

Project #21010B

**Food Safety Certificate for the Product
for the Cleaning of Natural and Artificial Stone Surfaces with Food Contact
AKEMI® Natural Stone Basic Cleaner**

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Important Abbreviations

ADI	Acceptable Daily Intake, see IPCS Document RISK ASSESSMENT TERMINOLOGY
bw	body weight
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
DNEL	Derived No effect Level
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
F	Modifying Factor
MoS	Margin of Safety
NO(A)EL	No Observed (Adverse) Effect Level
pADI	provisional Acceptable Daily Intake, proposed by the author, legally not binding

1 Objectives

The following certificate covers the safety of food, which has been prepared or placed on kitchen countertops being cleaned according to the use instructions with the product "AKEMI® Natural Stone Basic Cleaner".

Any issues with regard to worker safety, hazardous substance legislation, technical safety for users (e.g. also with regard to dermal exposure), regulatory affairs, labelling and efficacy are not the subject of this document.

2 Product Description

The use of the evaluated product is described by the sponsor by:

- AKEMI® Natural Stone Basic Cleaner is suited for a fast and thorough cleaning of kitchen worktops, counter tops and other small surfaces made of natural and artificial stone, e.g. marble, travertine, slate, granite, bricks and cotto slaps, tiles, fair-faced concrete and similar materials. It removes residues of food, slight traces of oil and grease as well as slight layers of stone care products and wax.

According to the product claims, the product to be evaluated may be used for cleaning of surfaces, on which food will be prepared or is supposed to be prepared.

3 Intended Application

The application to be evaluated is described by the sponsor by:

1. Spray AKEMI® Natural Stone Basic Cleaner evenly on the surface to be treated.
2. Spread with a humid cloth and allow it to work for a short period of time.
3. Take off the dirt with a humid cloth and wipe the surface well with a lint-free cloth until the surface is free of streaks.
4. For stubborn dirt repeat the procedure and allow AKEMI® Natural Stone Basic Cleaner to work for a longer period of time. If necessary, scrub the surface with a brush.

This document is intended solely for the purpose of consumer safety and the prevention of potential health hazards by consumption of food after having had contact with surfaces which had been cleaned with this product according to the use instructions (indirect oral uptake).

The product is used in professional and in private surrounding.

4 Methodology of the Toxicological Risk Evaluation

According to the definition in § 2 (6) No 7 of the LFGB - German Food, Consumer Goods and Feed Code - of 03/06/2013 (LFGB: "Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch": German Federal Law Gazette No 27 of 10/06/2013, page 1426) household cleaning products may be classified as consumer articles.

For such articles the above-mentioned Food, Consumer Goods and Feed Code states in § 30:

- "Consumer articles must not be produced if they, when used for their intended or foreseeable purpose, are able to impair health due to their composition, in particular due to toxicologically active substances or impurities" (quotation, translated from § 30 No 1 German Food, Consumer Goods and Feed Code)
- "Products are not allowed to be placed on the market if they, when used for their intended or foreseeable purpose, are able to impair health due to their composition, in particular due to toxicologically active substances or impurities" (quotation, translated from § 30 No 2 German Food, Consumer Goods and Feed Code).

In this document shall not be discussed, if these requirements have to be fulfilled from the formal or legal point of view, but they provide an acceptable general description of the aim of a toxicological risk assessment for cleaning products. Since they do not provide a methodology for a toxicological risk assessment in a precise manner, the algorithm of such an evaluation should be defined here:

Water is declared as safe without further considerations.

As next step has to be evaluated, if the formulation contains substances of high concern, which may pose a risk, if they may migrate from the cleaned surfaces to foodstuff. This means especially substances, which are classified as carcinogenic, mutagenic, or toxic to reproduction according to the CLP-Regulation 1272/2008 based on the safety data sheets. If the final product contains such a substance in a concentration, which leads to a classification of the formulation, the product is considered to be not suitable for cleaning of surfaces with food contact.

Any ingredient of the cleaning product, which comprises substances, which are used as food, or known as ingredients of food or are allowed as food additives in Europe or the USA or can be used as processing aids for food production is considered as safe without further evaluation.

Substances, being used as ingredients in cosmetic products for the application on human body like in mouthwash products in similar concentrations which are evaluated as safe, are also considered to be safe for the use in the evaluated product.

Regarding all other ingredients it is also taken into account, if only technically unavoidable residues may remain on the cleaned surface. Such residues are classified as acceptable, if an exposure scenario demonstrates, that the exposure is of no toxicological concern.

In any case for all ingredients with the exception of water, components of food stuff or fragrances a calculation of an pADI based on publicly available toxicological data is carried out.

The general formula to calculate the pADI-value is:

$$pADI = \frac{PoD}{F1 \times F2} \quad \text{formula (1)}$$

- PoD is the Point of Departure, which means the NOAEL of an animal study or also other published thresholds like an ADI from EFSA or a DNEL from ECHA.
- F1 is an assessment factor for the extrapolation of animal studies to human.
- F2 is an assessment factor for the consideration of the intraspecies variability within human populations.
- As default values for F1 and F2 EFSA recommends 10, if the PoD is a NOAEL from animal studies. This leads to a standard overall assessment factor of 100. (EFSA 2012)
- The application of the default values for the toxicological risk assessment for food is considered to be appropriate due to the use pattern and the claim of the evaluated product.

Now the exposure is calculated for the target group of the product considering the typical use pattern. For the input parameters, which are not provided by the sponsor (like the body weight of the consumer), default values from accepted guidelines will be used.

