

Lothar Fruth

Pharmacist

Specialist Pharmacist for Toxicology and Ecology
Publicly Certified and Authorized Expert for
Toxicological Risk Assessments (IHK Hanover)



Toxicology Expert Services Fruth

An der Feldscheide 1

D-37083 Göttingen

Germany

Phone +49 (0) 551/379 10 46

Fax + 49 (0) 551/379 11 47

E-mail: info@tox-expert.de

Food Safety Certificate for the Products

„AKEMI® Akepox 5000“
„AKEMI® Akepox 5010“
„AKEMI® Akepox 5010 Coloured“

for the Bonding of Natural and Artificial Stone Surfaces with Food Contact

Version final 01 dated December 4, 2018

Report: TESH #18048

Sponsor: AKEMI® chemisch technische Spezialfabrik GmbH
Lechstr. 28
D-90451 Nürnberg
Germany

1 Objectives

The following certificate covers the safety of food, which has been prepared or placed on kitchen countertops being bonded with these products. The essential prerequisite for the validity of this certificate is, that the product has been applied according to the use instructions, is totally cured and that bonded surfaces have been ventilated afterwards for several days before food contact.

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

2 Product Description

According to the product claims, the product to be evaluated is going to be used for bonding of surfaces such as kitchen countertops; in other words, surfaces on which food will be prepared or is supposed to be prepared.

This document is intended solely for the purpose of consumer safety and the prevention of potential health hazards by consumption of food prepared on kitchen countertops which had been bonded with this product.

3 Methodology of the Safety Evaluation

The phrase "food safety" is understood as an attribute of a product as laid down in Article 3(1) of the Directive 2001/95/EC:

"Producers shall be obliged to place only safe products on the market."

Regarding materials with food contact, this more general wording is specified in Article 3 (1) of the Regulation (EC) 1935/2004, which is providing:

"Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health; or

(b) bring about an unacceptable change in the composition of the food; or

(c) bring about a deterioration in the organoleptic characteristics thereof."

To check if these obligations are fulfilled, an evaluation has been carried out, which included different steps:

1. Check of the final product to be evaluated with respect to substances of very high concern (substances being classified as mutagenic, toxic to reproduction or carcinogenic, cat. 1A or 1B according to the CLP-Regulation 1272/2008) based on the provided Safety Data Sheets.

2. Identification of potentially critically substances according to the Regulation (EC) 10/2011, if applicable. Substances were classified as potentially critically in this context, if a SML was stated in the Regulation (EC) 10/2011. Step 1 and 2 were used for the design of the migration study as of step 3.
3. Migration studies based on the outcome of step 1 and 2 and on the reasonably foreseeable exposure scenario.
4. Tests regarding taste and odor.
5. Evaluation of the study results. If the study results are in line with the requirements for food contact material, it can be assumed, that the above cited article of the Regulation (EC) 1935/2004 is fulfilled and the product to be evaluated is classified as safe for food contact under the conditions of chapter 1.

4 Results of the Assessment and the Analytical Study

Details regarding the formulation, which are used for the assessment and the design of the analytical study cannot be laid down in this document, since it contains confidential business information.

The check for substances of very high concern did not lead to findings of concern.

Due to reasons of business secrets, the details of the analytical report are not published in this document.

They are available at the sponsor in the document:

- Wessling GmbH; Oststraße 7, 48341 Altenberge, Germany: Report #18-130868-3hve, 05/11/2018

The results of the studies are in line with the respective standards, findings of toxicological concern were not stated.

5 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 3, and the results of the conducted study (see chapter 4), can be stated, that

„AKEMI® Akepox 5000“
„AKEMI® Akepox 5010“
„AKEMI® Akepox 5010 Coloured“

are assessed to be safe for the bonding of natural and artificial stone surfaces with food contact.

6 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.

7 Approval

Author

Lothar Fruth

4/12/2018



Date, signature

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

