	1.80 mg
		Mn	0.27 mg
		F	0.50 mg
		Mo	100 µg
		Se	60.0 µg
		Cr	80.0 µg
		I	300 µg
		Others	
		L-Carnitine	75.0 mg
		Choline	700 mg
		Inositol	450 mg
		Taurine	235 mg
		*nil added	

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

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



DANONE

500 g e



149585



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PROTEIN STATEMENT**Product Name: PKU Nutri 1 Concentrated B5300**

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

- **Protein content: 50g/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	2.35
L-Arginine	1.95
L-Aspartic Acid	5.46
L-Cystine	1.33
L-Glutamic Acid	11.6
L-Glutamine	0.00
Glycine	1.35
L-Histidine	1.30
L-Isoleucine	3.29
L-Leucine	5.42
L-Lysine	3.84
L-Methionine	1.30
L-Proline	5.18
L-Phenylalanine	0
L-Serine	2.88
L-Threonine	2.58
L-Tryptophan	0.96
L-Tyrosine	3.22
L-Valine	3.80
Total Amino Acids	57.8



Diane Sheldon
Registration Officer

Date : 17/09/2021

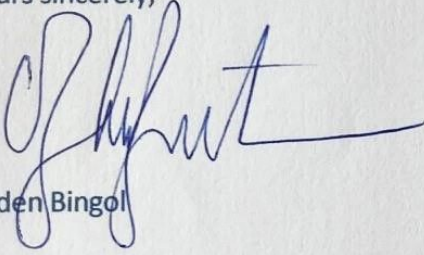
www.nutricia.com

Amsterdam, September 6th, 2021

To whom it may concern,

We herewith confirm that PKU NUTRI 1 CONCENTRATED (50g/100g) is registered and lawfully sold in the countries listed in the below table.

Yours sincerely,



Ozden Bingol

Global Market Access Director

Danone Specialized Nutrition

BrandName	Marketed	Country Name With Currency	Reimbursement Status
PKU NUTRI 1 CONCENTRATED 2X500G	YES	Serbia (€)	YES
PKU NUTRI 1 CONCENTRATED 2X500G	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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

composition		1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	content per 1 g protein	100 kJ ready to feed product
protein equivalent	g						50	5	17.2	1	4.1
vegetable protein	g										
amino acids	g						60	6	20.7	1.2	4.9
fat	g										
vegetable fat	g										
animal fat	g										
MCT	g										
digest. carbohydrates	g						22.5	2.3	7.8	0.5	1.8
dietary fiber	g										
salt equivalent	g						1.8	0.2	0.6	0.04	0.1
minerals (calculated)	g						15.3	1.5	5.3	0.3	1.2
water (calculated)	g						2.2	90.2	311.1	0.04	73.2
energy	kJ						1233	123	-		-
	kcal						290	29	-		-
vitamins											
A	µg RE						1750	175	603	35	142
D3	µg						22.5	2.3	7.8	0.45	1.8
E	mg TE						10	1	3	0.2	0.8
K1	µg						25	2.5	9	0.5	2
thiamin (B1)	mg						2	0.2	0.69	0.04	0.2
riboflavin (B2)	mg						1.8	0.2	0.61	0.035	0.14
B6	mg						1.5	0.15	0.52	0.03	0.12
niacin	mg						21	2.1	7.2	0.42	1.7
niacin equivalents	mg						37.7	3.8	13	0.8	3.1
biotin	µg						42	4	14	0.83	3
folic acid	µg						275	28	95	5.5	22
B12	µg						4	0.4	1.4	0.08	0.32
pantothenic acid	mg						11.5	1.2	4	0.23	0.9
C	mg						150	15	52	3	12
nutrient relation (energy %)											
protein	%						69	69			
fat	%						0	0			
carbohydrates	%						31	31			

