

Update April 2016

SCCS reassessment of the safety of Phenoxyethanol

Preservatives affected by changes
Phenoxyethanol (No change)

No changes are being made to the EU Cosmetic Regulation with respect **to the permitted use levels of Phenoxyethanol**

In September 2012 a risk assessment was submitted by the French Agency ANSM which raised concerns about the use of Phenoxyethanol as preservatives in cosmetic products.

The ANSM report suggested that the maximum authorised concentration (currently 1%) of Phenoxyethanol for use as a preservative should be reduced in cosmetic products designed for children less than three years of age.

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

Based on the additional evidence and a full re-evaluation, the SCCS concluded that children ≤ 3 years may be higher exposed to Phenoxyethanol in cosmetic products than adults. However, the Margin of safety derived from reasonable worst case scenarios were considered sufficient for this age group.

In conclusion, the SCCS has recommended the opinion that the 1 % maximum use level of Phenoxyethanol is Safe for use on adults and children under the age of 3.

The full draft opinion can be viewed online at:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf

Phenoxyethanol	EU Cosmetic Regulation (existing)	EU Cosmetic Regulation (future)
Leave-on	1 %	1 %
Rinse-off	1 %	1 %

Cosmetic Regulation labelling requirements
No special labelling requirements

Iscaguard products affected by changes

Iscaguard product affected	New use level		Recommended alternatives
	Leave-on	Rinse-off	
-	-	-	No changes

(this list is not exhaustive, as we offer many custom blends, please contact us for further information)