Report on the Influence of CLINOPTILOLITE and MANC® on the Natural Balance of Micronutrients

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Approval according to guideline 93/42/EWG
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This report was compiled from data gathered from different sources:

1. Literature
2. *In Vitro* studies
3. *In Vivo* studies

The conclusion, based on all the different data, is that taking the Clinoptilolite does not influence the natural balance of micronutrients.

Following are the results from each data gathering:

1. Data obtained from Literature: data was taken from 2 studies.

Study 1: **Tested the influence of Clinoptilolite on Vitamins & Microelements**

The Clinoptilolite was fed to pigs orally.
The balance of vitamins A, D & E were tested, along with a test on the balance of amino acids tryptophan and phenylalanine.
The results showed that the clinoptilolite did not influence the vitamins or the amino acids.

For further information please have a look at the sources: Auerbach, Scott M., Carrado, Kathleen A., Prabir, Dutta K., Handbook of Zeolite Science and Technology, New York: Marcel Dekker, Inc., 2003.

Study 2: **Tested the influence of Clinoptilolite on Vitamins & trace elements in the blood, liver and kidneys**

The Clinoptilolite was fed to sow orally.
The balance of vitamins A & E were tested, along with the balance of the minerals Potassium, Sodium, Phosphorous, Calcium, Magnesium, Copper and Zinc.

The results showed that the clinoptilolite did not have any influence on the vitamins or minerals above and the concentration in the blood, as well as the liver and kidneys showed that it had no influence on the intake and distribution of these vitamins and minerals.

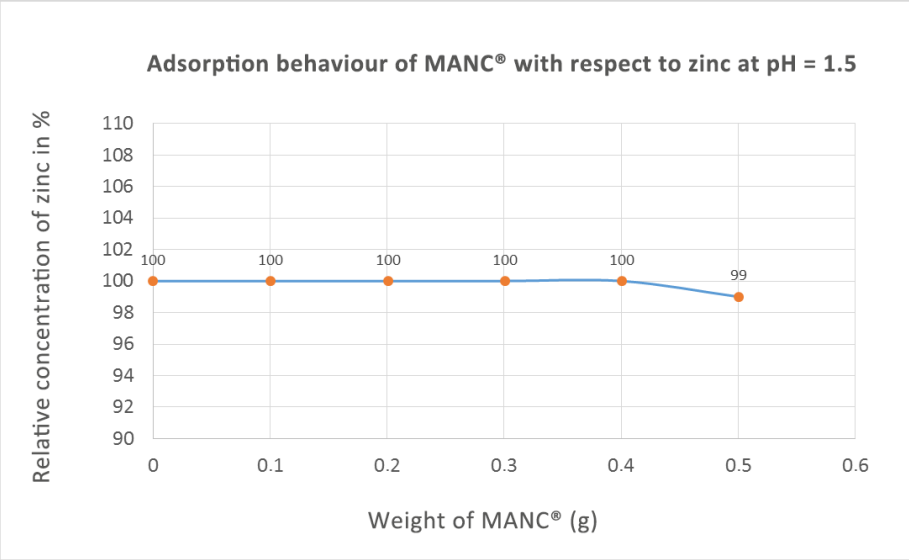
Source: Papaioannou, D. S. et al., (2000): "Effect of in-feed inclusion of a natural zeolite (Clinoptilolite) on certain vitamin, macro and trace element concentrations in the blood, liver and kidney tissues of sows".