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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

composition		1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	content per 1 g protein	100 kJ ready to feed product
minerals	g						15.3	1.5	5.3	0.3	1.2
sodium	mg						700	70	241	14	57
	mmol						30.4	3	10.5	0.6	2.5
potassium	mg						2230	223	769	44.6	181
	mmol						57.0	5.7	19.7	1.1	4.6
calcium	mg						1900	190	655	38	154
	mmol						47.4	4.7	16.3	0.9	3.8
magnesium	mg						190	19	66	3.8	15
	mmol						7.8	0.8	2.7	0.2	0.6
phosphorus	mg						1130	113	390	22.6	92
	mmol						36.5	3.6	12.6	0.7	3
chloride	mg						1400	140	483	28	114
	mmol						39.5	3.9	13.6	0.8	3.2
iron	mg						29	2.9	10	0.58	2.4
	mmol						0.5	0.1	0.2	0.01	0.04
Na+K+Cl	mol/l						1.3	0.1	0.4	0.03	0.1
Ca/P							1.7	1.7	1.7	1.7	1.7
trace elements											
zinc	mg						18	1.8	6.2	0.36	1.5
copper	mg						1.65	0.17	0.57	0.033	0.13
iodine	µg						260	26	90	5.2	21
manganese	mg						1.8	0.2	0.62	0.04	0.1
chromium	µg						75	8	26	1.5	6.1
fluoride	mg						0.5	0.05	0.17	0.01	0.04
molybdenum	µg						100	10	34	2	8.1
selenium	µg						74.5	7.5	25.7	1.49	6
choline	mg						450	45	155	9	37
inositol	mg						300	30	103	6	24

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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

composition	1	2	3	4	5	100 g dry product	100 g (ml) ready to feed product	100 kcal ready to feed product	content per 1 g protein	100 kJ ready to feed product
protein equivalent	g					50	5	17.2	1	4.1
amino acids						60			1.2	
essential amino acids										
cystine	g					1.4	0.14	0.5	0.028	0.11
histidine	g					1.4	0.14	0.5	0.028	0.11
isoleucine	g					3.4	0.34	1.2	0.068	0.28
leucine	g					5.7	0.57	2	0.113	0.46
lysine	g					4	0.4	1.4	0.08	0.32
methionine	g					1.4	0.14	0.5	0.028	0.11
phenylalanine	g									
threonine	g					2.7	0.27	0.93	0.054	0.22
tryptophan	g					1	0.1	0.34	0.02	0.08
tyrosine	g					3.4	0.34	1.2	0.068	0.28
valine	g					4	0.4	1.38	0.08	0.32
sum of ess. amino acids	g					28.4	2.8	9.8	0.567	2.3
sum of branched chain amino acids	g					13.1	1.31	4.5	0.261	1.06
non ess. amino acids										
alanine	g					2.4	0.24	0.83	0.048	0.2
arginine	g					2	0.2	0.69	0.04	0.16
aspartic acid	g					5.7	0.57	2	0.113	0.46
glutamic acid	g					11.9	1.2	4.1	0.237	1
glycine	g					1.4	0.14	0.5	0.028	0.11
proline	g					5.4	0.54	1.8	0.107	0.43
serine	g					3	0.3	1	0.06	0.24
sum of non-ess. amino acids	g					31.7	3.2	10.9	0.6	2.6
taurine	mg					250	2.9	10.1	5	2.4
carnitine	mg					75	5.9	20.3	1.5	4.8
chemical score* method										

