



Commentary

Opinion of the Scientific Committee on Consumer Safety (SCCS) –
Opinion on the safety of the use of β -arbutin in cosmetic productsSCCS ^{a,*}, Gisela H. Degen ^{b,1}^a SCCS Secretariat at the European Commission, Directorate General for Health and Food Safety, 11, rue E. Ruppert, L-2920 Luxembourg, Luxembourg^b Leibniz Research Centre for Working Environment and Human Factors (IfAdo), Dortmund, Germany

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ABSTRACT

Conclusion of the opinion: The SCCS considers the use of β -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% in face creams provided that the contamination of hydroquinone in the cosmetic formulations remain below 1 ppm.

A potential combined use of β -arbutin and other hydroquinone releasing substances in cosmetic products has not been evaluated in this Opinion.

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Link to the SCCS Opinion:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_169.pdf.

Submission I for β -Arbutin (CAS 497-76-7) with the chemical name 4-hydroxy-phenyl- β -D-glucopyranoside and the INCI name Arbutin was submitted in July 2005 by COLIPA.

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 depigmenting 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

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beta-Arbutin.

The SCCS considers the use of β -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% in face creams provided that the contamination of hydroquinone in the cosmetic formulations remain below 1 ppm.

A potential combined use of β -arbutin and other hydroquinone releasing substances in cosmetic products has not been evaluated in this Opinion.

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