Specification

MEGA NFC® medical[10]

created for: Nanoble Health Concept GmbH

Version: 01

Designation of the substance and the mixture and the company

Product name:	MEGA NFC® medical[10]
Applikationform:	Powder
Usage:	oral, see instructions for use
Classification	Medical device
Medical device class	Class IIa
Shelf life	4 Years from production date, see product
Exclusive distributor:	Nanoble Health Concept GmbH, Neuer Wall 63, D- 20354 Hamburg
Manufacturer:	FROXIMUN® AG, Neue Straße 2a, D - 38838 Schlanstedt
Contact details of the safety officer	Phone.: +49 (0) 39401 - 632 320, Fax: +49 (0) 39401 - 632 55 320 mobile: +49 (0) 151 - 113 175 16, E-Mail: ellen.goerner@froximun.ag

Composition / Component data

Active ingredient

Ingredient	MANC® (micronized, activated, natural clinoptilolite)
Product type	Zeolite
Classification	Framework silicates (tectosilicates)
Elements *	silicium, aluminium, calcium, potassium, magnesium, sodium, iron

* MANC® is a natural product and is subject to fluctuations

Additives

Calcium carbonate	Calcium carbonate is listed in Commission Directive 95/45/EC establishing specific purity criteria for food dyes under the number E170 as an approved food coloring matter.
Magnesium carbonate	Magnesium carbonate is listed as an authorized food additive in Commission Directive 2008/84/EC laying down specific purity criteria for food additives other than colors and sweeteners under the number E504 (ii).

Nutrition facts

Content	Nutrition facts	
Nutritional value	Unit	per Sachet*
Calories	kcal	0
Protein	g	0
Total Fat	g	0
Saturated Fat	g	0
Trans Fat	g	0
Total Carbohydrate	g	0
Sugars	g	0
Sodium	mg	17,81

Mineral nutrients

Element	Contents
Reference (report-nr.)	17060/14
Element	Contents in mg per 1 Sachet*
Silicon	1834,56
Calcium	84
Potassium	90
Magnesium	17,76
Sodium	21,12
Iron	54,72
Calcium carbonate	420
Magnesium carbonat	180

Heavy metal

Element	contents
Reference (report-nr.)	01680/16
Element	contents in mg/kg (ppm)
Lead**	7,8
Mercury **	< 0,01

* Salary refers to 1 sachet in the double sachet

** On the basis of clinical data, it has been demonstrated that the above named product does not lead to increased levels of aluminum, lead or mercury in the organism, which has been confirmed by blood, hair and urine analysis.

Mineralogical Analysis

Element	
Reference (Batch)	14-PZ006-33-36 (NC21032014)
Clinoptilolite	$(Na,K,Ca)_6(Si,A1)_{36}0_{72} \cdot 20H_20$
Heulandite	$Ca_{1,}23(AL2Si_7)0_{18} \cdot 6H_20$
Cristobalite	SiO_2
Quartz	SiO_2
Albite	$(Na,Ca)(Si,A0)_40_8$
Halloysit	$Al_2Si_20_5(OH)_4 \cdot 2H_20$
Nontronite	$Na_{0,3}Fe_2Si_40_{10}(OH)_2 \cdot 4H_20$

Food and Drug Administration of the USA (FDA)

The FDA has accepted Zeolite (CFR 21) 182.2727 and aluminosilicate under (CFR 21) 182.2227 as safe under the code of the Federal Regulation (CFR) Title 21."

food safety harmlessness

The food safety harmlessness has been issued by the ISEGA Research and Investigation Company (Aschaffenburg, Germany) with a Certificate of Conformity for the product.

Biocompatibility

In order to exclude biological risks for humans through MEGA NFC® medical[10] or their raw materials, the biocompatibility was tested and avaluated in biological assessments. Various tests were carried out in vivo and in vitro.

The laboratories appointed for this purpose are qualified specialist laboratories, which demonstrate the necessary expertise and meet the requirements for the relevant tests in accordance with the standards.

The biological assessment is based on DIN EN ISO 10993-1: 2010-04 - Biological evaluation of medical products, Part 1: Assessment and testing in the context of a risk management procedure.

Evaluation of the extractable components

Evaluation of calcium concentration

The recommended intake of an adult of calcium is approximately 1000mg/day. Based on the data, it can be seen that there is no calcium excess due to the application of MEGA NFC® medical[10].

Element	Gehaltsangabe
Reference (report-nr.)	17060/14
Content in mg pro 3000 mg	1 Sachet
Calcium (as oxid)	84
Calcium (out of additives)	168
Total calcium	252

Evaluation of sodium conzentration

The recommended intake of an adult is about 550 mg/day. On the basis of the data, it can be seen that the MEGA NFC® medical[10] does not result in a sodium surplus.