The calculated exposure has to be compared with the pADI by the calculation of the MoS (Margin of Safety):

$$MoS = pADI / \text{Exposure}$$

If the pADI is higher than the calculated exposure ($MoS > 1$), the health risk from the evaluated substance can be classified as negligible even for a daily uptake over the whole lifetime, whereas if the pADI is exceeded, a relevant risk for the target group (consumers) cannot be excluded. It has to be emphasized, that this does not mean, that an exposure, which exceeds the ADI must lead to adverse effects on human health.

The final step of the risk evaluation is an overall assessment based on the above described steps.

If these steps do not indicate a health risk for the consumers, who do eat foodstuff, which had been prepared or laid down on the cleaned surfaces, the evaluated product will be classified as safe.

5 Exposure Considerations

The exposure assessment was carried out based on theoretical assumptions, because measured data are not available.

It has to be emphasized, that in the data base CONSEXPO 5 and the respective „factsheets“, which are typically used for such exposure assessments in Europe the exact scenario, which is to be evaluated here, is not depicted. (Meesters JAJ 2018)

Only the application of all purpose cleaners on floors and the oral uptake by toddlers is described.

But in this exposure scenario is assumed, that the surface remains wet, which is equivalent to 40 mL water per m².

Here about 30% are considered available for an oral uptake by toddlers. That would be about 40 g/m² x 0.3 = 12 g/m² or 1.2 mg/cm².

But since the after the cleaning procedure with the evaluated product the surface is rubbed off with a cloth, this amount is not realistic, because the consumer will rub off the surface until it is more or less dry.

Consequently, a dish wash scenario is considered more appropriate. Here also a cleaner is applied on ceramic or stone like surfaces and afterwards is dried with a cloth. In this scenario residues of 5.5 x 10⁻⁵ mL/ cm² on the dishes are published in the CONSEXPO factsheets. (Meesters JAJ 2018)

This figure is used as input parameter for the exposure assessment. Additionally, the standard parameters from Article 17 of Regulation (EU) 10/2011 for Food Contact Materials was applied. According to this article, the ratio of surface to packed food stuff is 6 cm² per kg food. Further, an uptake of 1 kg food per person per day is stated as standard input parameter for the exposure scenarios for food contact material.

Based on these considerations input parameters of the exposure were stated according to Table 1.

Table 1: Input parameters of the exposure scenario

Parameter	Value	Dimension	Reference
Residuals on the surface	0,000055	ml/cm ²	(Meesters JAJ 2018)
Contact area	600	cm ²	Regulation (EU) 10/2011
Daily uptake of food per person	1	kg/person x d	Regulation (EU) 10/2011
Ratio Food/Food Contact Material	1 kg per 600 cm ²		Regulation (EU) 10/2011
Daily Uptake of cleaner	0.033	ml/day	0.000055 ml/cm ² x 600 cm ²
Density	1,4	g/ml	Assumption by the assessor
Daily Uptake of cleaner	0.0462	g	0,033 ml/day x 1.4 g/ml
Daily Uptake of cleaner	46.2	mg	Calculation
Body weight	60	kg	EFSA, female adult

The derivation of substance specific comparison pADIs and the comparison of the pADIs with the exposure values as such are confidential, but the MoS (Margin of Safety) can be disclosed.

The exposure assessment led to MoS values between 3.6 and 486.97. These exceed the minimum required MOS of 1 clearly, the exposure is classified as acceptable regarding the adverse effects on human health, provided, that the input parameters are not exceeded in the real exposure by the user of the product. It is in the responsibility of the user of the product to check this prerequisite.

6 Results of the Assessment

Details regarding the formulation, which are used for the assessment and the exposure assessment cannot be laid down in this document, since they contain confidential business information.

As overall conclusion can be stated, that the toxicological risk for consumers from food can be stated as negligible, if the evaluated product is applied according to the use instructions.

7 Conclusion

Based on prerequisites from chapter 1, the product description from chapter 2, the outcome of the evaluation according to the methodology as described in chapter 4, can be stated, that

AKEMI® Natural Stone Basic Cleaner

is considered to be safe for the cleaning of natural and artificial stone surfaces with food contact.

8 Validity

This certificate is valid as long as no significant changes, i.e. the technical instructions for use and any quantitative and/or qualitative changes in the formulation, are made.

A re-evaluation of a product is required when significant safety-related complaints are made arising from its use.

Also newly generated and sound scientific data on any of the raw materials may warrant a re-evaluation of this assessment.

9 Approval

Lothar Fruth

Specialist Pharmacist for Toxicology and Ecology

Publicly Certified and Authorized Expert for Toxicological Risk Assessments (IHK Hannover)



28/05/2021 *LF*

Date, signature

10 References

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- Meesters JAJ NM, Schuur AG, te Biesebeek JD (2018): Cleaning Products Fact Sheet : Default parameters for estimating consumer exposure - Updated version 2018, RIVM Rapport 2016-0179, published by: RIVM National Institute for Public Health and the Environment, P.O. Box 1 | 3720 BA Bilthoven The Netherlands, <https://www.rivm.nl/dsresource?objectid=28df5b49-e128-42df-9e7a-c6637f4a6382&type=pdf&disposition=inline>, 2018, available at: <https://www.rivm.nl/dsresource?objectid=28df5b49-e128-42df-9e7a-c6637f4a6382&type=pdf&disposition=inline>