

## SCIENTIFIC COMMITTEE ON CONSUMERS SAFETY (SCCS)

### Request for a scientific opinion: Arbutin (CAS 497-76-7). Submission II

#### 1. BACKGROUND

Submission I for  $\beta$ -Arbutin (CAS 497-76-7) with the chemical name 4-hydroxyphenyl- $\beta$ -D-glucopyranoside and the INCI name Arbutin was submitted in July 2005 by COLIPA<sup>1</sup>.

However, the ingredient alpha-Arbutin with the chemical name 4-hydroxyphenyl- $\alpha$ -D-glucopyranoside may also be used, and one member state has specifically asked for an evaluation of both  $\alpha$ - and  $\beta$ -arbutin.

The effect of Arbutin seems to be due to the fact that it hydrolyses to Hydroquinone. However, Hydroquinone is listed in Annex III (entry 14) of the Cosmetics Directive 76/768/EEC. Its permitted use is restricted to professional use in artificial nail systems in a concentration in the final product up to 0.02%. Since Hydroquinone could not be used as a skin whitener after introduction of a ban for this use by Cosmetic Directive 2000/6/EC, other substances have been used for that purpose, including Arbutin.

The first opinion (SCCP/1158/08) on beta-arbutin was adopted the 15 April 2008 with the conclusion: *"Although the general toxicological assessment of  $\beta$ -arbutin suggests that the substance may be safe, the bioavailability of hydroquinone under conditions of intended use of the substance is of concern. Whereas hydroquinone was initially permitted at a concentration of 2%, a 1998 opinion of the SCCNFP recommended that the substance should not be used any more as a depigmentating agent in cosmetic products due to observed clinical side effects, among which exogenous ochronosis [41].*

*Consequently, the SCCP considers the currently requested use of  $\beta$ -arbutin in cosmetic products unsafe.*

*In addition, it is the opinion of the SCCP that the same concern can be expressed for other products that result in the release and/or formation of hydroquinone before or upon application on the skin."*

The substance is used as a chemical ingredient alone and as a component of a plant extracts like Arctostaphylos Uva Ursi, Vaccinium Vitis-Idaea, Chimaphila Umbellata etc, all rich in content of arbutin, according to the information on skin lightening products available to the Commission Services.

The current submission II is a response to the first opinion on beta-Arbutin.

As the SCCP opinion states concerns with other substances resulting in the release and/or formation of hydroquinone, a dossier on the related substance, desoxyarbutin, which was submitted the European Commission, is included with this request.

#### 2. TERMS OF REFERENCE

1. Does the SCCS consider on the basis of the provided scientific data, the use of  $\alpha$ -arbutin to be safe for consumers in cosmetic products in a concentration up to 2% in face creams and up to 0.5% in body lotions?

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<sup>1</sup> COLIPA – The European Cosmetics Association

2. Does the SCCS consider on the basis of the provided scientific data, the use of  $\beta$ -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% in face creams?

3. Does the SCCS consider on the basis of the provided scientific data, the use of desoxyarbutin to be safe for consumers in cosmetic products in a concentration up to 3.0% in face creams?

4. And/or does the SCCS have any scientific concerns with regard to the use of arbutin ( $\alpha$ - and/or  $\beta$ -form), desoxyarbutin or related substances known to release hydroquinone in cosmetic products?