



EUROPEAN COMMISSION

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

Resources Based, Manufacturing and Consumer Goods Industries

Consumer Industry

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific advice on the threshold for the warning ‘contains formaldehyde’ in Annex V, preamble point 2 for formaldehyde-releasing substances

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

1. Background

Formaldehyde (CAS No. 50-00-0, EC No. 200-001-8) was classified as a Carcinogen substance of category 1B by Commission Regulation (EU) No 605/2014; in addition, the substance is also classified as Skin sensitizer Cat. 1 (H317 May cause an allergic skin reaction).

In November 2014, the SCCS concluded in its opinion SCCS/1538/14¹ that nail hardeners with a maximum concentration of about 2,2 % of free formaldehyde can be used safely to harden or strengthen nails.

However, the discussions in the Working Group on Cosmetic Products concluded that suitable alternative substances were available and hence a derogation request under Art. 15(2) was rejected. Consequently, the Commission Regulation (EU) No 831/2019 delisted formaldehyde from Annex V (preservatives) and added to the list of substances prohibited in cosmetic products in Annex II (entry 1577).

Annex V contains a number of substances that are releasing formaldehyde in order to achieve a preserving function on the final cosmetic product (so called formaldehyde releasers). In addition, point 2 of the preamble of Annex V requires that:

“All finished products containing substances in this Annex and which release formaldehyde must be labelled with the warning ‘contains formaldehyde’ where the concentration of formaldehyde in the finished product exceeds 0,05 %”.

This labelling was introduced several years ago by the *Eighth Commission Directive 86/199/EEC* of 26 March 1986 with the intention to inform/warn consumers on the presence of a substance that could trigger an allergic reaction (e.g. in people sensitised to Formaldehyde).

¹ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_164.pdf

In 2020, the Commission services received additional information suggesting that formaldehyde exposure to levels below 0.05% could cause contact dermatitis in persons with formaldehyde allergy, questioning the current provisions concerning the labelling of such substances in Annex V.

2. Terms of reference

- (1) *In light of the data provided and taking under consideration the available scientific literature, does the SCCS consider the 0.05% threshold for labelling formaldehyde releasing substances adequate to protect consumers?*
- (2) *Does the SCCS consider necessary to change the 0.05% threshold and at which level?*

3. Deadline

5 months

4. Supporting documents

- Cosmetic Products Working Group position paper
- Doi T, Kajimura K, Taguchi S. Survey of Formaldehyde (FA) Concentration in Cosmetics Containing FA-Donor Preservatives. *Journal of Health Science*. 2010;56(1):116–122
- Malinauskiene L, Blaziene A, Chomiciene A, Isaksson M. Formaldehyde may be found in cosmetic products even when unlabelled. *Open Med (Wars)*. 2015;10(1):323-328
- Noiesen E, Munk MD, Larsen K, Johansen JD, Agner T. Difficulties in avoiding exposure to allergens in cosmetics. *Contact Dermatitis*. 2007;57:105-109

The SCCS approved this mandate by written procedure on 12 February 2021.