

Market Surveillance Study on Formaldehyde in Cosmetic Products

Summary Report

The European Network of Official Cosmetics Control Laboratories (OCCLs) checked cosmetic products for the presence of formaldehyde and compliance with European and national regulatory requirements.

Formaldehyde is a substance presumed to have carcinogenic potential for humans (classified category 1B by Commission Regulation (EU) No 605/2014). Its use in cosmetic products is prohibited (entry 1577 of Annex II of Regulation (EC) No 1223/2009).

Product testing

Between 2018 and 2022, around 1000 products were sampled in nine countries. The majority of the samples were taken from retail shops (74%); others were collected at other stages of the distribution chain (importers, internet, etc.).

These products had been manufactured in numerous countries (43 identified countries of production), with the majority (59%) manufactured in Europe. They included different types of products, such as skin cleansing products (19%), skin care products (16%), nail varnish and remover products (13%), hair styling products (9%) and hair colouring products (9%).

Investigations

Thirteen OCCLs participated in the study. The products were analysed for the presence of formaldehyde and their labelling checked for any indication of formaldehyde and formaldehyde releasers.

The compliance of products with requirements other than those related to formaldehyde was also verified.

Results

Formaldehyde was quantified in 29.3% of the products tested; in one third of the products that tested positive, a formaldehyde releaser was part of the product composition, in the remaining two thirds, no formaldehyde releaser was identified.

DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea were the most frequently used formaldehyde releasers in the products tested. These preservatives are allowed in cosmetic products by Annex V of Regulation (EC) No 1223/2009. In accordance with this regulation, cosmetic products containing preservatives from Annex V that release formaldehyde must be labelled with the warning 'contains formaldehyde' if the concentration of formaldehyde in the finished product exceeds a threshold. The threshold was 0.05% at the time the market surveillance was run. Based on the scientific advice of the Scientific Committee on Consumer Safety (SCCS/1632/21), the threshold was decreased to 0.001% (10 ppm) as from 31 July 2022 to better protect consumers sensitised to formaldehyde from exposure to free formaldehyde from formaldehyde releasers.

Concentrations of 0.001% (10 ppm) up to 0.01% (100 ppm) were found in products without any formaldehyde releasers mentioned in the list of ingredients. For these products, the European legislation does not require the labelling of the warning 'contains formaldehyde'.

The products tested showed a good level of compliance with respect to formaldehyde. The percentage of non-compliant products due to formaldehyde was only 1%. Other reasons for non-compliance included the presence of prohibited ingredients, exceeding restriction limits and missing declarations. The overall compliance of products tested in this market surveillance study was 86%.

The study revealed that formaldehyde was frequently present at a level higher than 10 ppm in cosmetics containing no formaldehyde releaser listed in Annex V (16% of the products tested). As these products are not required to be labelled with the warning 'contains formaldehyde', this raises questions about the provision of information to sensitised consumers, as well as the consistency of labelling requirements for products with and without preservatives listed in Annex V. This issue may need to be further discussed by the market surveillance authorities.

The activities were co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM). For further information, please contact the national competent authorities responsible for market surveillance of cosmetics placed on the market or the EDQM.