Toxicology and tolerance of euxyl® K 703

euxyl® K 703 is a preservative concentrate, which is used in cosmetic preparations in a recommended use-concentration of 0.4 % to 1.2 %.

As active substances euxyl® K 703 contains a mixture of benzoic acid, dehydroacetic acid and phenoxy-ethanol all of which are listed in Appendix V of the EU Cosmetic Products Regulation 1223/2009/EC or in Appendix VI of EU Cosmetics Directive 76/768/EC respectively and approved for safe use throughout the EU.

On the basis of the results of toxicological tests and on the condition that no over-additive effects occur, the following assessment and evaluation of toxicology, tolerability and use was carried out. In the focus of evaluation are skin and mucosa irritant or corrosive effects.

Toxicity

The acute toxicity of the formulation is at both oral and dermal application rather low. The oral LD$_{50}$ of the undiluted product is expected in the range of 1300 mg/kg. The toxicity at use concentrations is expected even less.

The intake of toxicological problematic concentrations by inhalation is not expected at standard procedures.

Irritation

Based on the ingredients skin and mucosa irritant effects are expected with the undiluted product at local skin exposure. Irritation effects are not expected with the diluted product.

At direct eye contact irritations are expected. A thorough rinsing with water is recommended in such cases.

In general the active ingredients are non-volatile substances that do not result in toxicological relevant concentrations in the compartment air at the recommended use concentration. Nevertheless an irritant effect on mucosa of the respiratory tract cannot be excluded.
Sensitising potential
In terms of the possibility of sensitisation it should be noticed that biological active substances in general have a certain potential.
Sensitising effects in the meaning of contactallergical reactions at skin contact or chronic effects of the personnel are extremely seldom expected with appropriate contact.
The product should not be used if a proven hypersensitivity to one of the ingredients exists.

Mutagenicity
Based on the ingredients mutagen effects are not expected.

Labelling
The product needs labelling in accordance with the Dangerous Substances Directive. Please see MSDS for details.

Safe Use
According to the EU Cosmetic Products Regulation 1223/2009/EC or EU Cosmetics Directive 76/768/EC respectively all components may be used in concentrations of max. 0.5 % (benzoic acid), max. 0.6 % (dehydroacetic acid) and 1.0 % (phenoxyethanol), resp., which are considered safe up to these concentrations. The only restriction of annex VI is, that dehydroacetic acid is not allowed in aerosols.
These concentration limits are equivalent to a maximum use concentration of 1.23 % euxyl® K 703. With the recommended use concentration the euxyl® K 703 concentration used is less than this permissible concentration.
Relating to safety the Cosmetic Ingredients Review (CIR) in the USA draws the same or even higher safe concentrations for these active ingredients.
The „No Observed Adverse Effect Level“ (NOAEL) describes the hazard potential of a substance as it is the highest dosage (normally in an animal test) at which no harmful side effects or adverse reactions are caused by the substance. The NOAEL is used to evaluate the “Acceptable Exposure Levels” (AEL) for human applications. Within the estimation of human exposition is provides a basis for the definition of a “Margin of Safety” (MoS).
For cosmetic preservatives the NOAEL value is in principle not relevant as the safe level is already evaluated within the annex V of the EU Cosmetic Products Regulation 1223/2009/EC. Nevertheless sometimes also a NOAEL value for preservatives is required. The NOAEL of the product is calculated on the basis of the lowest NOAEL of the single ingredients taking into consideration the concentration of the ingredients in the product. For euxyl® K 703 the overall NOAEL is calculated as 526 mg/kg/d for oral applications.
This recommendation is subject to the required safety assessment that has to be performed for the individual cosmetic formulations according to the EU Cosmetic Products Regulation 1223/2009/EC. Especially for the use with children under the age of three a detailed safety assessment should be made.
Conclusion

Altogether euxyl® K 703 with the given upper concentration limits can be regarded as safe for its application from the toxicological point of view. Skin and mucosa irritant effect are expected with the undiluted product. The inhalation of atomized sprays must be avoided. When the above-mentioned use-concentrations are adhered to, neither local skin or mucous membrane irritation nor systemic side effects as a result of dermal absorption of the substances are to be expected.

Adequate protection measures are recommended particularly with regard to the rules of Employer’s Liability Insurance Associations or government safety organisations.

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For further information we refer to the following publications:
- opinion on Benzoic Acid and Sodium Benzoate, SCCP, 2005
- OECD SIDS, benzoates, 2001
- OECD SIDS, phenoxyethanol, 2004

1 In the transitional period of the EU Cosmetic Products Regulation 1223/2009/EC til 2013 the appendixes of the EU Cosmetics Directive 76/768/EC are still valid for harmonisation reasons.