

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

### Request for an addendum to scientific opinion: Ethyl Lauroyl Arginate HCl (ELA) (P95)

#### 1. Background

Ethyl Lauroyl Arginate HCl (ELA) CAS n. 60372-77-2 was evaluated by the SCCP in 2004 (SCCP/0837/04) and in 2007 (SCCP/1106/07).

Ethyl Lauroyl Arginate HCl (ELA) CAS n. 60372-77-2 is currently authorized as preservative under the Cosmetic Regulation n. 1223/2009 – Annex V/58 at maximum concentration of 0.4% in all cosmetic products except lip products, oral products and spray products. Ethyl Lauroyl Arginate HCl (ELA) is also regulated under Annex III/197 of Cosmetic Regulation n. 1223/2009 to be used for purposes other than inhibiting the development of micro-organisms exclusively in soap, anti-dandruff shampoos and deodorants (not in form of spray) at maximum concentration of 0.8%.

The SCCS adopted the third opinion (SCCS/1519/13) on Ethyl Lauroyl Arginate HCl (ELA) at its 3th plenary meeting of 19 September 2013 (revised in December 2013) with the following conclusion:

*The SCCS considers Ethyl lauroyl arginate HCl safe for use as a preservative, when used up to a maximum concentration of 0.15% in mouthwashes, though not in oral cosmetic products as a whole. As no human data concerning local toxicity of Ethyl lauroyl arginate HCl in toothpaste are available, the safety of Ethyl lauroyl arginate HCl in toothpaste cannot be assessed.*

In February 2014 the Commission received a document on Ethyl Lauroyl Arginate HCl (ELA) from the applicant Lamirsa that draws the attention on the EFSA assessment on ELA as food preservative and consequently on the total exposure of it used both in food and cosmetic products.

#### 2. Terms of reference

- 1) *In the light of the data provided, does the SCCS consider that Ethyl Lauroyl Arginate HCl is still safe for the consumers at current use in cosmetic product including mouthwashes, considering the exposure from other sources, such as food?*
- 2) *In particular does the SCCS consider that Ethyl Lauroyl Arginate HCl is safe at current use in cosmetic product including mouthwashes considering the specific age groups who might be particularly susceptible to the effects of total exposure to Ethyl Lauroyl Arginate HCl, used in both cosmetic and food products?*
- 3) *Does the SCCS have any further scientific concerns with regard to the use of Ethyl Lauroyl Arginate HCl in cosmetic products?*

**3. Deadline:** December 2014

**4. Supporting documents**

1. Lamirsa 's document AC-059/14 on Ethyl Lauroyl Arginate HCl (ELA)
2. Statement of EFSA- Refined exposure assessment of ethyl lauroyl arginate based on revised proposed uses as a food additive- EFSA Journal 2013;11(6):3294

Annex