

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: β -Arbutin (CAS 497-76-7) with the chemical name 4-hydroxy-phenyl- β -D-glucopyranoside

1. Background

Submission I for β -Arbutin (CAS 497-76-7; EC 207-850-3) with the chemical name 4-hydroxyphenyl- β -D-glucopyranoside and the INCI name Arbutin was submitted in July 2005 by COLIPA¹.

The effect of Arbutin seems to be due to the fact that it hydrolyses to Hydroquinone. However, Hydroquinone (CAS 123-31-9) is listed in Annex II/1339 of the Cosmetic Regulation No 1223/2009; it means it is banned as cosmetic ingredient with the exception of entry 14 in Annex III. 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, 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 β -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 β -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 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.

2. Terms of reference

(1) Does the SCCS consider on the basis of the provided scientific data, the use of β -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% in face creams?

(2) Does the SCCS have any further scientific concerns with regard to the use of β -arbutin in cosmetic products?

3. Deadline:

4. Supporting documents