

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

Suggested intake: Should be determined by a dinician 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-camitine-L-tartrate, ferrous sulphate, zinc sulphate. DL-o-tocopheryl acetate, nicotinamide, calcium D-pantothenate, copper sulphate, thiamin hydrochloride, retinyl acetate, riboflavin, pyridoxine hydrochloride, sodium fluoride, manganese sulphate, potassium iodide, chromium chloride, pterovimonodiutamic acid. sodium molybdate, sodium selenite. D-biotin. cholecalciferol, phytomenadione, cyanocobalamin.

Nutrition information per	100 g				
Energy	1251 kJ 299 kcal	L-Proline L-Serine	5.18 g 2.88 g	Na	ce elements (30.4 mmoll) 700 mg
Fat of which	0g	L-Threonine L-Tryptophan	2.58 g 0.96 g	K Q	(57.5 mmol) 2250 mg (39.5 mmol) 1400 mg
- Saturates	0 g	L-Tyrosine L-Valine	3.22 g 3.80 g	Ca P	(48.0 mmoll) 1925 mg (37.0 mmoll PO4) 1146 mg
Carbohydrate of which	25.6 g	Salt	1.8 g	Mg Fe	(9.87 mmol) 240 mg 35.0 mg
- Sugars	0.89 g	Vitamins Vit. A	1000.00	Zn	16.5 mg
Fibre Protein equivalent of which L-Marine Larginine L-Asparic acid L-Asparic acid L-Oystine L-Odutamic acid	0 g 50.0 g 2.35 g 1.95 g 5.46 g 1.33 g 11.6 q	Vit. A Vit. D Vit. E Vit. K Thiamin Riboflavin Niacin Pantothenic acid	1900 µg 42.5 µg (16.0 mg TE/ET) 21.7 mg 35.0 µg 2.00 mg 2.25 mg (38.5 mg NE/EN) 22.5 mg 15.0 mg	F Mo Se Cr I	1.80 mg 0.27 mg 0.50 mg 100 μg 60.0 μg 80.0 μg 300 μg
Glycine L-Histoline L-Isoleucine L-Lysine L-Wethionine L-Phenylalanine	1.35 g 1.30 g 3.29 g 5.42 g 3.84 g 1.30 g	Vit. B6 Folic acid Folate Vit. B12 Biotin Vit. C	1.75 mg 250 µg 417 µg 4.25 µg 50.0 µg 100 mg	L-Camitine	75.0 mg 700 mg 450 mg 235 mg

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.





500 g ⊖

DANONE

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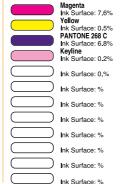


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Cyan Ink Surface: 8.8%

Separations



Certificate of Analysis

Batch Number: 111379548

Product: PKU NUTRI 1 CONC UPGRADE 2X500G EN (L)

Product Code: 149585 Corporate Code:

Date of Manufacture: 15-May-2024 Expiry Date: 15-May-2026

Test		Specification	Result
Physical/Chemical			
*QC_601_TOTAL	Total Amino Acids	52.0 to 63.5 g/100g	56.70 g/100g
QC_174	Magnesium	192 to 288 mg/100g	228.00 mg/100g
QC_174	Iron	28.0 to 42.0 mg/100g	35.90 mg/100g
QC_665	Vitamin C	80.0 to 180.0 mg/100g	89.00 mg/100g
*QC_601_ASP	Aspartic Acid	4.64 to 6.27 g/100g	5.33 g/100g
*QC_601_THR	Threonine	2.19 to 2.97 g/100g	2.43 g/100g
*QC_601_SER	Serine	2.45 to 3.31 g/100g	2.66 g/100g
*QC_601_GLU	Glutamic Acid	9.8 to 13.3 g/100g	11.88 g/100g
*QC_601_PRO	Proline	4.40 to 5.96 g/100g	5.18 g/100g
*QC_601_GLY	Glycine	1.15 to 1.55 g/100g	1.24 g/100g
*QC_601_ALA	Alanine	2.00 to 2.70 g/100g	2.18 g/100g
*QC_601_VAL	Valine	3.23 to 4.37 g/100g	3.50 g/100g
*QC_601_CYS	Cystine	1.13 to 1.53 g/100g	1.37 g/100g
*QC_601_MET	Methionine	1.10 to 1.49 g/100g	1.29 g/100g
*QC_601_ISO	Iso-Leucine	2.79 to 3.78 g/100g	3.06 g/100g
*QC_601_LEU	Leucine	4.61 to 6.24 g/100g	5.42 g/100g
*QC_601_TYR	Tyrosine	2.74 to 3.70 g/100g	3.28 g/100g
*QC_601_LYS	Lysine	3.26 to 4.42 g/100g	3.75 g/100g
*QC_601_HIS	Histidine	1.11 to 1.50 g/100g	1.27 g/100g

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Tested by and on behalf of SHS International Ltd. 100 Wavertree Boulevard Liverpool

L7 9PT

Tel.: +44 (0) 151 228 8161 Fax: +44 (0) 151 228 2650 Finished Product Certificate of Analysis Version: 10

Report: 56732 Date: 11/07/2024/08:46:29 From: LIMS_PROD_V7



Certificate of Analysis

Batch Number: 111379548

Product: PKU NUTRI 1 CONC UPGRADE 2X500G EN (L)

Product Code: 149585 Corporate Code:

Date of Manufacture: 15-May-2024 **Expiry Date:** 15-May-2026

Test		Specification	Result
*QC_601_TRP	Tryptophan	0.82 to 1.10 g/100g	0.95 g/100g
*QC_601_ARG	Arginine	1.66 to 2.24 g/100g	1.91 g/100g
*QC_601_TOTAL	Protein (FAO)	45.00 to 55.00 g	49.15 g
*QC_602	Phenylalanine	Less than or Equal to 5 mg/	4.00 mg/100g
APPEARANCE	Appearance	White to off white powder, free of lumps and foreign matter	Satisfactory
Microbiology			
QC_022_SUM	TVC	Less than or Equal to 5000 cfu/g	99.00 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_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	9.00 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_162_SUM	Listeria spp.	Absent	Absent
QC_242_EB_SUM	Enterobacteriaceae	Absent	Absent

Sensory

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Test		Specification	Result
QC_104	Reconstitution	Typical	Typical
QC_611	Sensory	Typical	Typical

GMP tested

Issued by: John Matthews

Issued on behalf of Claire Kilburn (Head of Quality)

This is an electronic signature.

Date of Issue : 11/Jul/2024 07:46:26

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

Replaces report : 56731 Date: 11/Jul/2024 By: Vicki Ellison



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.

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