



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 opinion on **Silver Zinc Zeolite (CAS No. 130328-20- 0, EC No. 603-404-0)**.

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

1. Background

Silver Zinc Zeolite (SZZ) (CAS No. 130328-20-0, EC No. 603-404-0) with INCI name 'Ammonium Silver Zinc Aluminium Silicate' is included in the European database for information on cosmetic substances and ingredients (CosIng) with the reported functions of 'absorbent', 'deodorant' and 'preservative'.

SZZ is used for the antimicrobial effects exerted by the silver ions released. Silver ions may interact with the cell membrane of microorganisms and the electron transport processes, bind to nucleic acids, inhibit enzymes and catalyse the formation of free radical oxygen species (ROS). Generally, the antimicrobial effect depends on how much of the silver is released.

In December 2015, the Risk Assessment Committee (RAC) of ECHA issued an Opinion¹ recommending a 'Toxic for reproduction Category 2' classification (i.e. suspected of damaging the unborn) for Silver Zinc Zeolite.

In May 2017, the Commission Regulation No. 2017/776² amended -for the purposes of its adaptation to technical and scientific progress- Regulation No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP Regulation). In particular, a new entry in Annex VI to the CLP Regulation was added for '*Silver Zinc Zeolite (Zeolite, LTA framework type, surface-modified with silver and zinc ions) [This entry covers LTA (Linde Type A) framework type zeolite which has been surface-modified with both silver and zinc ions at contents Ag+ 0,5 %-6 %, Zn2 + 5 %-16 %, and potentially with phosphorus, NH4+, Mg2+ and/or Ca2+ each at level < 3 %]*'.

In May 2019, the Commission Regulation No. 2019/831 amended Annexes II, III and V to Regulation (EC) No. 1223/2009 (Cosmetics Regulation) following the provisions of Article 15 on CMR substances and the substance Silver Zinc Zeolite was added in entry 1597 of Annex II as a prohibited substance in cosmetic products.

¹ <https://echa.europa.eu/documents/10162/ce343f0e-623b-7678-586e-613dffbcfe06>

² <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32017R0776>

In August 2020, the Commission services received a dossier submission by industry to support the safety assessment of SZZ as a preservative in cosmetic products, in particular in spray deodorant and powder foundation. A positive outcome of this assessment may support the de-listing of SZZ from Annex II and its inclusion under Annex V to the Cosmetics Regulation as an authorised preservative.

In March 2021, the Biocidal Products Committee (BPC) published their Opinion³ on the application for approval of the active substance Silver zinc zeolite. The overall conclusion of the BPC was that SZZ in product type (PT) 4 may not be approved. More specifically, according to the Committee the criteria laid down in point (b)(iii) of Article 19(1) of Regulation No. 528/2012 were not met. The active substance did not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation No. 528/2012. SZZ raised concerns for human health and the environment (Repr. 2, Skin Irrit. 2, Eye Dam. 1 and as Aquatic acute 1).

In light of the information provided, the Commission requests the SCCS to carry out a safety assessment on Silver Zinc Zeolite when used as a preservative in cosmetic products.

2. Terms of reference

- (1) *In light of the data provided and taking under consideration the classification as Toxic for reproduction Cat. 2, does the SCCS consider Silver Zinc Zeolite safe when used as a preservative in cosmetic products according to the specifications and concentration limits provided in the dossier submission?*
- (2) *Alternatively, what is according to the SCCS, the maximum concentration considered safe for use of Silver Zinc Zeolite as a preservative in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Silver Zinc Zeolite in cosmetic products?*

3. Deadline

9 months.

4. Supporting documents

ERM dossier on the safety of SZZ in Cosmetic Products.

→ The SCCS approved this mandate in the plenary meeting on 21-22 June 2022.

³ <https://echa.europa.eu/documents/10162/2bc163bb-1653-a756-6923-6546ea99f4b6>