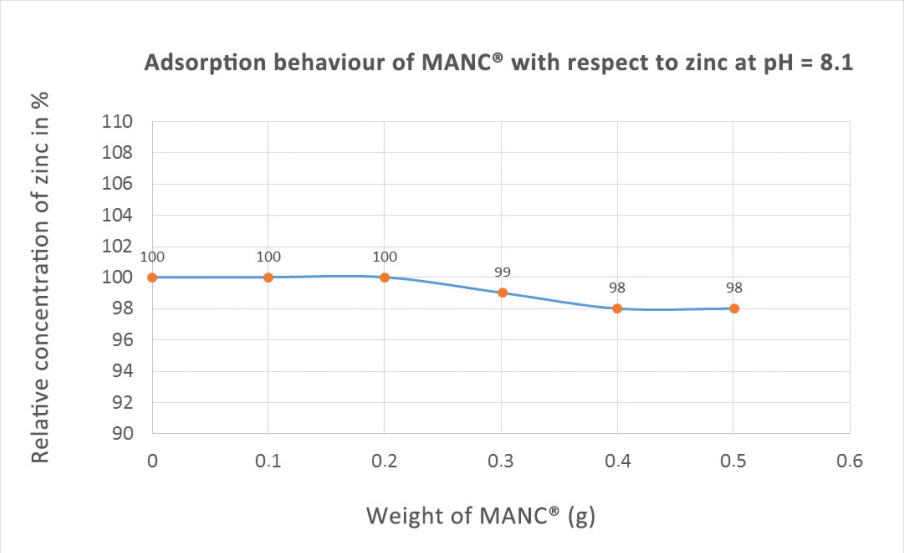
URL: http://www.sciencedirect.com/science?_ob=ArticleListURL&_method=list&_ArticleListID=-903762568&_sort=r&_st=13&view=c&md5=af9cd0c393749bc6d07965767c6bd11a&searchtype=a [Status: 20.12.1999].

2. Data obtained from *In Vitro* studies:

The binding of Zinc with MANC® was tested *in vitro* by simulating an alimentary canal.

The results showed:
At pH of 0.5-1.5, only approx.. 1% of the zinc was absorbed.
At pH of 8.1, only approx.. 1.6% of the zinc was absorbed.
(1% deviation can be attributed to measurement inaccuracy/measurement faults)

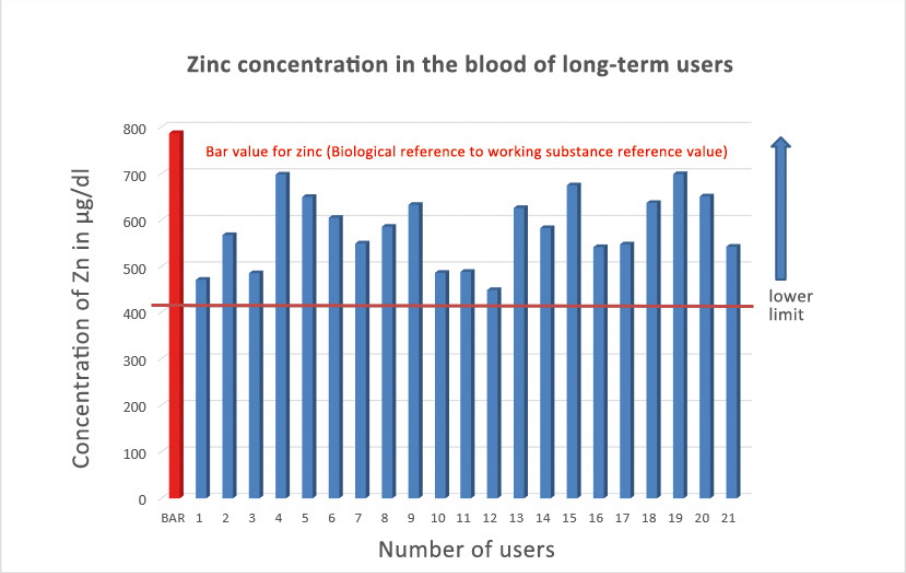




3. Data obtained from *In Vivo* studies:

Study 1: The binding of MANC® in long term use to essential substances such as Zinc was tested *in vivo* with 21 patients. The test was done by giving the patients a minimum of 2g of MANC® per day (either in capsule or powder form) and the concentration of zinc was determined by means of a blood test and compared to biological reference values. The study was conducted over a period of approx. 60 months whilst taking the Toxaprevent MANC® products.
The reference value: BAR reference are 408 - 787µg/dl.

