

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion: Ethyl Lauroyl Arginate HCl (CAS 60372-77-2) submission III (P95)**

### 1. Background

Submission I for Ethyl Lauroyl Arginate HCl was submitted in February 2003 by COLIPA<sup>1</sup>.

The Scientific Committee on Cosmetic Products (SCCP) adopted its opinion SCCNFP/0837/04 at the 3<sup>rd</sup> plenary meeting of 15<sup>th</sup> March 2005 with the conclusion, that *“The SCCNFP is of the opinion that the information submitted suggests that ethyl lauroyl arginate causes mucosal irritation. Before any further consideration, the following additional information is required by the end of 2005:*

*\* clarification on purity, composition and impurities;*

*\* an acute inhalation toxicity study.”*

With the submission II and II-bis for Ethyl Lauroyl Arginate HCl in April and October 2006, respectively, the additional data were provided by the applicant.

The Scientific Committee on Consumer Products (SCCP) adopted its opinion SCCP/1106/07 at the 15<sup>th</sup> plenary meeting of 15<sup>th</sup> April 2008 with the conclusion, that

*“Ethyl Lauroyl Arginate HCl is safe for the consumers, when used:*

*- up to a maximum authorised concentration of 0.4 % as a preservative in cosmetic products, but excluding products for the lips, oral hygiene products and spray products*  
*- up to a maximum authorised concentration of 0.8 % in soap, anti-dandruff shampoos, and non-spray deodorants.*

*This opinion is based on the use of ethyl lauroyl arginate HCl in the specified cosmetic products only. It takes no account of other possible and probable sources of exposure by the consumer of this substance.”*

The exclusion of the use of Ethyl Lauroyl Arginate HCl for oral hygiene products is contested by the applicant. An update to the dossier addressing this point was submitted in December 2008, containing expert statements in relation to the irritant potential of Ethyl Lauroyl Arginate as well as a report of the joint FAO/WHO Expert Committee on Food Additives that arrived at a higher ADI than the EFSA evaluation of 2007..

Moreover, in the light of concerns that were raised in relation to combined exposure of consumers to Ethyl Lauroyl Arginate HCl from cosmetics and food, the applicant in 2010 provided a new dermal absorption study to allow revision of the worst case assumption-based exposure assessment in opinion SCCP/1106/07.

---

<sup>1</sup> COLIPA - the European Cosmetics Association

## **2. Terms of reference**

- *In the light of the data provided, does the SCCS consider that Ethyl Lauroyl Arginate HCl is safe for the consumers, when used up to a maximum concentration of 0.75 % in toothpaste and 0.2% in mouthwash products in addition to the currently recommended uses as mentioned above?*
- *Taking into account the dermal absorption data submitted, the SCCS is requested to revise the exposure assessment for Ethyl Lauroyl Arginate HCl in cosmetics made in opinion SCCP/1106/07.*
- *Does the SCCS have any other scientific concerns of use for Ethyl Lauroyl Arginate HCl in cosmetic products based on the toxicological profile and foreseeable exposure?*

## **3. Deadline: June 2011**