

REPORT

Influence of CLINOPTILOLITE and MANC[®] on the natural balance of micronutrients

Producer and publisher: FROXIMUN[®] AG

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Patent-No. EP 1942914 A2

This report is intended solely for qualified individuals and professional circles.

1. Data obtained from literature

Target: Study of influence of clinoptilolite on vitamins or microelements

Administration: Oral intake

User: Pigs

Application: Feed supplement

Test: Test of vitamin balance regarding vitamin A, D, E
Test of amino acid balance regarding tryptophan and phenylalanine

Result: The intake of clinoptilolite has neither influence on the abovementioned amino acids nor on the vitamins

Source: Auerbach, Scott M., Carrado, Kathleen A., Prabir, Dutta K., Handbook of Zeolite Science and Technology, New York: Marcel Dekker, Inc., 2003.

Target: Study of influence of clinoptilolite on vitamins and trace elements in blood, liver and kidneys

Administration: Oral intake

User: Sow

Application: Feed supplement

Test: Test of vitamin balance regarding A, E
Test of mineral balance regarding K, Na, P, Ca, Mg, Cu, Zn

Result: The intake of clinoptilolite had no significant influence on the abovementioned minerals nor on the vitamins. The concentration of the substances in the blood (serum) as well as the liver and kidneys showed that the intake of clinoptilolite has no influence on the intake and distribution of substances in the body.

Source: Papaioannou, D. S. et al., (2000): „Effect of in-feed inclusion of a natural zeolite (Clinoptilolite) on certain vitamin, macro and trace element concentrations in the blood, liver and kidney tissues of sows“.

URL: http://www.sciencedirect.com/science?_ob=ArticleListURL&_method=list&_ArticleListID=-903762568&_sort=r&_st=13&view=c&md5=af9cd0c393749bc6d07965767c6bd11a&searchtype=a
[Status: 20.12.1999].

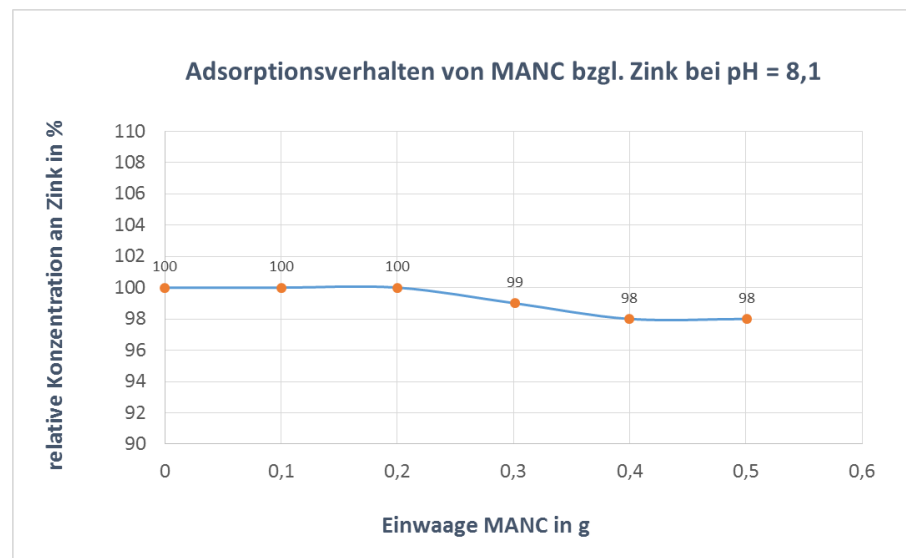
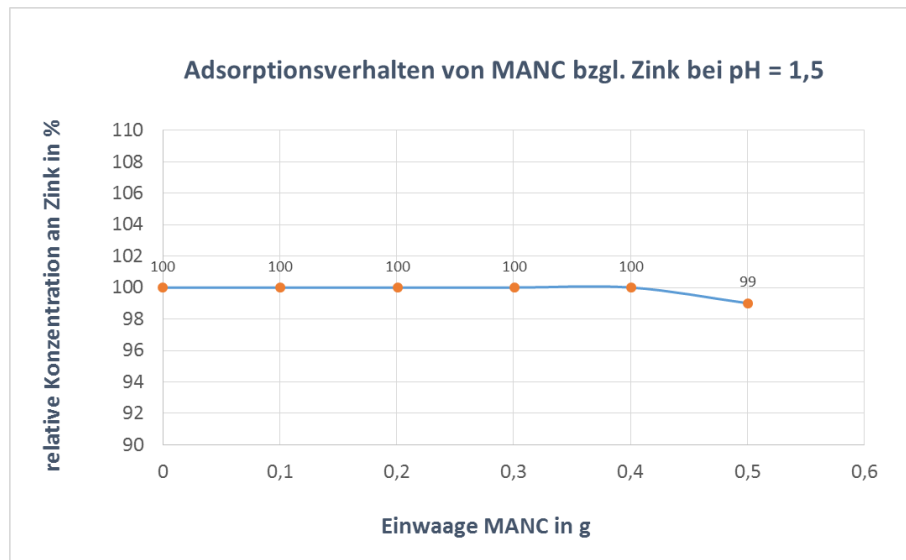
2. Data obtained from in vitro studies