Element	Gehaltsangabe
Reference (report-nr.)	17060/14
Content in mg pro 3000 mg	1 Sachet
Sodium (as oxid)	21,12
Sodium (out of addititves)	-
Total sodium	21,12

Evaluation of potassium conzentration

The recommended intake of an adult in potassium is approximately 2000 mg/day. On the basis of the data, it can be seen that the MEGA NFC® medical[10] does not result in a potassium surplus.

Element	Gehaltsangabe
Reference (report-nr.)	17060/14
Content in mg pro 3000 mg	1 Sachet
Potassium (as oxid)	90
Potassium (out of additives)	-
Total potassium	90

Evaluation of the "calcium carbonate"

- Calcium carbonate is listed in Commission Directive 95/45 / EC laying down specific purity criteria for food dyes under the number E170 as an approved food coloring matter.
- Calcium carbonate is listed in the Directive 2002/46 / EC of the European Parliament and of the Council on food supplements in Annex II among the minerals which may be used in the production of food supplements.
- Calcium carbonate is listed under category 2 in the Annex to Commission Directive 2001/15 / EC on substances which may be added for special nutritional purposes to foodstuffs intended for particular nutritional uses.
- Calcium carbonate is listed in Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins, minerals and certain other substances to foodstuffs
- Application: antacid, detergents in dental care products, coating agents, indifferent carrier in powders and ointments, food coloring agent, calcium source for food supplements, mild and drying straightening powder in cosmetics.
- Irradiation: The product or raw materials used have not been treated with ionizing radiation during production, storage or shipping. An identification according to Directive 2000/13 / EC, Article 5, paragraph 3 is therefore not necessary.
- Allergens: The calcium and magnesium carbonate additives meet the requirements of Directive 2000/13 / EC and are free from allergens, as specified in Appendix III a.
- Gluten: The additives calcium and magnesium carbonate may be labeled "gluten-free" in accordance with the provisions of Regulation (EC) No 41/2009.
- Transmissible spongiform encephalopathies: The additives calcium and magnesium carbonate are not derived from animal or human origin, therefore the risk of contamination with BSE / TSE can be excluded. The additives therefore comply with Regulation (EC) No 999/2001.
- Nutritional information: Calcium carbonate is suitable for the following nutritional types: kosher, halal, vegetarian, vegan
- Genetically Modified Organisms (GMOs): The product does not consist of genetically modified organisms nor does it contain or is produced from genetically modified organisms. It does not therefore fall within the scope of Regulation (EC) No 1829/2003 and is not subject to the obligation to label under Regulation (EC) No 1830/2003.

Evaluation of the "magnesium carbonate“

- Magnesium hydroxide carbonate is listed as an approved food additive in Commission Directive 2008/84 / EC laying down specific purity criteria for food additives other than colors and sweeteners under the number E504 (ii).
- Magnesium carbonate is listed in the Directive 2002/46 / EC of the European Parliament and of the Council on food supplements listed in Annex II among the minerals which may be used in the manufacture of food supplements
- Magnesium carbonate is listed under category 2 in the Annex to Commission Directive 2001/15 / EC on substances which are intended for special nutritional purposes for food intended for particular nutritional uses.
- Magnesium carbonate is listed in Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and certain other substances to foodstuffs.
- Irradiation: The product or raw materials used have not been treated with ionizing radiation during production, storage or shipping. An identification according to Directive 2000/13 / EC, Article 5, paragraph 3 is therefore not necessary.
- Allergens: The calcium and magnesium carbonate additives meet the requirements of Directive 2000/13 / EC and are free from allergens, as specified in Appendix III a.
- Transmissible spongiform encephalopathies: The additives calcium and magnesium carbonate are not derived from animal or human origin, therefore the risk of contamination with BSE / TSE can be excluded. The additives therefore comply with Regulation (EC) No 999/2001.
- Genetically Modified Organisms (GMOs): The product does not consist of genetically modified organisms nor does it contain or is produced from genetically modified organisms. It does not therefore fall within the scope of Regulation (EC) No 1829/2003 and is not subject to the obligation to label under Regulation (EC) No 1830/2003.
- Kosher/Halal: We hereby confirm that the above-mentioned product is produced from mineral raw materials in a chemical process. The product contains no animal components, blood or its by-products or alcohol. Alcohol was not used throughout the manufacturing process. The facilities used for the production and packaging of the said product shall not be used for the manufacture and packaging of products of animal origin or products containing animal constituents.

Ellen Görner, B.Sc.
Director Quality Management
Regulatory Affairs