Results: All 21 patients had a zinc level within the reference area. The average Zinc level was 532.45 µg/dl. None of the patients had a level lower than 408µg/dl or higher than 787µg/dl.
Clinical data shows that taking MANC® over a long period of time or a higher dosage does not have a negative influence on the natural balance of Zinc and the results obtained were in the acceptable range, therefore the *in vivo* study showed that the MANC® range of products does not bind to zinc in humans.

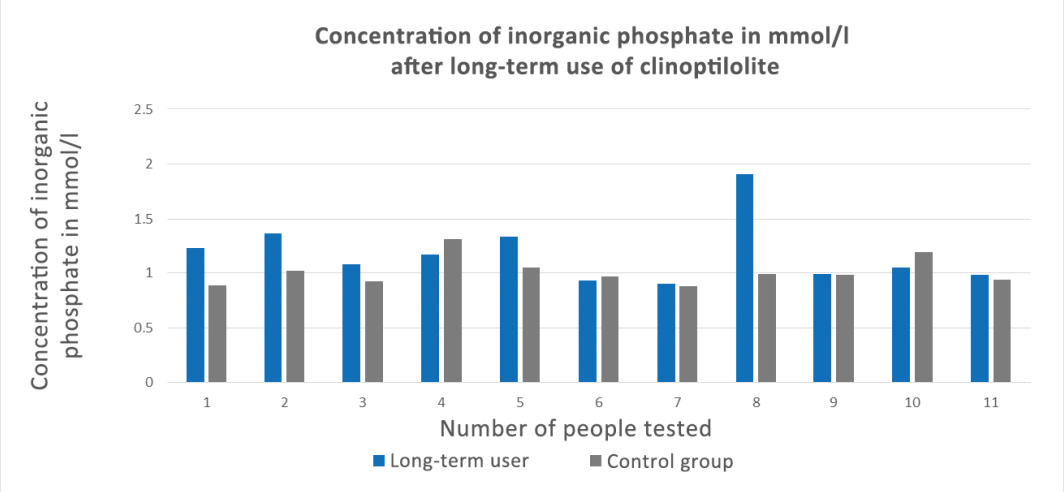


Study 2: The binding of MANC® in long term use to micro and macro elements such as inorganic phosphate, sodium, potassium, calcium, magnesium, chloride.
A minimum of 2g of Clinoptilolite (capsule or powder form) was taken orally each day.
The concentration of the elements listed were checked by means of a blood test in 11 people and compared to a control group of 11 people.

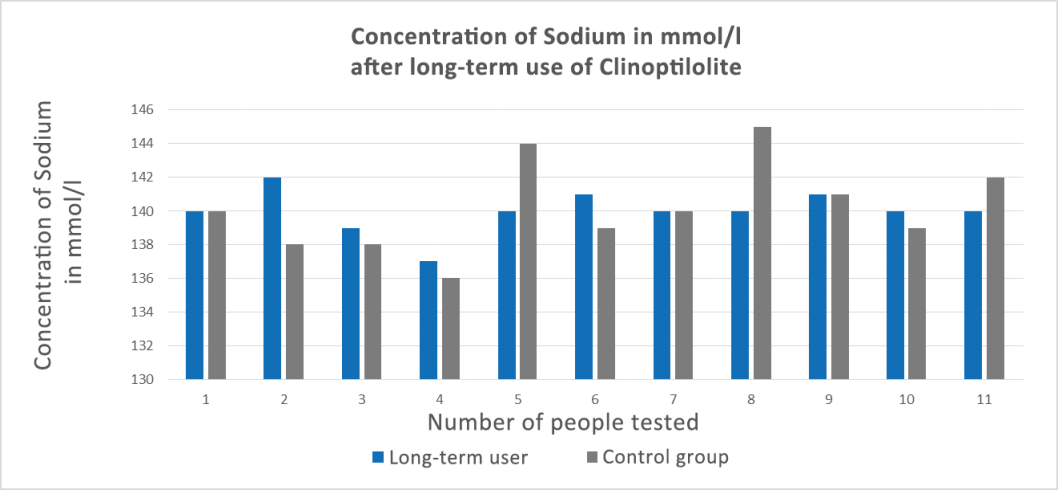
Reference Values:

Inorganic phosphate:	0.87 – 1.45mmol/l
Sodium:	132 – 145mmol/l
Chloride:	96 – 110mmol/l
Calcium:	2.10 – 2.60mmol/l
Potassium:	3.5 – 5.1mmol/l
Magnesium:	1.6 – 2.5mmol/l

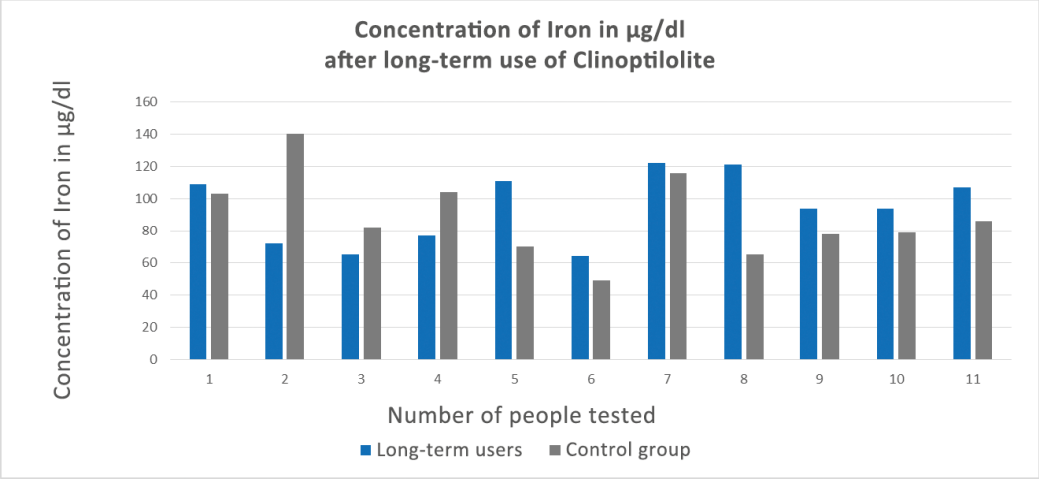
Results: The results showed that the concentration of the tested elements were within the required range in all the subjects in the study.
Therefore, *in vivo* studies have shown that taking clinoptilolite long term does not have a negative effect on the balance of micronutrients and macronutrients.