Target: Elimination of the binding of essential substances, according to the example with zinc

Measure: Execution of an in vitro study of the binding ability of zinc through MANC®

Test: Test of the binding of zinc through MANC® in the simulated alimentary canal

Result: Tests showed that with a pH value of 0.5-1.5 only a small amount of measurable absorption happened. Approximately 1 % of the zinc was absorbed. Furthermore, the tests revealed that with a pH value of 8.1 only a small absorption took place. Approximately 1.6 % of the zinc was absorbed. The one percent deviation can be ascribed to measurement inaccuracy or measurement faults.



3. Clinical data gained from *in vivo* studies

Target: Elimination of the binding of essential substances, according to the example of zinc in long-term application of medical products on MANC® basis

Administration: Oral intake

User: Human

Application: Capsule or powder product, minimum of 2 grams MANC® per day

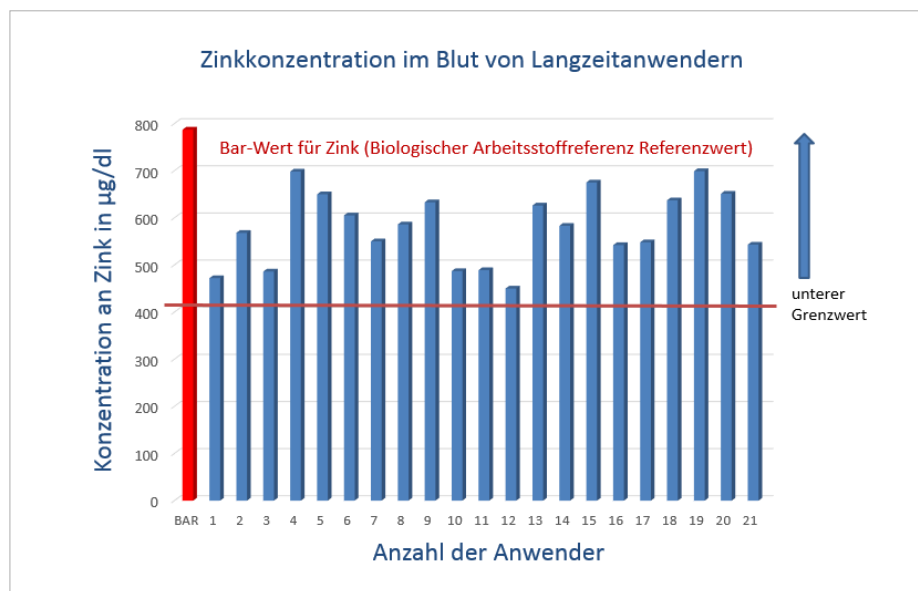
Test: Determination of the concentration of zinc on 21 people by means of a blood study, in comparison to biological reference values of the working material.

