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Commentary

# Opinion of the Scientific Committee on Consumer Safety (SCCS) – Final version of the opinion on Phenoxyethanol in cosmetic products

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ABSTRACT

The SCCS considers 2-phenoxyethanol safe for use as a preservative with a maximum concentration of 1.0%, taking into account the information provided.

The toxicokinetics default factor of 4.0 can be reduced to 1.0 yielding a minimum Margin of Safety (MoS) of 25 instead of 100 for the safety assessment of 2-phenoxyethanol.

Therefore, the MoS of about 50 for children also covers this specific age group who might be higher exposed to 2-phenoxyethanol than adults.

This Opinion does not take into account exposure from sources other than cosmetics.



Phenoxyethanol CAS n. 122-99-6 as preservative is regulated in Annex V/29 of the Cosmetics Regulation (EC) n. 1223/2009.

According to the Cosmetics Regulation (EC) n.1223/2009 Phenoxyethanol is authorized as a preservative in cosmetic formulations at a maximum concentration of 1.0%.

In September 2012, the Commission received a risk assessment submitted by the French Agency ANSM (Agence nationale de sécurité des médicaments et des produits de santé) which rose concerns about the use of Phenoxyethanol as preservatives in cosmetic products.

The ANSM report (Evaluation du risque lié à l'utilisation du phénoxyéthanol dans les produits cosmétiques) concludes that the maximum authorized concentration (currently of 1%) of Phenoxyethanol for use as a preservative should be lowered to 0.4% in cosmetic products for children less than three years. In addition, Phenoxyethanol should not be used in cosmetic products intended for their nappy area. The Commission received information from other member States which raised similar concern on the use of Phenoxyethanol, in particular on children.

In December 2013, in response to a call for data on Phenoxyethanol by the Commission, Cosmetics Europe submitted a safety dossier in order to defend the current use of Phenoxyethanol as preservative in cosmetic formulations at a maximum concentration of 1.0%.

In December 2014, additional information from Cosmetics Europe (Subm. II) was received by the Commission and in July 2015 the submission of data was complemented with a safety assessment tool, such as the physiologically based pharmacokinetic (PBPK) modelling, in order to provide a perspective on systemic exposure of phenoxyethanol in humans (absorption, distribution, metabolism and excretion).

The SCCS considers 2-phenoxyethanol safe for use as a preservative with a maximum concentration of 1.0%, taking into account the information provided.

The toxicokinetics default factor of 4.0 can be reduced to 1.0 yielding a minimum Margin of Safety (MoS) of 25 instead of 100 for the safety assessment of 2-phenoxyethanol.

Therefore, the MoS of about 50 for children also covers this specific age group who might be higher exposed to 2-phenoxyethanol than adults.

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## Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.yrtph.2016.11.007.

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