

# Market Surveillance Study on Allergenic Fragrance Compounds

## Summary Report

### Introduction

The presence of fragrance ingredients in skincare and other cosmetics can cause allergic reactions. Once sensitised, affected people will opt for perfume-free products relying on the claims that appear on the product labelling. The presence of an allergenic substance in a product presented as “perfume-free” (or a similar statement) is not only an issue of false claims but is an issue of consumer safety.

The European Network of Official Cosmetics Control Laboratories (OCCLs) decided to survey cosmetic products for allergens. For this purpose, the participants sampled cosmetic products claimed to be “perfume-free” (or with a similar statement) and other cosmetic products, including perfumes.

### Samples

In 2018 and 2019, 932 samples were collected in eight countries at various stages of the distribution chain (manufacturer, customs, retail, internet, etc.). The sampled products had been manufactured in numerous countries (34 identified countries of production), with the majority (85%) manufactured in Europe. Of these, 544 samples were marked “perfume-free” (or a similar statement).

### Investigations

The aim of this study was to check the compliance of cosmetic products with European or national regulations governing the labelling of allergenic fragrance compounds and product claims. Fifteen OCCLs tested a total of 932 samples for the presence of 24 allergenic fragrance compounds. Any of these compounds must be included in the labelled list of ingredients when above 0.01% (rinse-off products)/0.001% (leave-on products) according to Annex III of Regulation (EC) No 1223/2009<sup>1</sup>.

The compliance of products with requirements other than those for allergens was also verified.

### Results

The overall compliance of products tested in this market surveillance study was 80%. The percentage of compliant products fell to 59% for the perfumes tested.

- The analysis of allergenic fragrance compounds revealed that 7.7% of the samples were non-compliant due to a missing or false declaration of the ingredients in question and 2.3% due to claims that the authorities considered misleading. The confirmed presence of linalool, benzyl alcohol and limonene were the most common reasons for objection. Amongst the 544 samples presented as perfume-free, 17 samples (3.1%) were considered to have a misleading claim as allergenic fragrance compounds were detected in them.
- 12.7% of the samples were found non-compliant for other reasons than the analysis of the allergenic fragrance compounds. Two of them (0.2%) were assessed as unsafe products, one due to the prohibited use of iodopropynyl butylcarbamate in a body lotion and one because of microbiological contamination. Most of the other reasons were wrong labelling, unauthorised claims

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<sup>1</sup> Evernia prunastri extract and Evernia furfuracea extract – which are also allergenic fragrance compounds – were not part of the scope of this study because of their variable composition due to their natural origin.

or the missing or wrong notification in the CPNP portal. Preservatives not in accordance with Annex V of Regulation (EC) No 1223/2009 (iodopropynyl butylcarbamate, methylisothiazolinone), high content of cadmium or low molecular weight mineral-oil compound in lip-care products accounted for further objections.

There was no significant difference in the observed level of non-compliance within Europe.

Allergenic fragrance compounds are amongst the main causes for skin sensitisation and the correct labelling is a prerequisite to prevent an allergic reaction. The results of the study provide the evidence for the level of compliance and recurrent labelling errors related to allergenic fragrance compounds in common cosmetics.

The compliance of cosmetic products with potential health risks should be monitored. A close collaboration of market surveillance authorities is in the greatest interest of public health.

The activities were coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM). For further information, please contact your national authorities.