

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on propyl and butyl parabens

1. Background

"Parabens" are currently authorized as preservatives in entry 12 of Annex VI to the Cosmetics Directive at a maximum concentration of 0.4% when used individually or 0.8% when used as a mixture of esters. Different substances are covered by this entry, with the most commonly used being: methyl-, ethyl-, propyl-, butylparabens, isopropyl- and isobutylparabens.

Since 2005, these substances have been assessed by the subsequent Scientific Committees on a number of occasions. In March 2011, the Scientific Committee on Consumers Safety (SCCS/1348/10) considered that:

- Methylparaben and ethylparaben were safe, when used at the maximum authorized concentrations;
- Butylparaben and propylparaben were safe, if the sum of their individual concentrations did not exceed 0.19%.
- For isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentyparaben, the human risk could not be evaluated for lack of data.

On 21 March 2011, Denmark notified the Commission that it had banned propyl- and butylparaben, the isoforms and salts in cosmetic products for children up to three years of age. On 10 October 2011, the SCCS adopted a clarification to its previous opinion in light of the Danish clause of safeguard. The Committee (SCCS/1446/11) concluded that:

- For general cosmetic products containing parabens, excluding specific products for the nappy area, there was no safety concern in children.
- For leave-on cosmetic products designed for application on the nappy area and in the case of children below the age of six month, a risk could not be excluded in the light of both the immature metabolism and the possibly damaged skin in this area.

In March 2012, a Member State presented the results of a study on the reproductive toxicity of propylparaben to the Working Group on Cosmetic Products. The study showed no effects on the reproductive parameters; therefore it did not confirm the conclusions of the previous studies that pointed towards negative effects on reproduction.

2. Terms of reference

1. *Taking into consideration recent data, does the SCCS consider that its opinions of 2010 (SCCS/1348) and 2011 (SCCS/1446) on propylparaben when it is used as preservative in cosmetics products, both intended for adults and young children, need to be updated?*
2. *Taking into consideration recent data, does the SCCS consider that its opinions of 2010 (SCCS/1348) and 2011 (SCCS/1446) on butylparaben when it is used as preservative in cosmetics products, both intended for adults and young children, need to be updated?*
3. *Several Member States have highlighted that, despite the Commission's recommendation to avoid exposure to the sun of children below three years old, young children are exposed and they are protected from the harmful effects of the sunlight through the use of sunscreens. The SCCS is therefore asked to take into account in its assessment the information available about exposure to sunscreens, especially as far as children below three years old are concerned.*

3. Deadline: March 2013