

	<b>Product specification</b>	doku-no.:	1-20000-B-20170126_external
		version:	B
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<b>Product:</b>	<b>XPhe Infant Mix<sup>LCP</sup></b>	<b>Art.-no.</b>	<b>1-20000</b>
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## 1. Product description

Name : XPhe Infant Mix<sup>LCP</sup>

Extended name: XPhe Infant Mix<sup>LCP</sup>  
 Food for special medical purposes. Phenylalanine-free Infant Formula for the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA) in infants from birth to 1 year of age.

Sales denomination: Food for special medical purposes

## 2. Specific requirements according to food law

The product is intended as a dietary food for special medical purposes (balanced diet) according to Regulation (EC) No 609/2013.

The product complies with the relevant German, as well as European, provisions of the food law, especially the provisions of the Food, Consumer Goods and Feed Code (LFGB) and Regulation (EC) No 178/2002.

The product is produced in a factory that has a certified quality system (ISO 9001-2000).

The raw materials for the product correspond to the purity requirements obtainable according to the generally recognized rules of technology and are fully suitable for human consumption.

Packaging which can directly or indirectly influence the quality of the food must be suitable for use in foodstuffs. Packaging and transport containers are designed to protect the product against external influences. The packing materials and transport containers in contact with the raw material must not impair the quality of the raw material. The packaging materials used comply with the legal requirements of Regulation (EC) No 1935/2004 and Regulation (EC) No 10/2011 on materials and articles (made of plastic) intended to come into contact with foodstuffs. There is no odor, taste or other impairment of the delivered goods from the packaging material.

## 3. Product properties

### 3.1. Ingredients

Date: 30.03.2014

Vegetable oils (rape seed oil, corn oil, palm oil, sunflower oil), **lactose**, maltodextrin, modified starch, L-lysine-L-glutamate, calcium phosphate, L-leucine, potassium-L-glutamate, L-tyrosine, L-proline, L-arginine-L-aspartate, L-valine, L-isoleucine, L-serine, sodium chloride, magnesium L-aspartate, L-threonine, L-alanine, L-histidine, glycine, L-tryptophan, L-cystine, L-aspartic acid, L-methionine, emulsifiers: E 472c & **soy lecithin**, potassium citrate, potassium carbonate, docosahexaenoic acid (DHA)-rich fishoil (contains **milk components**), choline, inositol, vitamin C, taurine, vanillin, ferrous sulphate, zinc sulphate, niacin, L-carnitine, vitamin E, pantothenic acid, manganese sulphate, cupric sulphate, vitamin A, vitamin B2, vitamin B6, vitamin B1, sodium fluoride, chromium (III) chloride, sodium molybdate, potassium iodide, folic acid, sodium selenite, vitamin K, biotin, vitamin D, vitamin B12.

Created	26.01.2017	Checked:	Released :	
Katja Gaude		Angélique Gebbing	Dr. Bernhard Hoffmann	

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### 3. 2. Nutrition information

		100 g powder	100 ml ready to use
<b>Energy</b>	kJ	2124	319
	kcal	508	76
<b>Fat</b>	g	28	4
of which saturates	g	5	0,8
of which mono-unsaturates	g	11	1,6
of which polyunsaturates	g	12	1,7
<b>Carbohydrate</b>	g	54	8
of which sugars	g	25	4
Starch	g	0	0
<b>Protein eqv.</b>	g	11	1,7
<b>Salt</b>	g	0,6	0,1
<b>Vitamins</b>			
Vitamin A	µg	570	86
Vitamin D	µg	7	1
Vitamin E	mg	5	0,7
Vitamin K1	µg	24	3,6
Vitamin C	mg	58	9
Thiamin (Vit. B1)	mg	0,5	0,07
Riboflavin (Vit. B2)	mg	0,5	0,08
Niacin	mg	6	0,9
Vitamin B6	mg	0,5	0,08
Folic acid	µg	51	8
Vitamin B12	µg	1,3	0,2
Biotin	µg	14	2
Pantothenic acid	mg	4	0,6
<b>Minerals</b>			
Potassium	mg	500	75
Chloride	mg	380	57
Calcium	mg	500	75
Phosphorus	mg	335	50
Magnesium	mg	52	8
<b>Trace elements</b>			
Iron	mg	6	1
Zinc	mg	5	0,8
Copper	mg	0,36	0,05
Manganese	mg	0,4	0,06
Fluoride	mg	0,13	0,02
Selenium	µg	13	2
Chromium	µg	26	4
Molybdenum	µg	26	4
Iodine	µg	46	7