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 protein = casein

Product: PKU Nutri 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

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	content per 1 g protein	100 kJ ready to feed product
fat	g						0	0.0	0.0	0.0	0.0
fatty acids spectrum											
- butyric acid C4	g						0.00	0.000	0.000	0.0000	0.000
- caproic acid C6	g						0.00	0.000	0.000	0.0000	0.000
- caprylic acid C8	g						0.00	0.000	0.000	0.0000	0.000
- capric acid C10	g						0.00	0.000	0.000	0.0000	0.000
- lauric acid C12	g						0.00	0.000	0.000	0.0000	0.000
- myristic acid C14	g						0.00	0.000	0.000	0.0000	0.000
- myristolic acid C14:1w9	g						0.00	0.000	0.000	0.0000	0.000
- pentadecanoic a. C15	g						0.00	0.000	0.000	0.0000	0.000
- palmitic acid C16	g						0.00	0.000	0.000	0.0000	0.000
- palmitolic acid C16:1w7	g						0.00	0.000	0.000	0.0000	0.000
- margaric acid C17	g						0.00	0.000	0.000	0.0000	0.000
- stearic acid C18	g						0.00	0.000	0.000	0.0000	0.000
- elaidic acid C18:1tw9	g						0.00	0.000	0.000	0.0000	0.000
- oleic acid C18:1w9	g						0.00	0.000	0.000	0.0000	0.000
- vaccenic acid C18:1tw11	g						0.00	0.000	0.000	0.0000	0.000
- c-t linoleic acid C18:2ctw6	g						0.00	0.000	0.000	0.0000	0.000
- linoleic acid C18:2w6	g						0.00	0.000	0.000	0.0000	0.000
- gamma-linolenic a. C18:3w6	g						0.00	0.000	0.000	0.0000	0.000
- alpha-linolenic a. C18:3w3	g						0.00	0.000	0.000	0.0000	0.000
- arachidic acid C20	g						0.00	0.000	0.000	0.0000	0.000
- eicoseic acid C20:1w9	g						0.00	0.000	0.000	0.0000	0.000
- eicosadienoic acid C20:2w6	g						0.00	0.000	0.000	0.0000	0.000
- homo-g-linolenic a. C20:3w6	g						0.00	0.000	0.000	0.0000	0.000
- arachidonic acid C20:4w6	g						0.00	0.000	0.000	0.0000	0.000
- eicosapentanoic a. C20:5w3	g						0.00	0.000	0.000	0.0000	0.000
- behenic acid C22	g						0.00	0.000	0.000	0.0000	0.000
- erucic acid C22:1w9	g						0.00	0.000	0.000	0.0000	0.000
- docosatetraoic a. C22:4w6	g						0.00	0.000	0.000	0.0000	0.000
- docosapentanoic a. C22:5w3	g						0.00	0.000	0.000	0.0000	0.000
- docosahexanoic a. C22:6w3	g						0.00	0.000	0.000	0.0000	0.000
- lignoceric acid C24	g						0.00	0.000	0.000	0.0000	0.000
- non identified fa	g					100.0	0.0	0.0	0.0	0.0	0.0
fatty acids characteristics											
trans fatty acids	g					0.0	0.0	0.00	0.00	0.000	0.00
saturated fatty acids	g					0.0	0.0	0.00	0.00	0.00	0.00
unsaturated fatty acids	g					0.0	0.0	0.00	0.00	0.00	0.00
mono unsaturated fatty acids	g					0.0	0.0	0.00	0.00	0.00	0.00
poly unsaturated fatty acids	g					0.0	0.0	0.00	0.00	0.00	0.00
essential fatty acids *	g					0.0	0.0	0.00	0.00	0.00	0.00
w3 LCP	g					0.00	0.0	0.00	0.00	0.000	0.00
w6 LCP	g					0.00	0.0	0.00	0.00	0.000	0.00
w6/w3 fatty acids	g					0.0	0.0	0.00	0.00	0.00	0.00
linoleic / alpha-linolenic acid	g					0.0	0.0	0.00	0.00	0.00	0.00
poly. unsat./saturated fatty acids = P/S quotient						0.0	0.0	0.00	0.00	0.00	0.00
cholesterol	mg						0.0	0.00	0.0	0.0	0.0

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 =

* = Linoleic + alpha-Linolenic acid

Product: PKU Nutri 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

composition	1	2	3	4	5	100 g dry	100 g (ml) ready to feed product	100 kcal ready to feed product	% of carbohydrates ready to feed p.	content per 1 g protein	100 kJ ready to feed product
digest. carbohydrates	g					22.5	2.3	7.8	100	0.5	1.8
carbohydrates											
sugars	g					0.9	0.1	0.3	4	0.02	0.1
- glucose	g					0.3	0.03	0.1	1	0.01	0.02
- fructose	g										
- lactose	g										
- sucrose	g										
- maltose	g					0.6	0.06	0.2	2	0.01	0.05
- galactose	g										
polysacch., digest.	g					21.6	2.16	7.4	96	0.4	1.8
dietary fiber (AOAC)	g										
- soluble	g										
- insoluble	g										
starch	g										
polyols	g										
- sorbitol	g										
bread unit						1.9	0.2				

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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

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: g powder + 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

0 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 1 Concentrated

PD Recipe No.: 11/08/06

SP Recipe No.: B3169

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

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



OGYÉI
Országos Gyógyszerészeti
és Élelmezés-egészségügyi Intézet

Országos Élelmezés- és Táplálkozástudományi Intézet Főigazgatóság

1097 Budapest, Albert Flórián út 3./a.

Levélcím: 1372 Postafiók 450.

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

E-mail: ogyei@ogyei.gov.hu

Web: www.ogyei.gov.hu

Iktatószám: 1096/2015. OÉTI

Budapest, 2015. június 04.

