



Commentary

Opinion of the Scientific Committee on Consumer Safety (SCCS) – The safety of the use of formaldehyde in nail hardeners



On behalf of Scientific Committee on Consumer Safety (SCCS)*, Ulrike Bernauer, Pieter-Jan Coenraads, Gisela H. Degen, Maria Dusinska, Werner Lilienblum, Andreas Luch, Elsa Nielsen, Thomas Platzek, Suresh Rastogi, Christophe Rousselle, Jan van Benthem, Alfred Bernard, Ana M. Giménez-Arnau, Tamara Vanhaecke

ARTICLE INFO

Article history:

Received 24 February 2015

Available online 27 March 2015

ABSTRACT

Keywords:

SCCS

Scientific opinion

Formaldehyde

Regulation 1223/2009

CAS Number 50-00-0

EC Number 200-001-8

© 2015 Elsevier Inc. All rights reserved.

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. 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 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.

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 cuticles with grease or oil’.

On 23 May 2013, the European Commission published 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 a full application from Cosmetics Europe which supports the use of formaldehyde in nail hardeners at the maximum level of 2.2% (as free formaldehyde).

In view of the data that became available, the independent Scientific Committee on Consumer Safety (SCCS) was asked (i) 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) and (ii) to indicate if there are any further scientific concerns with regard to the use of formaldehyde in nail hardeners.¹

¹ http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm. ² http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_164.pdf.

* Corresponding author.

The SCCS concluded that nail hardeners with a maximum content of about 2.2% free formaldehyde can be used safely to harden or strengthen nails. Although “peak values” of formaldehyde reached in ambient air surrounding the application area may approach the WHO indoor guideline value of 100 µg/m³ formaldehyde (30 min exposure), thereby exceeding this concentration level only for a short period immediately after application, formaldehyde levels will rapidly decrease to background levels again within a few minutes. Further, the SCCS expresses concerns about the sensitisation potential of nail hardeners containing formaldehyde.

The SCCS also concluded that, in order to reduce inhalation exposure to formaldehyde, the room should be ventilated when applying nail hardeners. The risk of local effects in the skin, such as sensitisation, can be minimised if the products are used properly and according to the present EU Cosmetics Regulation. In light of the very low concentration of formaldehyde that has been

suggested to be capable of eliciting allergy in already sensitized individuals (>0.006%), careful usage and handling of nail hardeners is recommended. Severely damaged nails should not be exposed to nail hardeners containing formaldehyde.

This SCCS Opinion however did not assess the risk for professionals who offer application of nail hardeners as part of their service. Such individuals may be more frequently exposed to formaldehyde.

Transparency Document

The [Transparency document](#) associated with this article can be found in the online version.