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## office for risk assessment

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### Opinion of the Director of the Office for Risk Assessment

To the Minister of Health, Welfare and Sport and the Minister of Agriculture, Nature and Food Quality

### Subject

Opinion on Recommendation on chemical contaminants in mineral clay

### Summary

*In recent years the Dutch Food and Consumer Product Safety Authority (VWA) has analysed a number of mineral clay products intended for internal use. These products are various sorts of clay for use by pregnant women and intestinal cleansing clays. The mineral clay products have been analysed for the presence of dioxins and/or (heavy) metals. On the basis of the results, the VWA has carried out further investigations.*

*Using the results of this survey, the Office for Risk Assessment has assessed the health risk for the consumer and unborn children. This has led to the following recommendations:*

- *As all the types of pregnancy clay that were analysed can have negative effects for pregnant mothers and their unborn children, the consumption of this clay is strongly advised against. Given the user market for these products a package of measures is required to effectively ensure that these products are not consumed.*
- *The repeated or long-term use of intestinal cleansing products that contain contaminated clay is advised against. As not all of these products pose a health risk for short-term use, retailers can prevent unnecessary exposure to contaminants by offering the correct choice of products to customers.*

### Introduction

Mineral clay is used internally (orally) by certain groups of consumers. It has two applications: as pregnancy clay and as intestinal cleansing clay. Pregnancy clay is primarily consumed by pregnant women of non-Dutch (Surinamese or African) origin suffering from nausea during the first months of their pregnancy [1]. The composition of pregnancy clay is not clearly defined: it can be a mixture of chalk, clay, mud and/or ash.

The product is known by many names, including calabash chalk, white clay, mabele, pimba, etc. The products sold in the Netherlands are imported from abroad. In recent years the sale of these products from stores (particularly ethnic grocery stores or *tokos*) has fallen considerably, but it is not known if the amount of products purchased through other channels has also fallen. There are no European and national product standards for the presence of (heavy) metals or dioxins in pregnancy clay.

Intestinal cleansing clays are used by people wishing to rid their bodies of waste and toxins. This often occurs by following a cleansing course of several weeks. The range of intestinal cleansing clays is limited and they are only sold at health food stores or offered via the internet. It is not known if these products are also consumed by children. The cleansing agents are considered food supplements, and since 1 July 2009 have been subject to product standards for cadmium, mercury and lead [2]. In recent years the VWA has analysed various clay products for the presence of dioxins and/or metals. Based on these findings, the VWA then carried out a survey at *tokos* and health food stores. The levels of dioxins and heavy metals that were detected in these clay products were deemed to pose a risk to the consumer.

### **Questions**

The VWA has analysed 16 types of mineral clays intended for internal use for the presence of (heavy) metals, dioxins, and dioxin-like PCBs. The primary objective was to assess the health risk to the consumer of taking these products orally. The possibility of determining the origins of these products was also assessed as on this basis possible conclusions could then be established as to the nature of the contaminant and the safety of the product.

The Office for Risk Assessment posed the following questions:

1. What is the health risk to a pregnant woman and her unborn child associated with the use of the different types of pregnancy clay?
2. What is the health risk to the consumer (adults and children) associated with the use of cleansing agents containing mineral clay?
3. Can anything be established about the possible origin of the mineral clay based on the congener pattern of the dioxins?
4. Can anything be established about the possible origin of the mineral clay based on the pattern of the various metals?

### **Approach**

The Front Office of RIVM-RIKILT (the Institute of Food Safety and the Institute for Public Health and the Environment) was brought in to perform the risk assessment for the chemical substances (dioxins, dioxin-like PCBs and 9 heavy metals). The recommendation of the Office for Risk Assessment is based on the report of the Front Office [3] and earlier risk assessments of cleansing agents.

Two experts from the Office for Risk Assessment, who were not involved in the assessment, were asked to provide an independent critical appraisal of the recommendation.

### **Points of departure for the risk assessment**

#### *Health standards*

When determining the risk of exposure to the chemical substances detected in the mineral clay, both long-term and short-term exposure were considered.

To determine the harmful effects of a chemical substance on the health of a consumer, health standards are applied that are defined as the maximum tolerable single intake of the substance in question or the maximum tolerable daily or weekly intake during a longer period of the substance in question.

It is assumed that negative health effects of a substance cannot be excluded when the health standard in question is exceeded.

#### *Analysis*

The VWA analysed the types of mineral clay for the presence of the following metals: aluminium, chrome, iron, copper, zinc, arsenic, cadmium, mercury and lead. The clay samples were also analysed for the presence of dioxins and dioxin-like PCBs. For all the metals, the total content was determined irrespective of the form in which it can be present.

#### *Worst-case scenarios*

For mineral clay products, the degree to which (heavy) metals and dioxins are released into the stomach and intestine and subsequently absorbed by the body (the bioavailability) is not known. As a worst-case scenario it

was assumed that the bioavailability of the compounds present in the clay is similar to the bioavailability of the form that was used in animal tests to determine the health standards.

The total content was determined for each of the metals; for the metals chrome, arsenic and mercury, it was not known in which form (valence, organic/inorganic) they are present. As a result, the worst-case approach for the risk assessment assumes that all metals and dioxins were present in the form that is most harmful.

## **Risk Assessment**

### *Pregnancy clay*

In five of the nine clay products (all five of which were *Mabele* clay) the dioxin concentration was so high that long-term exposure at the indicated dosage can exceed the health standards 20 to 30 fold. When this clay is used daily over a period of several months health risks for pregnant women and their unborn children cannot be excluded. Following birth, children can suffer negative health effects (such as reduced quality of sperm in male offspring).