Notifikációs szám: T/1976/2015.

Zimai Veronika

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

Numil Kft.

Ügyfélszolgálat: (+36) 1 476 64 40

1134 Budapest

ugyfelszolgalat@oeti.antsz.hu

Róbert Károly krt. 82-84.

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 1 Concentrated

Ízesítés nélküli speciális - gyógyászati célra szánt - tápszer fenilketonúriás (PKU) és
hiperfenilalaninémiás (HPA) csecsemők számára.

4. Termék besorolása:

Speciális – gyógyászati célra szánt – tápszer

1096/2015 OÉTI

Notifikációs szám: T/1976/2015

5. Termék összetevői csökkenő mennyiségi sorrendben:

maltodextrin, L-lizin-L-glutamát, L-glutaminsav, L-leucin, L-prolin, kálium-citrát, kalcium-ortofoszfát, L-valin, L-aszparaginsav, L-izoleucin, L-tirozin, L-szerin, L-treonin, magnézium-L-aszpartát, L-alanin, L-arginin, nátrium-klorid, L-hisztidin, L-metionin, L-cisztin, glicin, kalcium-karbonát, kolin-bitartrát, L-triptofán, kálium-klorid, inozitol, taurin, L-aszkorbinsav, L-karnitin-tartarát, vas-szulfát, aroma (vanillin), cink-szulfát, niacinamid, DL-alfa-tokoferil-acetát, kalcium-D-pantotenát, réz-szulfát, mangán-szulfát, tiamin-mononitrát, retinil-acetát, piridoxin-hidroklorid, riboflavin, nátrium-fluorid, pteroil-monoglutaminsav, króm(III)-klorid, kálium-jodid, nátrium-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 1 Concentrated, ízesítés nélküli speciális - gyógyászati célra szánt - tápszer fenilketonúriás (PKU) és hiperfenilalaninémiás (HPA) csecsemők 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 fenilketonúriás vagy hiperfenilalaninémiás csecsemők részére.

1096/2015 OÉTI

Notifikációs szám: T/1976/2015

11. Adagolás:

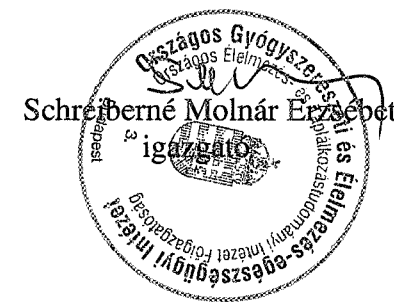
Az adagot csak orvos és dietetikus határozhatja meg. Az adag függ az életkortól, a testsúlytól és az egyén egészségi állapotától. A javasolt napi bevitelt rendszeres orvosi ellenőrzés alatt kell tartani.

Elkészítés: A javasolt adag elosztandó 3-5 egyenlő részre a nap folyamán és előre kiszámított mennyiségű más étellel, itallal (pl. vízzel, csecsemőtápszerrel, 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 1 Concentrated

Ízesítés nélküli speciális – gyógyászati célra szánt – tápszer fenilketonúriás (PKU) és hiperfenilalaninémiás (HPA) csecsemők 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 fenilketonúriás vagy hiperfenilalaninémiás csecsemők 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, csecsemőtápszerrel, gyümölcspürével) együtt fogyasztandó. Csecsemőtápszerhez történő hozzáadás esetén kövesse a szigorú higiéniai szabályokat a szennyeződés elkerülése érdekében. Elkészítés után azonnal használja fel. A megfelelő elkészítéshez vegye figyelembe a csecsemőtápszerre vonatkozó gyártói utasításokat. ne hagyja, hogy a tápszer hosszú időn keresztül érintkezzen babája/gyermeké fogával. Biztosítsa a fogak tisztaságát az utolsó esti etetés után. **Tárolás:** Tárolja hűvös, száraz helyen (<25°C). Használat után mindig zárja vissza a doboz tetejét. Felbontás után használja fel 4 héten belül. Védőgáz csomagolású termék.