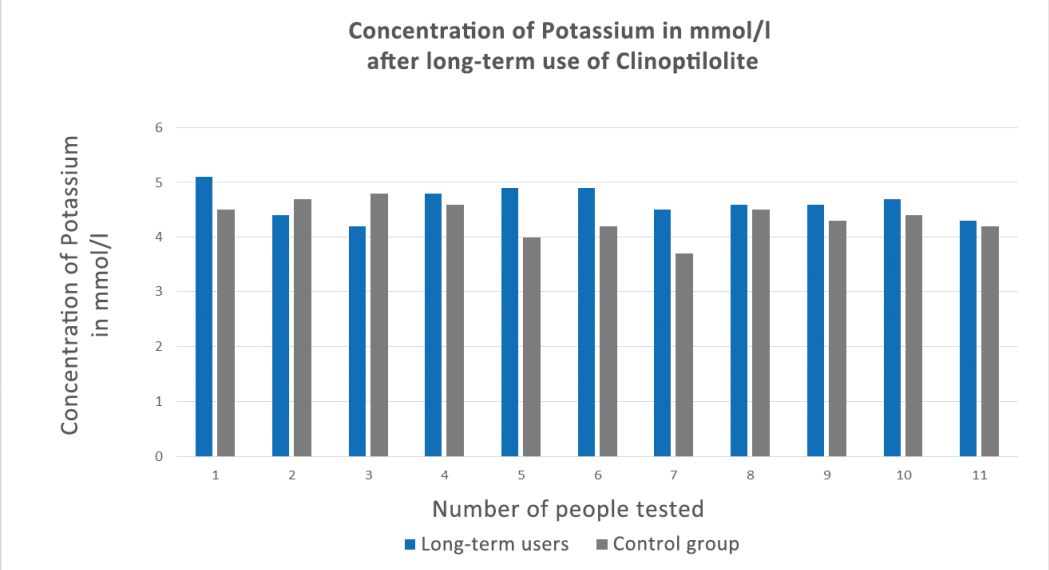
REFERENCE AREA OF INORGANIC PHOSPHATE: 0.87 – 1.45mmol/l
* 1 user was found to be ~0.46mmol/l above the reference area for inorganic phosphate



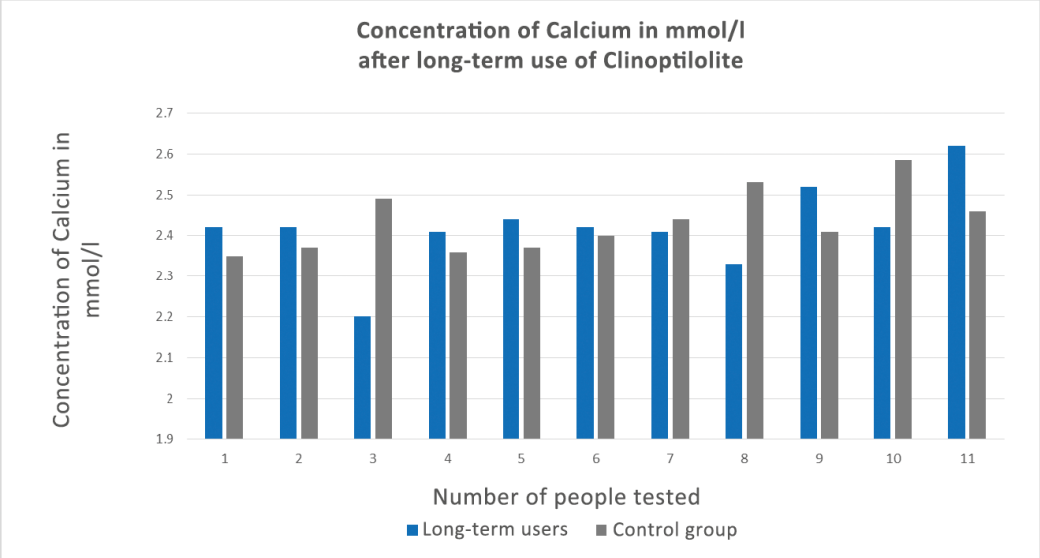
REFERENCE AREA OF SODIUM: 132 – 145 mmol/l
* All users were within the reference area for Sodium