Negative health effects caused by short-term exposure to high concentrations of arsenic in four of the nine samples of clay analysed can also not be excluded. Furthermore, in five of the nine clay samples levels of aluminium and iron were detected that exceed health standards by over ten times. The bioavailability for these metals is likely to be much lower than in the worst-case scenario assumed by the RIVM-RIKILT Front Office [4, 5], which means a considerable overestimation of exposure. Through long-term use all products can cause negative effects such as exposure to cadmium, chrome, mercury and lead. Particularly metals such as aluminium, mercury and lead can have a negative effect on the mental development of the child. For an overview of all the possible negative effects caused by short and long-term exposure the reader is referred to the assessment performed by the RIVM-RIKILT Front Office [3].

### *Intestinal cleansing clays*

Two out of seven intestinal cleansing clays contain detectable amounts of dioxins. A course of treatment over several weeks using products contaminated with dioxins can lead to an exceedence of the dioxin health standard by 20%. Following several courses of treatment over a year, the total body burden for dioxins can increase slightly. This is an undesirable situation, even though it is unlikely to lead to direct negative health effects.

The levels of most heavy metals present in the cleansing clay are lower than in the pregnancy clay, and the daily intake is also lower. Negative health effects caused by exposure to aluminium cannot be excluded for short-term use of four of the seven products. All the cleansing clays contain such high concentrations of iron that intake of this clay can lead to an exceedence of the health standard. However, once again, the bioavailability for aluminium and iron is likely to be much lower than in the worst-case scenario assumed by the RIVM-RIKILT Front Office.

The intake could still result in possible negative effects for children in the event of a short-term exposure to arsenic (for four of the seven products).

Adults and children who use these products repeatedly and on a long-term basis can in addition suffer negative effects through exposure to arsenic, cadmium, chrome, mercury and lead (for three to five of the seven products).

### *Origin*

In the Netherlands, dioxins have previously been detected in kaolinite, a mineral clay used in animal feed. Only two intestinal cleansing clays contain dioxins and they have a congener pattern that resembles the kaolinite from the Eifel region in Germany. The congener pattern of the pregnancy clay with high levels of dioxins (*Mabele* clay) does not resemble the mineral clay from the Eifel. Based on the current analysis of metals, it is not possible to clearly define the origin of the mineral clay. The composition of the mineral clay is geographically determined, but human activities (soil use, pollution, etc.) can also affect the composition. If good reference material is obtained, the origin can be further investigated with the help of other chemical analyses.

## **Conclusions**

Based on the risk assessment the conclusions can be divided into two sections: health risks, related to pregnancy clays and intestinal cleansing clays, and the possible origin of these types of clay.

### *Health risks*

The consumption of all the pregnancy clays that were studied can have negative effects on mothers and their unborn children when used over a period of several months. Negative effects caused by short-term exposure to metals can also not be excluded for four to five of the nine products.

Negative health effects for adults and children cannot be excluded through long-term or repeated treatment courses with intestinal cleansing products. Short-term use of certain types of cleansing clays that contain low levels of contaminants are not expected to pose any health risk.

### *Origin*

The congener patterns of dioxins and (heavy) metals do not provide a clear indication of the origin of the various types of clay. Two of the seven intestinal cleansing clays contain dioxins, with a congener pattern that resembles kaolinite for the Eifel region in Germany. Based on the current analysis of metals it is not possible to clearly define the origin of the mineral clay.

## **Recommendations**

Based on the assessment the following measures can be considered.

### *Pregnancy clay*

As all the types of clay that were analysed can have negative effects on the mother and unborn child, the consumption of this clay is strongly advised against. As this type of clay does not come from the Netherlands, is primarily used by pregnant women of non-Dutch origin and is sold through retail outlets in limited quantities, consumption can only be reduced by introducing a package of measures:

- Warning the target group through leaflets.
- Prohibiting the import of pregnancy clay.
- Continuing to monitor the limited supply at ethnic grocery stores (*tokos*).

### *Intestinal cleansing clay*

- Long-term or repeated treatment courses involving some of these products are advised against. There are intestinal cleansing clays on the market that pose little or no risk to consumers in the event of short-term use.
- The VWA can bring this matter to the attention of the retail trade.

Due to the fact that the use of these sorts of clay occurs, and is more prevalent in other countries I have decided to translate this recommendation into English and submit it to the European Food Safety Authority (EFSA) and the World Health Organisation (WHO).

Yours sincerely,

Professor E.G. Schouten  
Director, Office for Risk Assessment

## **Appendix**

- Report by RIVM-RIKILT Front Office 'Risk assessment concerning dioxins and heavy metals in clay products for human consumption', 2009.

## References

1. Schuttelaar & Partners. 2003. Dutch Ministry of Health, Welfare and Sport, Calabash chalk in the Netherlands (in Dutch).
2. Commission Regulation (EC) No. 629/2008 amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs.
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4. Abrahams PW, Follansbee MH, Hunt A, Smith B, Wragg J. Iron nutrition and possible lead toxicity: An appraisal of geophagy undertaken by pregnant women of UK Asian communities. *Applied Geochemistry*. 2006; 21(1): 98-108.
5. Dean JR, Deary ME, Gbafa BK, Scott WC. Characterisation and analysis of persistent organic pollutants and major, minor and trace elements in Calabash chalk. *Chemosphere*. 2004; 57(1): 21-25.