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FURTHER NUTRITION INFORMATION			
Lactose	g	24	3,5
Maltodextrin	g	22	3
Starch	g	8	1,2
Sodium	mg	260	39
L-Carnitine	mg	11	1,6
Choline	mg	77	12
myo-Inositol	mg	51	8
Taurine	mg	39	6
<b>Amino acids</b>	g	13	2
L-Alanine	g	0,5	0,08
L-Arginine	g	0,5	0,08
L-Aspartic acid	g	1,1	0,17
L-Cystine	g	0,3	0,05
L-Glutamic acid	g	1,8	0,27
Glycine	g	0,4	0,06
L-Histidine	g	0,4	0,06
L-Isoleucine	g	0,8	0,12
L-Leucine	g	1,3	0,20
L-Lysine	g	0,9	0,14
L-Methionine	g	0,2	0,03
L-Phenylalanine	g	-	-
L-Proline	g	1,1	0,17
L-Serine	g	0,7	0,11
L-Threonine	g	0,6	0,09
L-Tryptophan	g	0,3	0,05
L-Tyrosine	g	1,2	0,18
L-Valine	g	0,8	0,12

#### 4. Quality parameters and reference values

##### 4.1. Sensoric properties

appearance:	white powder
consistency:	fine powder
odour:	characteristical
taste:	characteristical, neutral, milk-like

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#### 4.2. Potential allergens

Potential allergen	present (Y/N)	Cross-contamination possible (Y/N)
Cereals containing gluten and products thereof	N	N
Crustaceans and products thereof	N	N
Eggs and products thereof	N	N
Fish and products thereof	N	N
Peanuts and products thereof	N	N
Soybeans and products thereof	Y	-
Milk and products thereof (including lactose)	Y	-
Nuts and products thereof	N	N
Celery and products thereof	N	N
Mustard and products thereof	N	N
Sesame seeds and products thereof	N	N
Sulphur dioxide at concentration > 10mg/kg (SO <sub>2</sub> )	N	N
Lupin and products thereof	N	N
Molluscs and products thereof	N	N

#### 4.3. Statement on GMO

Neither genetically modified raw materials, nor genetic engineering methods are used in the production of the above-mentioned product. The product is therefore not subject to the requirements of Regulation (EC) No 1829/2003 on genetically modified food and feed and is not subject to labeling requirements in accordance with Regulation (EC) No 1830/2003 on the traceability and labeling of genetically modified organisms..

#### 4.4. Microbiological requirements

	Unit	Guide value	Warn value
TAMC	CFU/g	$5 \times 10^0$	$5 \times 10^3$
Cronobacter spp.	CFU/g	-	bld in 25 g
Enterobacteriaceae	CFU/g	-	bld in 10 g
Yeast & Moulds	CFU/g	$5 \times 10^1$	$5 \times 10^2$
Spores of sulfite-reducing Clostridia	CFU/g		$1 \times 10^1$
presumptive B. cereus	CFU/g	$5 \times 10^1$	$5 \times 10^2$
Salmonella spec.	CFU/g	-	bld in 125 g
coagulase positive Staphylococci	CFU/g	-	bld in 1 g
L. monocytogenes	CFU/g	-	bld in 250 g

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#### 4.5. Chemical and physical properties

	Average values	Solution
pH-value	7,0 – 7,6	15 g + 90 ml water
Humidity	< 2 %	powder
Osmolality	330-390 mosmol/kg	15 g + 90 ml water
Bulk density	0,30 – 0,38 g/cm <sup>3</sup>	powder

#### 5. Form of delivery

Packaging:

Tin can Pirlo- Art.-no. 111099 149A1- 500 g

Scoop No. 4020 PP blue Henke – Art.-no. 308113

#### 6. Shelf life

12 months after production date

#### 7. Storage

Cool and dry

#### 8. Traceability

The traceability is guaranteed by the best before date and by the batch number.

#### 9. Reference

Packed under protective atmosphere.