Toxicology and tolerance of euxyl® K 903

euxyl® K 903 is a preservative concentrate, which is used in cosmetic preparations in a recommended use-concentration up to 1.2 %.

As active substances euxyl® K 903 contains a mixture of benzoic acid, dehydroacetic acid and benzyl alcohol which are all listed in Appendix V of the EU Cosmetic Products Regulation 1223/2009/EC 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 product can be evaluated through the LD_{50} values of the components. Please see MSDS for further information. The toxicity at use concentration is expected even less due to dilution at use.

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 with the undiluted product. 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. The inhalation of atomized sprays must be avoided.

Sensitising potential

In terms of the possibility of sensitization it should be noticed that biological active substances in general have a certain potential.

Sensitizing 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.

Schülke & Mayr GmbH
Robert-Koch-Str. 2 | D-22851 Norderstedt | Postal address: D-22840 Norderstedt
Phone: +49 40 521 00 -0 | Fax : +49 40 521 00 -577
mail@schuelke.com | www.schuelke.com

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 all components may be used in concentrations of max. 1.0 % (benzyl alcohol), max. 0.5 % (benzoic acid) and max. 0.6 % (dehydroacetic acid), which are considered safe up to these concentrations. The only restriction of annex V is, that dehydroacetic acid is not allowed in aerosols.

These concentration limits are equivalent to a maximum use concentration of 1.23 % euxyl® K 903. With the recommended use concentration the euxyl® K 903 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 values of the below mentioned ingredients of the product taking into consideration the concentration in the product should be used.

substance**	Mean Concentration* within the product [%] *please see MSDS or contact us for further details	NOAEL of pure substance [mg/kg/d]	NOAEL share of substance within the product [mg/kg/d] =NOAEL * 100 / concentration	Reference of NOAEL value
benzyl alcohol	78-84: 81	400	494	SIDS, 2001
Benzoic acid	11-13: 12	500	4167	SCCP 2005
Dehydroacetic Acid	6.5-7.5: 7	50	714	CIR 1985

** concentrations are based on average content and are not batch related.

The product should only be used in consideration of protection and safety instructions. Please see MSDS for details.

Conclusion

Altogether euxyl® K 903 with the given upper concentration limits may be regarded as safe for its application from the toxicological point of view.

This conclusion is a general one and does not free the formulator of a cosmetic product to perform the required safety assessment that has to be performed for the individual cosmetic formulations and its ingredients 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.

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

Dr. Susanne Hendrich
Head of Regulatory Affairs Department
Schülke & Mayr GmbH

5. Feb. 2015

For further information we refer to the following publications:

- OECD SIDS, benzoates (incl. benzyl alcohol), 2001
  http://www.inchem.org/documents/sids/sids/BENZOATES.pdf
- opinion on Benzoic Acid and Sodium Benzoate, SCCP, 2005
  http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm#id1
- CIR, Final Report on the Safety Assessment of Sodium dehydroacetate and Dehydroacetic acid. J. American College Toxicol. 4 (3): 123-59 (1985)
  http://www.cir-safety.org/ingredients