FISEVIER

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph



Official report

Opinion of the Scientific Committee on Consumer safety (SCCS) - Opinion on the safety of the use of α -arbutin in cosmetic products



SCCS 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

ARTICLE INFO

Article history: Received 17 November 2015 Accepted 17 November 2015 Available online 2 December 2015

Keywords: SCCS Scientific opinion α-Arbutin Regulation 1223/2009 CAS 84380-01-8 EC 440-470-8

ABSTRACT

Conclusion of the opinion: The SCCS considers the use of α -Arbutin safe for consumers in cosmetic products in a concentration up to 2% in face creams and up to 0.5% in body lotions. A potential combined use of α -Arbutin and other hydroquinone releasing substances in cosmetic products has not been evaluated in this Opinion.

© 2015 Published by Elsevier Inc.

Opinion to be cited as: Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on α -arbutin, 27 May 2015, SCCS/1552/15.

Authors of the Opinion

SCCS members: Dr. U. Bernauer, Prof. P.J. Coenraads, Prof. G. H. Degen (rapporteur), Prof. M. Dusinska, Dr. W. Lilienblum, Dr. E. Nielsen, Prof. T. Platzek, Dr. S.C. Rastogi (chairman), Dr. Ch. Rousselle, Dr. J. van Benthem

Former SCCS member: Prof. A. Luch.

External experts: Prof. A. Bernard, Prof. A.M. Giménez-Arnau, Prof. T. Vanhaecke, Dr. J. Ezendam

SCCS Number: SCCS/1552/15.

Doi:/

Adopted on: 27 May 2015. Link to the SCCS Opinion:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_176.pdf.

α-Arbutin INCI name Alpha-Arbutin (CAS 84380-01-8; EC 283-934-3) with the chemical name 4-Hydroxyphenyl-alpha-p-glucopyranoside is a cosmetic ingredient that is not regulated under

E-mail address: SANTE-C2-SCCS@ec.europa.eu (SCCS).

Cosmetic Regulation No 1223/2009. It is used as antioxidant, for skin bleaching and skin conditioning.

The structurally related compound beta-Arbutin (CAS 497-76-7) is also used as a depigmentating agent in cosmetic products. The safety of beta-Arbutin has been assessed previously (SCCP/1158/08); its effect 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 alpha-Arbutin and beta-Arbutin.

As the SCCP opinion (SCCP/1158/08) stated concerns with other substances resulting in the release and/or formation of hydroquinone, a safety assessment of Alpha-Arbutin (CAS 84380-01-8; EC 283-934-3), has been considered as necessary. A Dossier on alpha-Arbutin was submitted in January 2011 in response to the EU Commission's Call for Scientific data on alpha-Arbutin published in November 2010.

The SCCS considers the use of α -Arbutin safe for consumers in cosmetic products in a concentration up to 2% in face creams and up to 0.5% in body lotions.

A potential combined use of α -Arbutin and other hydroquinone

^b Leibniz Research Centre for Working Environment and Human Factors (IfADo), Dortmund, Germany

^{*} Corresponding author.

¹ Rapporteur of the Opinion.

releasing substances in cosmetic products has not been evaluated in this Opinion.

Reference:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_176.pdf.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.yrtph.2015.11.008.