Execution of an in-vivo long-term study (approximately 60 months) under intake of FROXIMUN® medical products, whereby different products are consumed on the basis of MANC®. The daily intake of a dose per person was more than 2 grams of MANC®.

Reference value: BAR reference area: 408 – 787 µg/dl

Result: All 21 users had a zinc level in the reference area. The average zinc level was 532,45 µg/dl. No study participant was under 408 µg/dl or over 787 µg/dl.

Clinical data shows that the intake of MANC® over a long period of time and a higher dosage does not have a negative influence on the natural zinc balance. The obtained data showed results that are in a healthy centre span. Therefore, the in vivo evidence was rendered that FROXIMUN® medical products on a MANC® basis does not bind the essential zinc in the human organism.



Target: Elimination of the binding of micro and macro elements, on the example of minerals: an-organic phosphate, sodium, potassium, calcium, magnesium, chloride in long-term use.

Administration: Oral intake

User: Human

Application: Capsule or powder product, minimum of 2 grams clinoptilolite per day

Test: Determination of the concentration of the abovementioned substances on 11 people by means of a blood test in comparison to a control group of 11 people.

Reference value: An-organic phosphate: 0.87-1.45 mmol/l

Calcium: 2.10-2.60 mmol/l

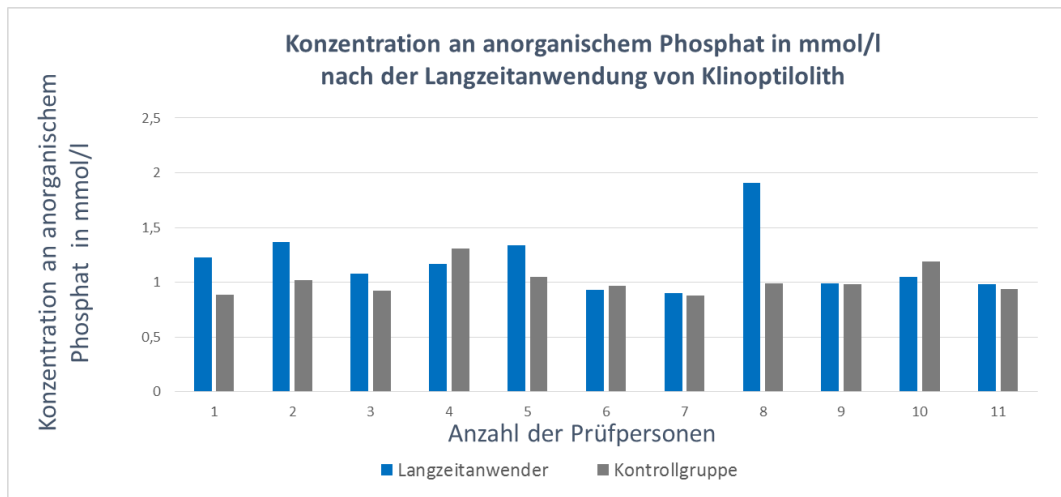
Sodium: 132-145 mmol/l

Potassium: 3.5-5.1 mmol/l

Chloride: 96-110 mmol/l

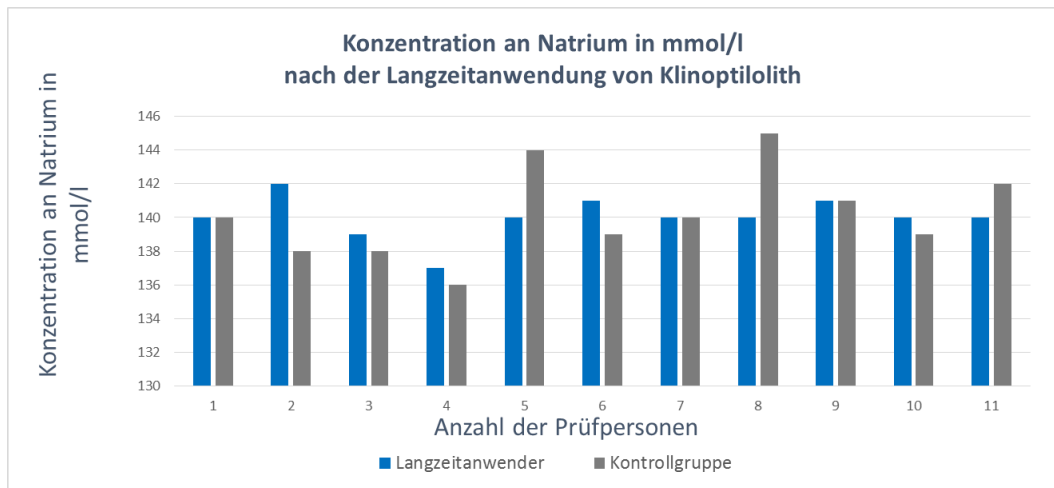
Magnesium: 1.6-2.5 mg/dl

Result: The results prove that the intake of clinoptilolite in long-term users showed no negative mineral status. The obtained data revealed values, which are located in the required range of each element. Therefore, in vivo evidence was provided that products on the basis of clinoptilolite in long-term use have no negative affect on the balance of micronutrients and macronutrients.

