SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for a scientific opinion: Ethyl Lauroyl Arginate HCl (ELA) submission IV (P95)

1. Background

Submission I for Ethyl Lauroyl Arginate HCl (ELA) CAS n. 60372-77-2, was submitted in February 2003 by COLIPA¹.

Submission II and II-bis for Ethyl Lauroyl Arginate HCl (ELA) was submitted respectively in April and October 2006.

Submission III contained a dossier, submitted in December 2008, and additional data submitted in 2010. The aim of the applicant was to demonstrate the safety use of Ethyl Lauroyl Arginate HCl (ELA) in oral hygiene products.

The Scientific Committee on Consumer Safety (SCCS) adopted at 11th plenary meeting of 21 June 2011 the opinion (SCCS/1415/11) with the following conclusion:

The SCCS considers the additional data provided on mucosal irritation does not alter its earlier opinion on ethyl lauroyl arginate HCl. The concern that in the general population, regular use of toothpaste and possible additional use of a mouthwash containing ethyl lauroyl arginate HCl could cause local mucosal irritation, was not addressed by the submitted studies.

Submission IV for Ethyl Lauroyl Arginate HCl (ELA) was submitted in September 2012.

This submission is intended to demonstrate the safety of the ingredient ELA for use as preservative in oral products at a level up to 0.15%

2. Terms of reference

1) 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 0.15 % in oral products?

2) Does the SCCS have any further scientific concerns with regard to the use of Ethyl Lauroyl Arginate HCl in cosmetic products?

¹ Cosmetics Europe, ex- COLIPA (European Cosmetics Toiletry and Perfumery Association)