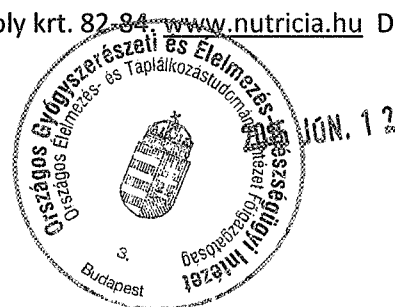
Összetevők: maltodextrin, L-lizin L-glutamát, L-glutaminsav, L-leucin, L-prolin, kálium-citrát, kalcium ortofoszfát, L-valin, L-aszparaginsav, L-izoleucin, L-tirozin, L-szerin, L-treonin, magnézium L-aszpartát, L-alanin, L-arginin, nátrium-klorid, L-hisztidin, L-metionin, L-cisztin, glicin, kalcium-karbonát,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

Átlagos tápérték/100 g termék: **Energia** 1233 kJ/290 kcal, **Zsír** 0g, amelyből Telített zsírsavak 0 g, **Szénhidrát:** 22,5 g, amelyből cukrok: 0,9g, **Rost** 0g, **Fehérje ekvivalens:** 50g, **Só** 1,8 g, **Aminosavak:** 60 g, L-cisztin 1,4 g, L-hisztidin: 1,4g, L-izoleucin 3,4g, L-leucin 5,7g, L-lizin 4g, L-metionin 1,4 g, L-fenilalanin 0g, L-treonin 2,7 g, L-triptofan 1g, L-tirosin 3,4g, L-valin 4g, L-alanin 2,4g, L-arginin 2g, L-aszparaginsav 5,7g, L-glutaminsav 11,9g, Glicin 1,4g, L-prolin 5,4g, L-szerin 3g. **Ásványi anyagok:** Nátrium 700mg, Kálium 2230 mg, Kalcium 1900 mg, Magnézium 190 mg, Foszfor 1130 mg, Klorid 1400 mg, **Nyomelemek:** Vas 29 mg, Cink 18 mg, Réz 1,65 mg, Jód 260 mcg, Mangán 1,8 mg, Króm 75 mcg, Fluor 0,5 mg, Molibdén 100 mcg, Szelén 74,5 mcg, **Vitaminok:** A-vitamin 1750 mcg RE, D- vitamin 22,5 mcg, E- vitamin 10 mg TE, K- vitamin 25 mcg, Tiamin 2 mg, Riboflavin 1,8 mg, B6-vitamin 1,5 mg, Niacin 37,7 mg NE, 21 mg, Folsav 275 mcg, Biotin 42 mcg, B12- vitamin 4 mcg, Pantoténsav 11,5 mg, C- vitamin 150 mg, Egyéb: L-karnitin 75 mg, kolin 450 mg, Inozitol 300 mg, Taurin 250 mg.

Minőségét megőrzi: doboz alján látható időpontig

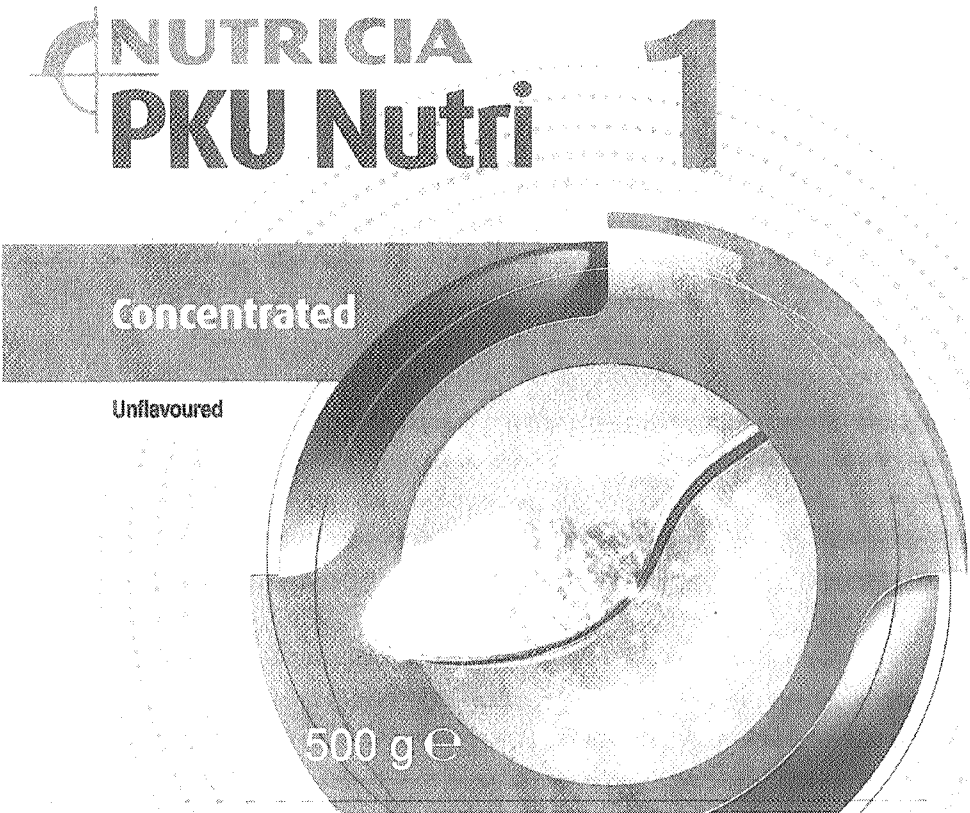
Gyártja: SHS International Ltd., 100 Wavertree Boulevard, Liverpool L79PT, Egyesült Királyság.