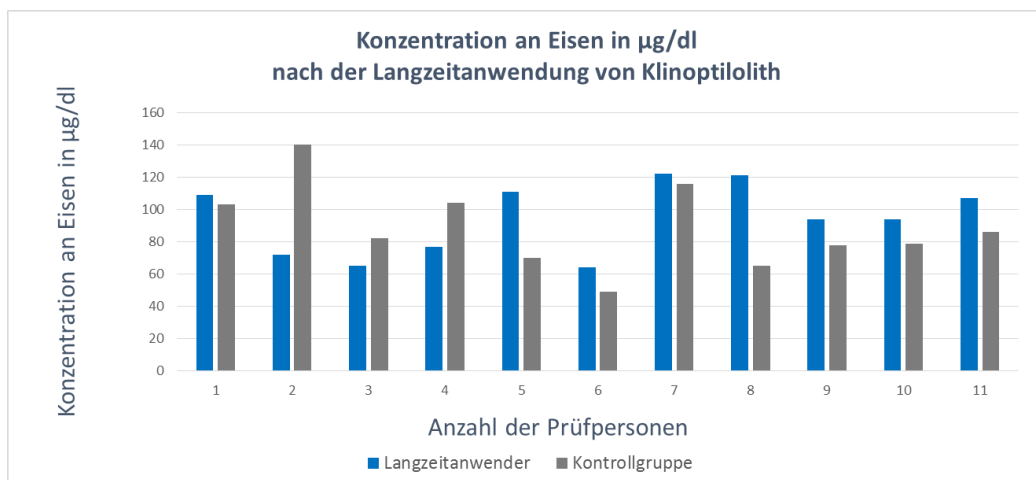


Reference area an-organic phosphate: 0.87-1.45 mmol/l

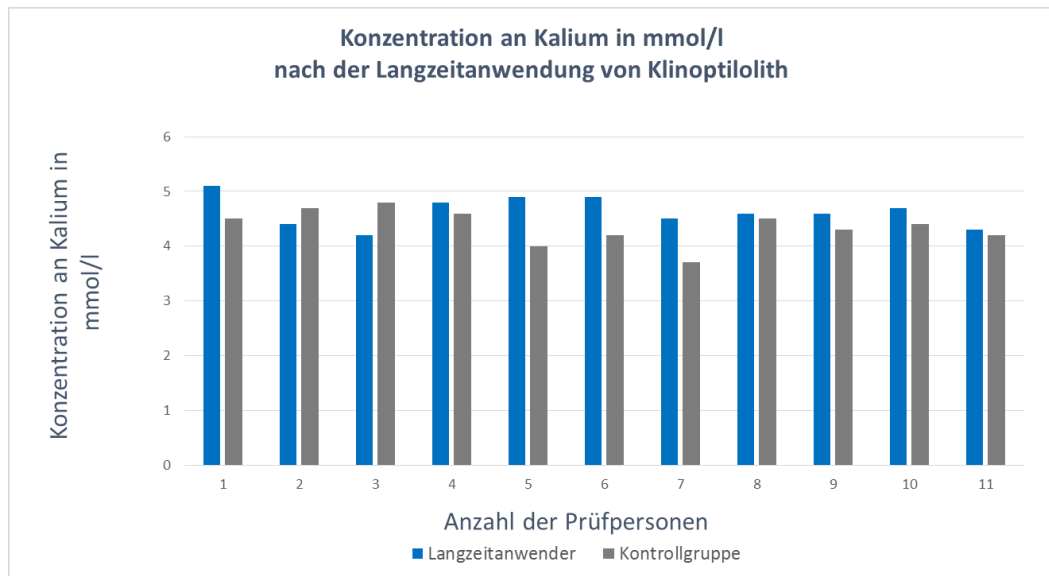
One user was around 0.46mmol/l above