

**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 : 13.10.2023**

[www.nutricia.com](http://www.nutricia.com)

## Certificate of Analysis

**Batch Number:** 111252307  
**Product:** PKU NUTRI 1 CONC UPGRADE 2X500G EN (L)  
**Product Code:** 149585 **Corporate Code:**  
**Date of Manufacture:** 12-May-2023  
**Expiry Date:** 11-May-2025

Test	Specification	Result
<b>Physical/Chemical</b>		
QC_174	Magnesium	192 to 288 mg/100g
QC_174	Iron	28.0 to 42.0 mg/100g
QC_665	Vitamin C	80.0 to 180.0 mg/100g
*QC_601_ASP	Aspartic Acid	4.64 to 6.27 g/100g
*QC_601_THR	Threonine	2.19 to 2.97 g/100g
*QC_601_SER	Serine	2.45 to 3.31 g/100g
*QC_601_GLU	Glutamic Acid	9.8 to 13.3 g/100g
*QC_601_PRO	Proline	4.40 to 5.96 g/100g
*QC_601_GLY	Glycine	1.15 to 1.55 g/100g
*QC_601_ALA	Alanine	2.00 to 2.70 g/100g
*QC_601_VAL	Valine	3.23 to 4.37 g/100g
*QC_601_CYS	Cystine	1.13 to 1.53 g/100g
*QC_601_MET	Methionine	1.10 to 1.49 g/100g
*QC_601_ISO	Iso-Leucine	2.79 to 3.78 g/100g
*QC_601_LEU	Leucine	4.61 to 6.24 g/100g
*QC_601_TYR	Tyrosine	2.74 to 3.70 g/100g
*QC_601_LYS	Lysine	3.26 to 4.42 g/100g
*QC_601_HIS	Histidine	1.11 to 1.50 g/100g
*QC_601_TRP	Tryptophan	0.82 to 1.10 g/100g
*QC_601_ARG	Arginine	1.66 to 2.24 g/100g
*QC_601_TOTAL	Total Amino Acids	52.0 to 63.5 g/100g
*QC_602	Phenylalanine	Less than or Equal to 5 mg/100g
APPEARANCE	Appearance	White to off white powder, free of lumps and foreign matter

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Test		Specification	Result
<b>Microbiology</b>			
QC_022_SUM	TVC	Less than or Equal to 5000 cfu/g	<100 cfu/g
QC_252_SUM	Cronobacter	Absent	Absent
QC_256_SUM	SRC	Less than 100 cfu/g	<10 cfu/g
QC_666_SALM	Salmonella	Absent	Absent
QC_674_SUM	Listeria spp.	Absent	Absent
QC_025_SUM	Enterococci/Streptococci	Less than or Equal to 500 cfu/g	<10 cfu/g
QC_039_SUM	Coag Pos Staph	Less than or Equal to 100 cfu/g	<10 cfu/g
QC_151_SUM	Yeast and Mould	Less than or Equal to 500 cfu/g	<10 cfu/g
QC_152_SUM	Bacillus cereus	Less than or Equal to 500 cfu/g	<10 cfu/g
QC_242_EB_SUM	Enterobacteriaceae	Absent	Absent
<b>Sensory</b>			
QC_104	Reconstitution	Typical	Typical
QC_611	Sensory	Typical	Typical

## Certificate of Analysis

SHS INTERNATIONAL LTD.  
100 WAVERTREE BOULEVARD  
WAVERTREE TECHNOLOGY PARK  
LIVERPOOL L7 9PT  
UNITED KINGDOM  
REGISTERED IN ENGLAND, NUMBER 112075

GMP tested

**Issued by:**

Vicki Ellison

Issued on behalf of Claire Kilburn (Head of Quality)

This is an electronic signature.

**Date of Issue :**

31/May/2023 11:01:36

These results apply only to the items tested as received. This Certificate of Analysis shall not be reproduced, except in its entirety, without the written approval of SHS International



This laboratory is accredited in accordance with the recognised International Standard ISO/IEC 17025. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

This accreditation relates only to methods specified by \*

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Tested by and on behalf of

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Finished Product Certificate of Analysis Version: 10

Report: 52482 Date: 31/05/2023/12:01:39 From: LIMS\_PROD\_V7



**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 rearm 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, D-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
<b>Energy</b>	1251 kJ 299 kcal	L-Proline 5.18 g L-Serine 2.88 g L-Threonine 2.58 g L-Tryptophan 0.96 g L-Tyrosine 3.22 g L-Valine 3.80 g
<b>Fat</b>	0 g	<b>Salt</b> 1.8 g
of which	0 g	<b>Vitamins</b>
- Saturates	0 g	Vit. A 1900 µg Vit. D 42.5 µg Vit. E (16.0 mg TE/ET) 21.7 mg Vit. K 35.0 µg Thiamin 2.00 mg Riboflavin 2.25 mg Niacin (38.5 mg NE/EN) 22.5 mg Pantothenic acid 15.0 mg Vit. B6 1.75 mg Folic acid 250 µg Biotin 417 µg Vit. B12 4.25 µg Lysine 50.0 µg Methionine 1.30 g Phenylalanine 1.30 g
<b>Carbohydrate</b>	25.6 g	
of which	0.89 g	
- Sugars	0 g	
<b>Fibre</b>	0 g	
<b>Protein equivalent</b>	50.0 g	
of which	2.35 g	
L-Alanine	1.96 g	
L-Arginine	5.46 g	
L-Aspartic acid	1.33 g	
L-Cysteine	11.6 g	
L-Glutamic acid	1.35 g	
Glycine	1.30 g	
L-Histidine	3.29 g	
L-Isoleucine	5.42 g	
L-Leucine	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	(38.5 mmol) 1400 mg
Ca	(48.0 mmol) 1925 mg
P	(37.0 mmol PO <sub>4</sub> ) 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
<b>Others</b>	
L-Carnitine	75.0 mg
Choline	700 mg
Inositol	450 mg
Taurine	235 mg
*nil added	

**500 g e**

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DANONE

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