

**Dr. Joachim Haselbach**  
Publicly Certified and Authorized Expert  
for Toxicology of Cosmetics and Consumer Articles  
Attested by the Chamber of Commerce of „Mittlerer Niederrhein“  
Expert Toxicologist („Fachtoxikologe“) DGPT/Eurotox Registered Toxicologist (ERT)

Hülser Str. 283  
D-47803 Krefeld

Telefon: +49 (0) 2151 7842563

Telefax +49 (0) 2151 7842565

Mobile: +49 (0) 173 9635387

E-mail: [joachim.haselbach@tox-consult.de](mailto:joachim.haselbach@tox-consult.de)

Internet: [www.tox-consult.de](http://www.tox-consult.de)

**Evaluation of the Human Toxicological Safety of the Product  
"AKEMI® Farbtonvertiefer Super" (AKEMI® Darkener Super)  
Used for the Treatment of Natural and Artificial Stone Surfaces  
with Food Contact**

**Commissioned by:** AKEMI Chemisch Technische Spezialfabrik GmbH  
Lechstr. 28  
D-90451 Nürnberg

**Contact:** Mr. Dieter Zimmermann: [D.Zimmermann@akemi.de](mailto:D.Zimmermann@akemi.de)  
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### **Preliminary Remarks:**

In this opinion, "human toxicological safety for treatment of natural and artificial stone surfaces with food contact" is understood as an attribute of a product that allows for the safe commercialisation, i.e. placing on the market (see Article 3(1), (2) and (3) with regard to Article 2b of the Directive 2001/95/EC of the European Parliament and the Council of 03/12/2001 on General Product Safety (L 11, Official Journal of the European Communities of 15/01/2002, page 4: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:011:0004:0017:EN:PDF>).

The relevant requirement for producers is accordingly generalized in the following (*quotation*):  
*"Producers shall be obliged to place only safe products on the market."*

For certain products there are additional, specific requirements to be considered with regard to safety when placing a product on the market (see section below "Legal Requirements").

The following evaluation is solely for the safety of consumers in order to prevent health hazards when eating foods that have, for example, been prepared or placed on kitchen countertops that, according to the instructions, have been treated with the product "AKEMI® Farbtonvertiefer Super" (AKEMI® Darkener Super).

Here, it is understood that the product has been totally cured according to the usage guidelines in the instructions and that treated surfaces have been ventilated afterwards for several days.

The issues of work 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 human toxicological evaluation.

### **Product Description:**

According to the product claims, the issue at hand is "AKEMI® Farbtonvertiefer Super" (AKEMI® Darkener Super), a product used to treat surfaces such as kitchen countertops; in other words, surfaces on which food is prepared (or supposed to be prepared).

This evaluation is intended solely for the purpose of consumer safety and the prevention of health hazards for consumers if they eat foods that have been placed on or prepared on kitchen countertops on which the product has been applied and cured.

This ready for use product is sold in standardized one-litre and five-litre containers. It is used undiluted. The target group for use is commercial and private consumers.

Due to the confidentiality of information, the qualitative and quantitative composition of the product and the documents on the "Human Toxicological Evaluation of Raw Materials and the End Product" are documented separately and are thus not part of this evaluation.

### **Legal Requirements:**

For the product in question, one must categorically clarify which relevant legal requirements it is

subject to with regard to product safety in terms of the above mentioned Directive 2001/95/EC.

According to the definition in § 2 (6) No. 7 of the LFGB - German Food, Consumer Goods and Feed Code - of 01/09/2005 (LFGB: "Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch": German Federal Law Gazette No. 55 of 06/09/2005, page 2618; modified through the version of 03/06/2013, German Federal Law Gazette No. 27 of 10/06/2013, page 1426), "AKEMI® Farbtonvertiefer Super" (AKEMI® Darkener Super) is a consumer article used to waterproof materials with food contact.

According to Article 1 (2)a of the Regulation (EC) No. 1935/2004 of European Parliament and of the Council of 27/10/2004 (Official Journal of the European Communities L 338 of 13/11/2004, page 4) this consumer article (called a finished product) is intended to come into contact with food.

The above mentioned Food, Consumer Goods and Feed Code states:

- *"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 or agents must not be 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).
- Furthermore, it is prohibited to use consumer articles or to place them on the market if they do not comply to the requirements of Article 3 (1) and (2) of the above mentioned Regulation (EC) No. 1935/2004 (see § 31 of the German Food, Consumer Goods and Feed Code).

According to this (Article 3 (1)), it is particularly not permissible (quotation) "...to have constituents migrated into food in amounts that can cause the following under normal or foreseeable conditions of use:

- a) a human health hazard
- b) an unjustifiable change in the composition of food
- c) an impairment of the organoleptic attributes of food"

#### **Human Toxicological Evaluation:**

According to the above mentioned legal requirements, the human toxicological evaluation of the raw materials according to the recipe and in consideration of the possible exposure to humans and the specifications for use clearly indicate that

**"AKEMI® Farbtonvertiefer Super" (AKEMI® Darkener Super)**

**is evaluated as safe for the intended purpose of treating natural and artificial stone surfaces**

**with food contact and it can thus be considered to be foodsafe.**

This evaluation is based on the following:

- the toxicological safety evaluation of all raw materials with consideration of any prohibited substances according to chemical legislation
- the toxicological safety evaluation of the finished product taking into consideration the formulation in comparison to relevant use conditions
- the toxicological safety evaluation of the degree of exposure with consideration for the intended und foreseeable use
- further elements relevant for toxicological safety evaluation such as specifications for use with regard to warning phrases

**Validity:**

This human toxicological evaluation is valid as long as no significant changes are made, i.e. the technical safety of use, quantitative and/or qualitative changes in the formulation and changes in the product's actual use.

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

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