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**Evaluation of the Human Toxicological Safety of the Product
"AKEMI® Transformer"
for Use of Treatment of Natural and Artificial Stone Surfaces with
Food Contact**

Commissioned by: AKEMI Chemisch Technische Spezialfabrik GmbH
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Preliminary Remarks:

In this opinion, the phrase *"human toxicological safety of products for treatment of natural and artificial stone surfaces with food contact"* is understood as an attribute of a product that allows for its 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 (Official Journal of the European Communities (OJ) L 11 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 defined by the following (*quotation*):

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

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

The following evaluation solely covers the safety of consumers in order to prevent potential health hazards when food would be consumed by humans that had been prepared or placed on kitchen countertops which, following the use instructions, had been surface treated with the product "AKEMI® Transformer".

It is understood that any product used for this surface treatment has been totally cured according to the use instructions and that treated surfaces have been ventilated afterwards for several days.

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 human toxicological evaluation.

Product Description:

According to the product claims, the product "AKEMI® Transformer" is going to be used for treatment of surfaces such as kitchen countertops; in other words, surfaces on which food will be prepared (or is supposed to be prepared).

This evaluation 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 treated with this product.

This ready-for-use product is sold mainly in one-litre and five-litre containers. They are used undiluted. The target groups for use comprise commercial enterprises and private consumers.

Due to the confidentiality of information, the qualitative and quantitative composition of the product and its toxicological evaluation as has been prepared by the signatory authors is documented separately and is thus not attached to this certificate.

Legal Requirements:

For the product in question, it is to be clarified which relevant legal requirements it belongs 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 03/06/2013 (LFGB: "Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetz-buch": German Federal Law Gazette No 27 of 10/06/2013, page 1426: <http://www.gesetze-im-internet.de/bundesrecht/lfgb/gesamt.pdf> (in German)) the product "AKEMI® Transformer" may be defined as consumer article used to waterproof materials with food contact.

According to Article 1 (2)a of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27/10/2004 (OJ L 338 of 13/11/2004, page 4: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF>) this consumer article 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 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).

Furthermore, consumer articles are to be manufactured such that they do comply with 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 this Article 3 (1) and (2) it is particularly mandatory that (citation):

*"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."*

Human Toxicological Evaluation:

Taking into account above defined legal provisions, the human toxicological evaluation of the raw materials forming part of the recipes together with the exposure scenarios relevant for humans and considering the use instructions for the surface treatment, it is clearly indicated that

"AKEMI® Transformer"

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

This product can therefore be considered to be in compliance with legal requirements applicable for food contact and safe from a health point of view.

This evaluation is based on the following:

- Toxicological safety evaluation of all raw materials with additional consideration of any "critical" substances according to chemical legislation.
- Toxicological safety evaluation of the finished product taking into consideration the formulations in comparison to relevant use conditions.
- Toxicological safety evaluation of the degree of exposure with consideration of the intended and foreseeable use scenarios.
- Further elements relevant for the toxicological safety evaluation such as specifications for use with regard to use instructions.

Validity:

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

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

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

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