

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for a scientific opinion of the safety of the use of formaldehyde in nail hardeners.

1. Background

The substance formaldehyde (CAS Number 50-00-0) is anticipated to be classified as a carcinogen category 1B under the CLP Regulation (EC) No 1272/2008, following a qualified majority in favour of the Committee opinion adopted on 17 December 2013. This classification shall apply by 1st April 2015.

Regulation (EC) No 1223/2009 foresees that the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) substances, of category 1A or 1B, under Part 3 of Annex VI to the Regulation (EC) No 1272/2008, is prohibited.

However, such substances may be used in cosmetic products **by way of exception** where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, **all of the conditions** (hereafter reported) of Article 15.2 of the Cosmetics Regulation are fulfilled:

- (a) **they comply with the food safety requirements** as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety;
- (b) there are **no suitable alternative substances available**, as documented in an analysis of alternatives;
- (c) the application is **made for a particular use of the product category with a known exposure**; and
- (d) they have been **evaluated and found safe by the SCCS for use in cosmetic products**, in particular in view of exposure to **these products and taking** into consideration the overall exposure from other sources, taking particular account of vulnerable population subgroups.

The regulatory measures authorising such exemption for use shall be adopted within **15 months** of the classification as CMR 1A or 1B of the substance(s) concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Nail hardeners are very specialized cosmetics used to harden or strengthen natural nails, especially soft, brittle or fragile nails. Formaldehyde is used in nail hardeners for its specific cross-linking functionality with keratin.

The use of formaldehyde in nail hardeners is currently restricted as specified in the Entry 13 of Annex III of Regulation (EC) No 1223/2009 - i.e. a maximum

concentration in the finished products of 5% (as formaldehyde); labelled as '*contains formaldehyde*' when the finished cosmetic product contains formaldehyde in a concentration above 0,05% and with the warning '*protect cuticules with grease or oil*'

Additionally the use of formaldehyde (CAS 50-00-0) as preservative for cosmetics is also allowed under restricted conditions [Entry 5 of Annex V].

In July and November 2013, Cosmetics Europe representing an industry consortium, submitted a full application to support the use of formaldehyde in nail hardeners at the maximum level of 2.2% (as free formaldehyde).

The industry consortium considers that its application for exemption contains the data supporting the fulfilment of conditions a), b) and c) of Article 15.2. The application contains an evaluation of the toxicological profile of formaldehyde, a global human exposure assessment to formaldehyde and an assessment of the safety of free formaldehyde released by the usage of nail hardeners under the current conditions for use (see above).

The Commission published on 23 May 2013, a call for data on formaldehyde use in cosmetics and/or formaldehyde released by others substances used in cosmetics, seeking also information of the suitable alternatives. The Commission only received information from Cosmetics Europe that is included in the application submitted.

The Commission considered that the substantiation of the three first conditions of Article 15.2 are fulfilled, allowing that the SCCS proceeds now with its scientific assessment.

2. Terms of reference

In view of above, and taken into account the data provided in the application, and from other sources, SCCS is requested:

- 1) To assess if condition d) of Article 15.2 is fulfilled, in order to confirm or not the safe use of formaldehyde in nail hardeners at the maximum level of 2.2% (as free formaldehyde).*
- 2) To indicate if there are any further scientific concerns with regard to the use of formaldehyde in nail hardeners*

SCCS should convey its overall assessment in an opinion to be adopted as a matter of urgency.

Deadline: 1st October 2014

Annex:

Cosmetics Europe's application on formaldehyde with regards to the safety of the use of formaldehyde in nail hardeners.