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



V=+109.
B=+318.

5



Food for special medical purposes. For the dietary management of phenylketonuria (PKU) and hyperphenylalaninaemia (HPA) in infants. 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 infants. 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 diettitian 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, infant formula, fruit puree. If added to infant formula, follow strict hygienic measures to prevent contamination. Use immediately after reconstitution. Refer to infant formula manufacturer's instructions for correct preparation and use.

Do not allow prolonged or frequent contact of feeds with your baby's teeth. Clean teeth after last feed at night.

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.

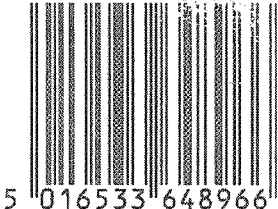
Ingredients: Maltodextrin, L-Lysine L-Glutamate, L-glutamic acid, L-leucine, L-proline, potassium citrate, calcium orthophosphate, L-valine, L-aspartic acid, L-isoleucine, L-tyrosine, L-serine, L-threonine, magnesium L-aspartate, L-alanine, L-arginine, sodium chloride, L-histidine, L-methionine, L-cystine,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

Best before: See base of can.

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

Nutrition information:		per 100 g	
Energy	1233 kJ / 290 kcal	L-Tryptophan 1 g	F 0.5 mg
		L-Tyrosine 3.4 g	Mo 100 µg
Fat of which - Saturates	0 g	L-Valine 4 g	Se 74.5 µg
	0 g	L-Alanine 2.4 g	
Carbohydrate of which - Sugars	22.5 g	L-Arginine 2 g	Vitamins
	0.9 g	L-Aspartic Acid 5.7 g	Vit. A 1750 µg RE/ER
Fibre	0 g	L-Glutamic acid 11.9 g	Vit. D 22.5 µg
		Glycine 1.4 g	Vit. E 10 mg α-TE/ET
Protein equivalent	50 g	L-Proline 5.4 g	Vit. K 25 µg
		L-Serine 3 g	Thiamin 2 mg
Salt	1.8 g	Minerals	Riboflavin 1.8 mg
			Vit. B6 1.5 mg
Amino Acids	60 g	Na (30.4 mmol) 700 mg	Niacin (37.7 mg NE/EN) 21 mg
		K (57 mmol) 2230 mg	Folic acid 275 µg
L-Cystine	1.4 g	Ca (47.4 mmol) 1900 mg	Biotin 42 µg
L-Histidine	1.4 g	Mg (7.8 mmol) 190 mg	Vit. B12 4 µg
L-Isoleucine	3.4 g	P (36.5 mmol PO4) 1130 mg	Pantothenic acid 11.5 mg
L-Leucine	5.7 g	Cl (39.5 mmol) 1400 mg	Vit. C 150 mg
L-Lysine	4 g	Trace elements	Others
L-Methionine	1.4 g		
L-Phenylalanine	-	Fe 29 mg	L-Carnitine 75 mg
L-Threonine	2.7 g	Zn 16 mg	Choline 450 mg
		Cu 1.65 mg	Inositol 300 mg
		I 260 µg	Taurine 250 mg
		Mn 1.8 mg	
		Cr 75 µg	

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ARTWORK PREPRESS

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Email:
info@ds-n.com

www.ds-n.com

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Separations

