

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion for the use of 2-Phenoxyethanol CAS n. 122-99-6 as preservative

1. Background

Phenoxyethanol CAS n. 122-99-6 as preservative is regulated in Annex V/ 29 of the Cosmetics Regulation (EC) n. 1223/2009¹.

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 authorised 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 (Sub II) was received by the Commission and in July 2015 the submission of data was completed 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).

2. Terms of reference

1. *Does SCCS consider Phenoxyethanol safe for use as preservative with a maximum concentration of 1.0 %, taking into account the information provided?*
2. *The SCCS is asked, when making the assessment, to take into account the specific age groups who might be particularly susceptible to the effects of Phenoxyethanol used as preservatives in cosmetic products.*
3. *Does the SCCS have any further scientific concerns with regard to the use of Phenoxyethanol in cosmetic products?*

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>