New chemicals involved in skin allergies related to clothing and footwear

Clothing and footwear contain dozens of chemicals, either used intentionally or found as impurities. Some of them can cause skin allergies. ANSES set up a study between 2016 and 2018 to improve knowledge of the substances responsible for these allergies and update the regulations. It identified allergens in clothing and footwear that are responsible for skin allergies and deserve to be regulated, as well as substances that are already banned or for which the regulations have turned out to provide inadequate protection of consumer health. ANSES then joined with Sweden to propose a regulation at European level that would restrict over a thousand skin allergens in clothing and footwear.

A known problem

Clothing and footwear contain dozens or even hundreds of chemicals. Some of these substances, such as dyes, are used intentionally at the time of manufacture, while others are residues or impurities found in varying concentrations, such as residues left over from the manufacture of rubber. Many substances are already known to be allergenic but others have yet to be identified. Dermatologists regularly see patients with eczema or even skin burns as a result of wearing shoes or clothing. They then carry out patch tests, i.e. they apply very small quantities of various known allergens to the patient’s skin. If the patient develops redness and/or swelling of the skin after several hours or days of contact with one or more substances, it is a sign that they are allergic to it. However, the dermatologist has no way of verifying that the substance(s) were actually in the clothing or footwear in question, and thus confirming with certainty the source of the problem.

This is because the regulations covering clothing and footwear do not require manufacturers or distributors to list the chemicals present in the items they sell. The manufacture of an item of clothing can involve dozens of different companies, making traceability sometimes very difficult. The European regulation currently only covers 12 classes of chemicals in these items. It includes nickel, for example, which is known to cause skin allergies and which must not be present in metal parts (e.g. jacket buttons, shoe buckles) at a level exceeding 0.5 µg/cm²/week. The concentration of chromium VI, another known skin allergen, must not exceed 3 mg/kg in leather items.

Reference laboratories specialising in the chemical analysis of leather or textiles carry out hundreds of tests every day on behalf of the authorities or manufacturers wishing to ensure compliance with existing regulations. However, some substances are identified, sometimes in non-negligible concentrations, without any link being established with possible allergenic effects. These are mainly substances for which no toxic effects have been reported in the literature.

2. Amount of nickel released per cm² of metal over a period of one week of contact with this metal, in the presence of a sweat simulant to mimic dermal exposure
ANSES’s proposal to address this

As already mentioned in the article in the June 2018 issue of Vigil’Anses [1], and following a request from the Directorate General for Health (DGS) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), ANSES conducted a study to identify the chemicals responsible for skin allergies observed in patients and confirm their presence in the clothing or footwear worn [2].

This study had several objectives:

- to confirm the medical diagnosis of allergy to a substance by chemical analysis of the item by the laboratory, or confirm the involvement of a substance identified by the laboratory through a new series of patch tests on the patient;
- to identify new skin sensitisers in order to update the regulations and improve the safety of these items.

The results of this study have been used for both health and regulatory purposes [3].

Unregulated chemicals clearly identified as causing allergies

For 15 of the 50 patients in the study, the substances causing the skin allergies were identified with certainty because they yielded positive patch tests and were also found in the suspect items.

These were substances whose skin sensitising potential has been reported in the literature and which are included in the batteries of patch tests routinely used by dermatologists. However, they are not subject to any regulations limiting or prohibiting their presence in these items.

The substances found in the clothing and footwear were as follows:

- a formaldehyde-based resin, used in footwear as an additive in rubber adhesives (p-tert-butylphenol formaldehyde resin);
- a substance found in shoe adhesives (rosin);
- plasticiser for polymers used in the manufacture of footwear textiles (benzyl benzoate);
- synthetic textile fibre dyes (CI Disperse Red 17 and CI Disperse Blue 106).

For one patient, the dye causing the allergy (CI Disperse Orange 37/76) was identified at a later stage through an additional patch test, as it was not included in any of the commercial batteries of patch tests. The laboratory that identified this substance in the suspect item sent a small amount to the dermatologist, who fabricated an ad hoc patch test that proved positive.