the reference value for the an-organic phosphate.



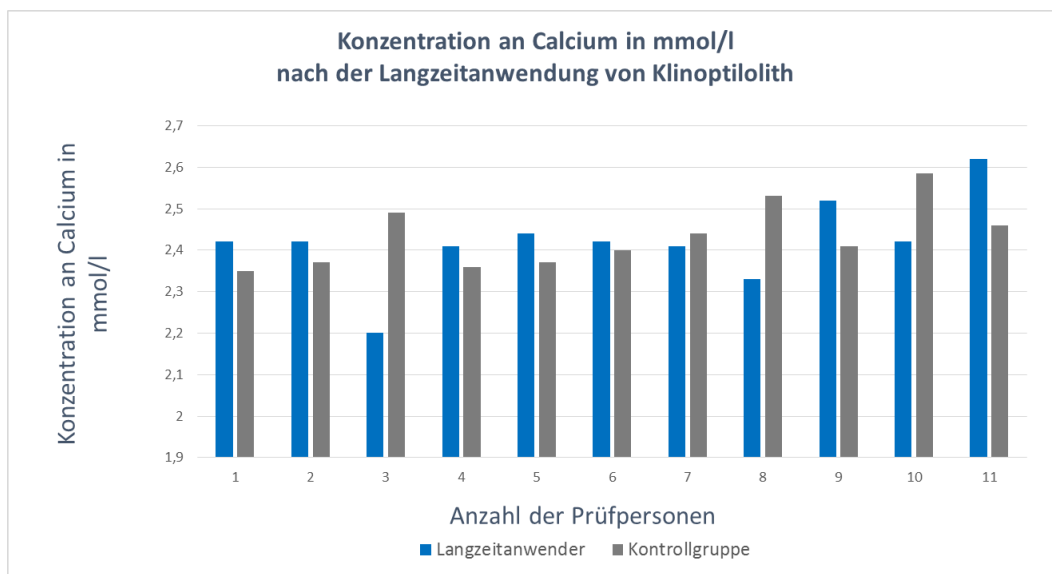
Reference area sodium: 132-145 mmol/l. All users were in the reference area.



