

# Safety Data Sheet

in accordance with Regulation (EC) No. 1907/2006

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Trade name:	MANC <sup>®</sup> by HENA <sup>®</sup>	Version :	05
Last revised:	01.07.2016	Replaces version:	04
Valid from:	01.07.2016	Prepared by:	E.G.

## SECTION 1: Designation of the substance and the mixture and the company

### I.1 Product identifier

- MANC<sup>®</sup> by HENA<sup>®</sup>

### I.2 Relevant identified uses of the substance or mixture and uses which are contraindicated

- Do not take this product simultaneously with other medications: Wait at least 60 minutes after taking medications before using MANC<sup>®</sup> by HENA<sup>®</sup> or NANOBLE HEALTH CONCEPT medical products.

### I.3 Details of the supplier who provides the Safety Data Sheet

Manufacturer/Supplier	FROXIMUN AG
Street address/P.O. box	Neue Straße 2a
Country code/Postal code/City	DE-38838 Schlanstedt
Phone /Fax / E-mail	+49 39401 632-0
E-mail	info@froximun.ag

## SECTION 2: Possible risks

### 2.1 Classification of the substance or mixture

Applicable standard	Description	Evaluation
DIN EN ISO 14971:2013-04	Application of risk management to medical devices and products	Conforms with risk management
DIN EN ISO 10993-1:2010-04	Biological assessment of medical products based on MANC <sup>®</sup> by HENA <sup>®</sup>	Tested and approved by TÜV:
DIN EN ISO 10993-11:2009-08	Tests for acute systemic toxicity	No systemic toxicity
DIN EN ISO 10993-10:2010-12	Tests for irritation and skin sensitization	No irritation or skin sensitization
European Pharmacopoeia 2.6.12 / 2.6.13	Microbiological hygiene test for medical devices/products	Conforms
In-house validation	Ion exchange capacity	Conforms
DIN EN ISO 11885 E22 DIN EN 1483 (E12), DIN EN 13346, UCC specification	Heavy metal burden	Conforms
In-house test method	Determination of particle size	Conforms
XRD, EDX	Mineral composition	Conforms
XRD, EDX, RFA	Chemical composition	Conforms



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The active substance has been classified as safe and non-hazardous to health.

## 2.2 Labelling elements

- DIN EN 1041:2008-11 - Provision of information on medical devices/products, labelling of the active substance on the medical products
- DIN EN ISO 15223-1:2013-02 – Symbols and markings to be used in the labelling of medical devices/products



*Symbol:*  
Manufacturer



*Symbol:*  
Green Point (Dual System Germany)



*Symbol:*  
Keep out of reach of children



*Symbol:*  
LOT, Batch number



*Symbol:*  
Store in a dry place



*Symbol:*  
store at temperatures between 5°C and 40°C



*Symbol:*  
Expiry date



*Symbol:*  
Protect from sunlight

## Safety information and instructions

- If you are pregnant or nursing or have a medical problem, consult your physician before using MANC® by HENA®-based medical
- Do not take this product simultaneously always close with other medications: Wait at least 60 minutes after taking medications before using MANC® by HENA® or FROXIMUN® medical devices.
- Please take care to avoid dust generation when removing the products from larger packages. products.
- Please wear a protective mask.
- Do not leave the MANC® by HENA® open; the package so that it is airtight.
- Stop using the treatment if you notice any unusual effects.

## 2.3 Other risks

- None

## SECTION

### 3: Composition / Component data

#### 3.1 Substances

Ingredient	MANC® by HENA® (micronized, activated, natural clinoptilolite)
Product type	zeolite
Classification	framework silicates (tectosilicates)



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Use	in oral, cutaneous and dental medical devices and cosmetics of FROXIMUN <sup>®</sup> AG
Elemente *	silicium, aluminium, calcium, potassium, magnesium, sodium, iron

\* MANC<sup>®</sup> by HENA<sup>®</sup> is a natural product and is subject to fluctuations.

## 3.2 Mixtures

- None

## SECTION 4: First aid measures

### 4.1 Description of first aid measures General information:

- Please comply with the instructions for use for the relevant MANC<sup>®</sup> by HENA<sup>®</sup>-based products After inhalation:
- Products in capsule form or stirred in liquid cannot be inhaled.
- After inhale a big cloud of dust, please consult a doctor if breathing problems develop.

After skin contact:

- There is no danger. The product can come into contact with the skin.

After eye contact:

- Avoid getting the product in your eyes! Rinse your eyes immediately with plenty of water in the event of contact. If there is no improvement, consult an ophthalmologist.

After swallowing:

- There is no danger. The product is intended for oral use. Drink (200 –300 ml) water with it.

### 4.2 The most important acute and delayed symptoms and effects

- There is no danger. Overdoses are not possible. The product does not cause any side effects. If you drink too little liquid with it, it can cause constipation.

### 4.3 Information on emergency medical assistance and special treatment

- Stop using the treatment if you notice any unusual effects. Do not take this product simultaneously with other medications: Wait at least 60 minutes after taking medication before using MANC<sup>®</sup> by HENA<sup>®</sup> or TOXAPREVENT<sup>®</sup> products.