For five patients, laboratory analyses ruled out any responsibility of the clothing or footwear in the occurrence of the allergies. The laboratories instead concluded that the items had been contaminated by external substances such as perfume, paint or detergent. Thanks to the medical questionnaires completed previously by the dermatologists, it was confirmed that substances applied to the items were indeed responsible. The doctors were able to inform these 15 patients of the substances responsible for their allergies and advise them on how to avoid any recurrence: no longer buy or wear clothes made of similar materials or colours, and no longer use certain types of household products containing these allergens.

Breaches and shortcomings of the current regulations

The analyses carried out by the laboratories revealed several non-compliances with regard to the substances responsible for the patients’ skin allergies:

- Nickel concentration above the regulatory threshold in shoe buckles for one patient;
- Chromium VI concentrations above the regulatory threshold in pairs of shoes for four patients;
- The presence of benzidine (a chemical intermediate in the synthesis of dyes) in an item of clothing. Benzidine is a carcinogen* and should never be found in finished products such as clothing.

These substances are regularly mentioned in reports by the European inspection authorities of non-compliance of items leading to their withdrawal from the market. The non-compliances identified here were therefore forwarded to the DGCCRF.

Another situation arose during this study: a patch test confirmed an allergy to an already regulated substance that had also been identified in the item but at a concentration below the regulatory threshold, and therefore in compliance. One patient was allergic to nickel in clothing, while four others were allergic to chromium VI in shoes. These cases show that the threshold in the regulation does not provide adequate protection for allergic consumers and should be lowered.

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3. According to the European Regulation 1272/2008 on Classification, Labelling and Packaging (CLP).
An unprecedented biomedical study in Europe

ANSES received a favourable opinion from the health and ethical authorities, which is an essential step for any research involving examinations on the human body.

To be included in this study, a patient had to have a skin allergy suspected of being caused by clothing or footwear purchased new. They had to give their consent and agree to hand over the offending item.

The study excluded pregnant or breastfeeding women, individuals receiving immunosuppressive treatment and patients with injuries due to personal protective equipment intended for professional use only, or items purchased second-hand.

The allergy had to be diagnosed by one of the doctors participating in the study:

- dermatologist-allergists from the Revidal-Gerda network\(^5\) practising in hospitals;
- a doctor from each of the eight poison control centres;
- a doctor from each of the occupational disease consultation centres.

Two laboratories also took part in the study: the Technical Centre for Leather (CTC) for footwear, and the French Textile and Apparel Institute (IFTH) for clothing.

In the end, 50 patients were included and 60 items (30 pairs of shoes and 30 garments) were analysed. The results were then compared with the patch test data to correlate, or not, the presence of an allergen in the item worn by the patient. The approach followed is summarised in the diagram below:

![Decision tree](image)

**Figure 1**: ANSES biomedical study on footwear and textile clothing: decision tree followed by the steering committee for investigating the cases

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5. Dermato-allergology vigilance network, bringing together 130 allergists from France, Belgium and Switzerland (association governed by the French Act of 1906).
Proposal for a more protective European regulation

These results led ANSES, jointly with Sweden, to suggest a specific framework under the REACH Regulation for textiles, leather, fur and animal hides used in clothing and footwear in particular. A specific restriction in these items was therefore proposed, for more than 1000 skin sensitisers, including those identified in this study.

If adopted, such a regulatory step forward, designed to achieve stronger consumer protection, will limit the presence of substances whose allergenic potential is known but for which no regulation currently applies. It will prohibit all so-called disperse dyes, which, as this study has shown, are often implicated in skin allergies. It will lower the regulatory thresholds for nickel and chromium VI, which do not currently provide enough protection. Any new substance classified as a "skin sensitiser" under the CLP Regulation will be added to the 1000 substances already proposed, further enhancing consumer safety in relation to these items.

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References:


[3] ANSES. 2021. ANSES Opinion summarising two stages of the biomedical study on the safety of footwear and textile clothing. ANSES Opinion summarising two stages of the biomedical study on the safety of footwear and textile clothing