

Market Surveillance Study on Skin Whitening Products

Summary Report

The European Network of Official Cosmetics Control Laboratories (OCCLs) decided to survey skin whitening products for the presence of hydroquinone, mercury and/or glucocorticoids and collect data on arbutin and kojic acid.

Hydroquinone, mercury and glucocorticoids are banned in cosmetic products and listed under Annex II of Regulation (EC) No 1223/2009 on prohibited substances. The use of arbutin and kojic acid is allowed in cosmetic products and the Scientific Committee on Consumer Safety (SCCS) has published safe concentrations for their use in face cream and body lotion.

Sampling

In the years 2021 and 2022, a total of 189 cosmetic products were sampled by the competent authorities of seven European countries (Austria, Belgium, Croatia, Germany, Netherlands, Sweden and Switzerland). Most of the samples were taken from retail shops (55%); others were collected from the internet (16%) and customs (10%) or at other stages of the distribution chain.

These products had been manufactured in numerous countries (24 identified countries of production), about half of them in Europe.

Product testing

Nine OCCLs participated in the study. The products were analysed for the presence of arbutin, kojic acid, hydroquinone, mercury and/or glucocorticoids. In total, 693 analyses were carried out.

Results

Prohibited hydroquinone, mercury and glucocorticoids were detected in 5%, 13% and 14%, respectively, of the samples tested for these ingredients. In total, 18% of the products were found non-compliant due to the presence of at least one of these prohibited substances.

Clear trends could be noted for the geographical origin of the samples and the type of prohibited substances. All skin whitening products containing mercury had been manufactured in Asia. Almost three-quarters of the samples from Pakistan were found to contain this toxic element. Most of the products containing glucocorticoids and/or hydroquinone were produced in Africa. Half of the samples manufactured in sub-Saharan Africa were non-compliant due to the presence of at least one of these prohibited skin whitening substances.

Of the samples analysed for arbutin and kojic acid, 5% and 13%, respectively, showed the presence of these skin whitening components. For one sample, the concentration of α -arbutin exceeded the safe concentration established by the SCCS. For kojic acid, about half of the analysed positive samples showed concentrations above the safe concentration recommended by the SCCS.

Conclusion

The study revealed the presence of unsafe skin whitening products in Europe. Products manufactured outside Europe showed a higher rate of non-compliance with EU regulations. It highlights the need for close monitoring of this product type by authorities to protect European citizens.

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.