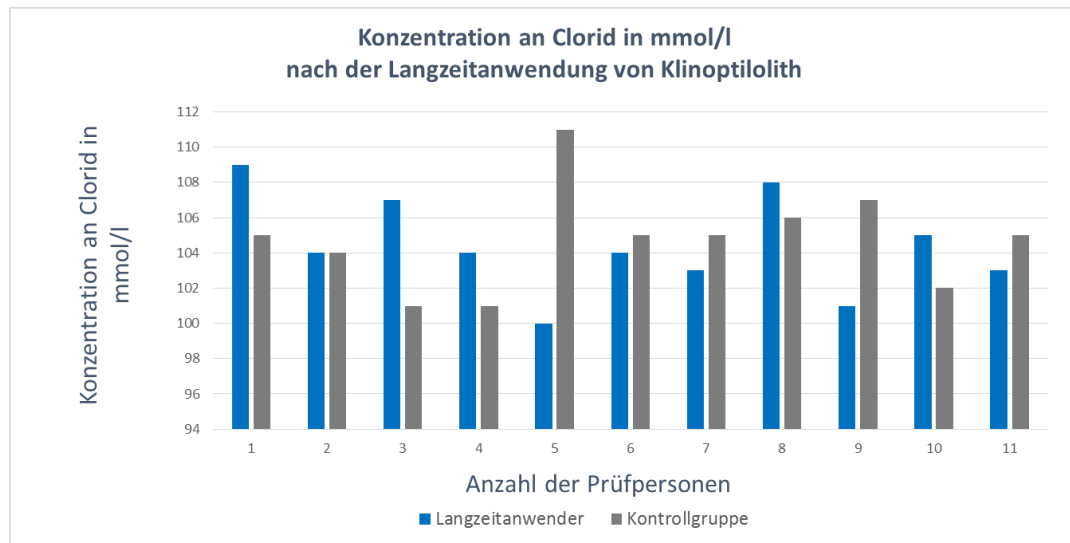
Reference area iron: 33-193 µg/dl. All users were in the reference area.



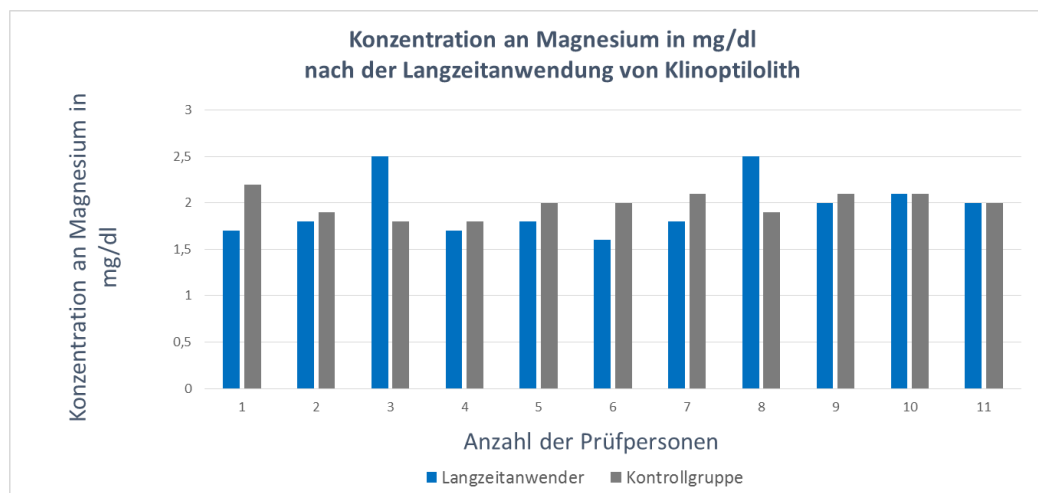
Reference area potassium: 3.5 – 5.1 mmol/l. All users were in the reference area.



Reference area calcium: 2.10 – 2.60 mmol/l. One user was around 0.02mmol/l above the reference area.



Reference area chloride: 96 – 110 mmol/l. All users were in the reference area.



Reference area magnesium: 1.6 – 2.5 mg/dl. All users were in the reference area.

4. Conclusion

The tests show, within their different procedures, that the intake of medical products based on clinoptilolite has no influence on the natural balance of micronutrients.

Schlanstedt, December 2015

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