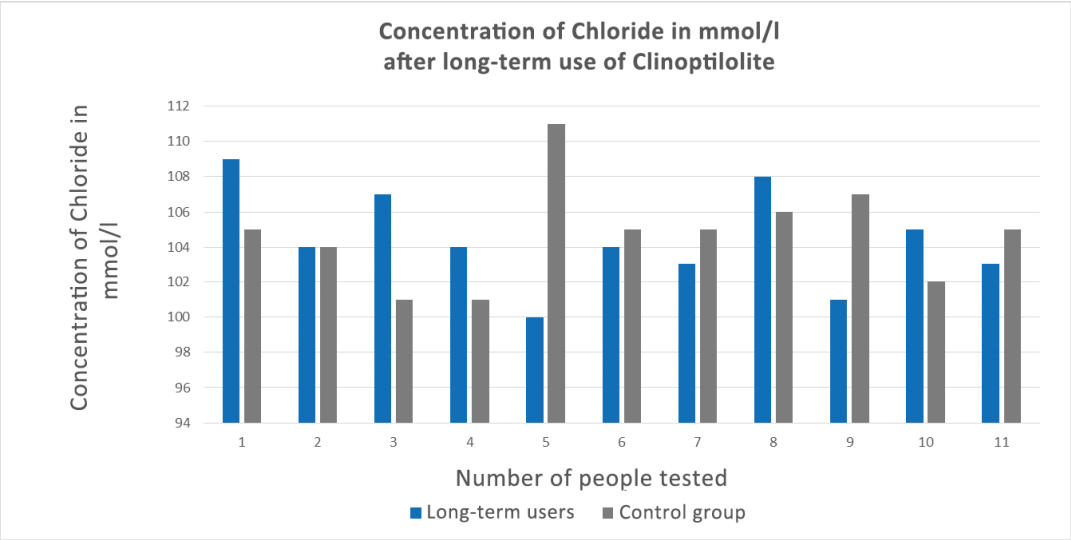
REFERENCE AREA OF IRON: 33 - 193µg/dl
* All users were within the reference area for Iron



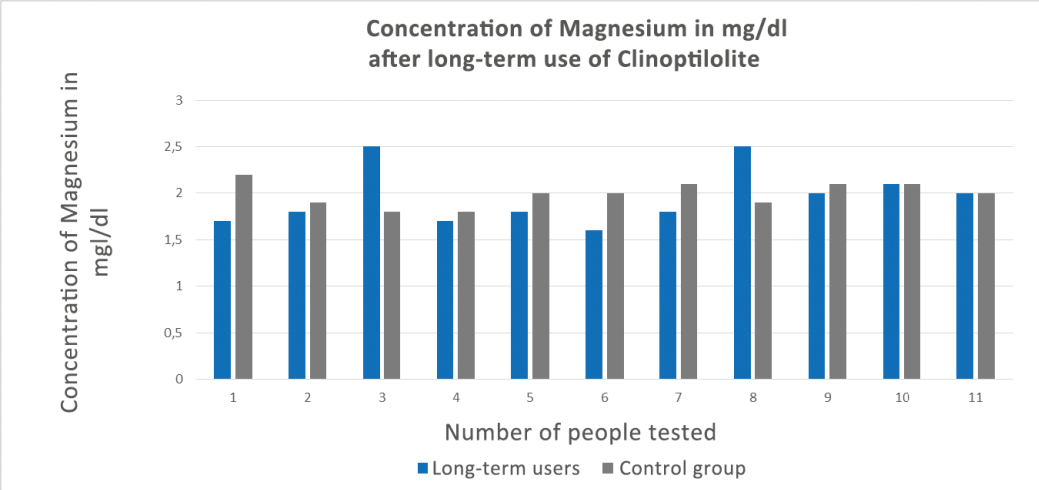
REFERENCE AREA OF POTASSIUM: 3.5 – 5.1 mmol/l
* All users were within the reference area for Potassium



REFERENCE AREA CALCIUM: 2.10 – 2.60 mmol/l.
* One user was around 0.02mmol/l above the reference area.



REFERENCE AREA OF CHLORIDE: 96 - 110 mmol/l
* All users were within the reference area for Chloride



REFERENCE AREA OF MAGNESIUM: 1.6 - 2.5 mg/dl
* All users were within the reference area for Magnesium

4. Conclusion

In conclusion, the results of all the tests and studies show that taking Clinoptilolite in the form of MANC®, does not affect the natural balance of micronutrients.

Schlanstedt, December 2015

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