



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Dir F: Ecosystems I: Chemicals, food, Retail

Unit F2: Bioeconomy, Chemicals & Cosmetics

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

#### **Request for a scientific on the safety of alpha- (CAS No. 84380-018, EC No. 617-561-8) and beta-arbutin (CAS No. 497-76-7, EC No. 207-8503) in cosmetic products.**

**Commission Department requesting the Opinion:** Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

#### **1. Background**

Alpha-arbutin ( $\alpha$ -arbutin) (INCI name: Alpha-Arbutin, Chemical name: 4-Hydroxyphenyl-alpha-D-glucopyranoside, CAS No. 84380-01-8, EC No. 617-561-8) and the structurally related compound (optical isomer) beta-arbutin ( $\beta$ -arbutin) (INCI Name: Arbutin, Chemical name: 4-Hydroxyphenyl-b-D-glucopyranoside, CAS No. 497-76-7, EC No. 207-850-3) are similar cosmetic ingredients currently not regulated under the Cosmetic Regulation (EC) No. 1223/2009. Among the reported functions for both  $\alpha$ - and  $\beta$ -arbutin are antioxidant, skin bleaching and skin conditioning.

The safety of  $\alpha$ - and  $\beta$ -arbutin has been previously assessed in the SCCS/1552/15<sup>1 2 3</sup> and SCCS/1550/15, respectively. The effects of arbutins on the skin could be attributed to their gradual hydrolysis and release of hydroquinone (HQ). Hydroquinone (CAS No. 123-31-9, EC No. 204-617-8) is listed in entry 1339 of Annex II to the Cosmetic Regulation; which means that it is prohibited as cosmetic ingredient with the exception of entry 14 in Annex III (restricting its use to professionals in artificial nail systems with a maximum concentration up to 0.02% in the finished product).

In the relevant SCCS Opinions (SCCS/1552/15 and SCCS/1550/15), the SCCS concluded that

1. the use of  $\alpha$ -arbutin is safe for consumers in cosmetic products in a concentration up to 2% in face creams and up to 0.5 % in body lotions.
2. the use of  $\beta$ -arbutin is 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.

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<sup>1</sup> [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_176.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_176.pdf)

<sup>2</sup> [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_169.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_169.pdf)

<sup>3</sup> [https://ec.europa.eu/growth/content/call-data-ingredients-%E2%80%98alpha-and-beta-arbutin%E2%80%99-under-regulation-ec-](https://ec.europa.eu/growth/content/call-data-ingredients-%E2%80%98alpha-and-beta-arbutin%E2%80%99-under-regulation-ec-12232009_en)

Nevertheless, the SCCS highlighted in both opinions that a potential combined use of hydroquinone releasing substances in cosmetic products has not been evaluated.

During previous discussions within the Working Group on Cosmetic Products, concerns have been raised on the HQ content, its release, as well as on the aggregate exposure from cosmetic products containing  $\alpha$ -arbutin and/or  $\beta$ -arbutin. This led to additional consultation with the SCCS and resulted in the identification of a number of issues in the previous submissions. Notably, the stability and dermal absorption of  $\alpha$ -arbutin and/or  $\beta$ -arbutin, the release rate of HQ and the aggregate exposure calculation from cosmetics exposure.

Following this, a call for data was launched from July 2020 to April 2021 (9 months). More specifically, interested parties were asked to contribute with data/information relevant to the stability of  $\alpha$ - and  $\beta$ -arbutin, their dermal absorption, the HQ release rate (including biotransformation) and the aggregate exposure.

## **2. Terms of reference**

- (1) *In light of the data provided, does the SCCS consider  $\alpha$ -arbutin safe when used in face creams up to a maximum concentration of 2% and in body lotions up to a maximum concentration of 0.5 %?*

*In the event that the estimated exposure to  $\alpha$ -arbutin from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits.*

- (2) *In light of the data provided, does the SCCS consider  $\beta$ -arbutin safe when used in face creams up to a maximum concentration of 7%?*

*In the event that the estimated exposure to  $\beta$ -arbutin from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits.*

- (3) *In light of the data provided, does the SCCS consider that the presence of hydroquinone in the cosmetic formulations must remain below 1 ppm for both  $\alpha$ - and  $\beta$ -arbutin containing products?*

- (4) *Does the SCCS have any further scientific concerns regarding the use of  $\alpha$ - and  $\beta$ -arbutin in cosmetic products in relation to aggregate exposure from such substances in cosmetics?*

## **3. Deadline: 9 months**

## **4. Supporting documents: Data/information received during the Call for data.**

The SCCS approved this mandate at plenary meeting on 24 -25 June 2021.