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## SECTION 5: Fire-fighting procedures

### 5.1 Extinguishing materials

Suitable extinguishing materials

- Not applicable, as the substance is not flammable

Extinguishing materials unsuitable for safety reasons

- Not applicable, as the substance is not flammable

### 5.2 Special risks posed by the substance or mixtures

- None

### 5.3 Information on fighting fires

- Not applicable, as the substance is not flammable

## SECTION 6: Procedures in the event of accidental release

6.1 Personal precautionary measures, protective equipment and emergency measures  
Procedures to be used

- None

6.2 Environmental protection measures

- None

6.3 Methods and material for retention and cleaning

- None

6.4 Cross-references to other sections

- None

## SECTION 7: Handling and storage

7.1 Protective measures for safe handling

Instructions for safe handling

- Keep out of reach of children!
- Store in a dry place at a temperature below 5°C und 40°C, keep out of direct sunlight.
- Use by: See labeling.
- Open the package immediately before use and close it again immediately afterwards.
- Process immediately if possible.

7.2 Conditions for safe storage, taking incompatibilities into account

Requirements for storage facilities and containers

- Recommended storage temperature: room temperature, do not store at temperatures over 40°C.
- Do not store with outgassing substances.
- Do not store with open paints and varnishes. Store in sealed, airtight containers.



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### 7.3 Spezifische Endanwendungen

- Use exclusively for the stated use.

## SECTION 8: Limitation and monitoring of exposure/Personal protective equipment (PPE)

### 8.1 Parameters to be monitored

- None

### European Union limits

- None

### 8.2 Limitation and monitoring of exposure/Personal protective equipment (PPE)

#### Suitable technical control facilities

- None

## SECTION 9: Physical and chemical properties

### 9.1 Information on the basic physical and chemical properties

parameters	minimum value	average grit size	processing method
particle size distribution MANC <sup>®</sup> by HENA <sup>®</sup>	0,1 µm	1,5 - 2,5 µm	validated

parameters	value	method	comment
Appearance	Light gray/white	Visual	----
Odor	Odorless	Olfactory	----
pH value	6.5 - 7.5		In aqueous solution
Melting point	Not determined	Unknown	According to supplier
Freezing point	Not determined	----	----
Boiling point/Flash point	1340°C	----	----
Evaporation speed	Not determined	----	----
Flammability	Not determined	----	----
Vapor pressure	Not determined	Unknown	Unknown
Vapor density	Not determined	Unknown	Unknown
Solubility	Insoluble	----	In water and alcohol



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#### 12.1 Toxicity

- There is no toxicity.

#### 12.2 Persistence and degradability

- There are no environmental risks. The ingredient is a natural substance.

#### 12.3 Bioaccumulation potential

- None

#### 12.4 Mobility in the soil

- Can seep into the soil.

#### 12.5 Results of the PBT/vPvB assessment

- No harm or damage is to be expected in any case.

#### 12.6 Other harmful effects

- No data available

### SECTION 13: Instructions for disposal

#### 13.1. Procedures for handling waste

- The product can be disposed of with household waste.

#### Waste code

- None

#### Uncleaned packaging

- Not applicable

#### Cleaned packaging

- Not applicable

### SECTION 14: Transport information

#### 14.1 UN number

- None

#### 14.2 Proper UN shipping designation

- Not applicable

#### 14.3 Transport hazard classes

- Not applicable

#### 14.4 Packaging group

- Not applicable

#### 14.5 Environmental hazards

- None

#### 14.6 Special warnings and precautions for users

- See sections 6 - 8

#### 14.7 Bulk cargo transport in accordance with Annex II of the MARPOL Convention 73/78 and in accordance with the IBC code

- Not applicable

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## SECTION 15: Statutory regulations

### 15.1 Safety, health and environmental protection regulations /Legislation specific to the substance or the mixture

#### Validation / Qualification:

- The manufacture is subject to a validated process.

#### Conformity:

- Every batch gets an EC Declaration of conformity.

#### Notified Body:

- TÜV Rheinland LGA Products GmbH, Tillystraße  
2, D-90431 Nürnberg

#### Approval:

- Manufacturing, research and development, sales and distribution according to directive 93/42/EEC Annex II, article 3 (quality assurance system), Registration No.: 60105631 0001

#### Certificate:

- TÜV Rheinland certified that MANC<sup>®</sup> and the MANC<sup>®</sup>-based products are manufactured concerning the quality management system for medical devices EN ISO 13485:2012/AC:2012.

#### Radiation:

- The product or the raw materials used were not treated during production, storage or transport with ionizing radiation.

## SECTION 16: Other information

### 15.2 Substance safety assessment

- The substance contained in the product was subjected to a biological assessment and a risk assessment and classified as safe. The assessments were reviewed and approved by a Notified Body.
- This data sheet was prepared in good conscience to the best of our knowledge.
- It is intended exclusively for specialist retailers, practices and medical facilities.

