

Overview of thoughts on skin testing

Social Dialogue, 9 February 2016

COIFFURE EU - Miet Verhamme



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Working group 'skin testing' (23 June 2015)

7 countries:

- Ireland
- UK
- Norway
- Germany
- Malta
- France
- Belgium (presidency)



Problems encountered by hairdressers with skin testing

Problems in Ireland & UK

Hairdressers are not trained to accurately interpret tests

The test is not practical (48 hours in advance)

Hairdressers want to work with products that are healthy for themselves and for their customers

Hairdressers do not want to be held responsible for the skin testing if a client develops an allergic reaction



Problems encountered by hairdressers with skin testing

Research Croatia as part of SafeHair project (2010 -2012)

Data collected via EvaHair questionnaire
213 questionnaires were analysed

One of the results:

- 57% needed assistance with interpreting information about products, laws and regulations (= more than 1 out of 2!)



Current status of skin testing

2011 (April): The cosmetics industry should submit a new concept for the test, addressing the need for a better harmonized and standardized method. The new concept shall aim at answering questions raised by the SCCP in 2007

Current status:

- A sub-group called ‘*skin allergens*’ has been created for Europe.
- The cosmetics industry is working on an improved harmonization of the allergy test for consumers.
- The new protocol must guarantee ‘sensitivity’ and ‘specificity’. Safety must also be guaranteed.
- The report on this project will be available by the end of 2017.



Positions regarding skin testing

- The European Society of Contact Dermatitis
- COST Action StanDerm
- Insurance companies
- Federal Institute for Risk Assessment (BfR) - Germany
- Medical Products Agency - Sweden
- Austria legal reasons
- Scientific Committee on Consumer Safety (SCCS), the former European Commission's Scientific Committee on Consumer Products (SCCP), the former Scientific Committee on Cosmetic Products and Non-food products intended for Consumers (SCCNFP)
- Cosmetics or medicines?



The European Society of Contact Dermatitis

Problem 1:

- *the recommendations and instructions on how to perform the hair dye self-tests vary greatly*
- *even among products from the same company*
- *it is our impression that most were not really ‘recommendations’ but obligations*



The European Society of Contact Dermatitis

Problem 2:

the test has been evaluated among the wrong target group

The test must be validated among the target audience, in this case individuals from the general public who intend to dye their hair.

However, the self-test has been carried out on patients who suffer from PPD allergies.

Proper validation among the target audience would produce different results.



The European Society of Contact Dermatitis

Problem 3:

it is not a screening test, but a diagnostic test

- consumers without symptoms are screened
- dermatitis patients are diagnosed

The survey was carried out among patients suffering from dermatitis and not among consumers without symptoms.

This means that the figures represent the results of a 'diagnostic' test rather than as a 'screening' test.



The European Society of Contact Dermatitis

Problem 4:

skin reactions have been read by dermatologists and not by the targeted group (consumers and hairdressers)

The intention of the self-test is that hairdressers or consumers should read and interpret the test reaction.

However, the self-test has been read and interpreted by dermatologists.

No survey has yet evaluated the results produced by hairdressers and consumers. A correct interpretation of the test is a prerequisite for correct validation of the self-test.



The European Society of Contact Dermatitis

Problem 5:

the test has not been validated according to the basic criteria defined by scientists

The screening test must be performed in accordance with high methodological scientific standards. The test has critical limitations: lack of:

- controls
- an appropriate spectrum of participants
- blind
- information on reproducibility
- information on adverse effects



The European Society of Contact Dermatitis

Problem 6:

hair dyes contain strong and extreme sensitizers that are left on the skin in high concentrations, potentially resulting in active sensitization

The self-test carries a significant risk of sensitization to hair dyes.

Studies have shown that the risk of sensitization increases with:

- the allergen dose per unit area
- the frequency of exposure
- the duration of exposure
- the occlusion
- the presence of penetration-enhancing factors
- the impairment of skin barrier function and the relation to anatomical site



The European Society of Contact Dermatitis

Problem 6

the concentration of PPD used can lead to sensitization.

The dose of allergens per unit area

Applying allergens to a 'small' area of skin does not diminish the risk of sensitization compared to larger areas of skin treated with the same dose of allergens.

Thus, repeated exposure to low doses of contact sensitizers, as is the case with self-tests, may considerably increase the risk of sensitization.



The European Society of Contact Dermatitis

Problem 6

Frequency of exposure

Basketter survey:

‘Repeated short-term exposure’ to hair dyes with a ‘low concentration’ of PPD increases the risk of PPD sensitization more than prolonged exposure to a higher concentration of PPD, but with a longer time interval.



The European Society of Contact Dermatitis

Problem 6

The risk of developing a skin reaction and thus an allergy.

A contact allergy to hair dyes can also cause swelling of the neck and face, as well as obstruction of the respiratory tract.

Conclusions:

- The ideal self-test that doesn't cause active sensitization has not yet been developed.
- The number of surveys are insufficient to make exact predictions.



Other problems/difficulties regarding the skin test

- The responsibility of the manufacturer has shifted to the hairdresser/consumer.
- From a practical point of view, it is very difficult to carry out the self-test. It's difficult to tell a customer that s/he has to come back after 48 hours.
- Some sensitized individuals tend to keep dyeing their hair despite the risk of developing dermatitis and swelling.
- There is no standardized testing procedure, there is a lot of confusion.
- No information is provided about unwelcome side-effects, such as active sensitization. This information is essential for healthcare providers.
- No back-up system is available.



Other problems/difficulties regarding the skin test

- Nearly all tests may result in false-positive and false-negative results.
- The advantage of screening is that it is possible to detect and treat a condition at an early stage. The disadvantages include:
 - false-positive results: unnecessary investigations and treatments
 - false-negative results: positive test reactions may sometimes appear after several days. Hence, when restricting the test to 48 hours (2 days), false-negative readings may appear, resulting in a false sense of security.



General conclusions about the skin test

- A lack of clear scientific evidence
- The self-test increases the risk of developing an allergic reaction. Allergies will last a whole lifetime. Once acquired not only will rashes be caused by hair dyes, but also dyed leather clothing, black rubber and many other everyday products.

Conclusion:

According to scientists, the test is not reliable and has harmful effects on public health.

Repeated application of hair dye to the skin with the self-test could, in its current form, be compared to experimental human sensitization tests.



Economic consequences for hairdressers

- If hairdressers follow the instructions of manufacturers, they may lose customers.

If there is a positive skin test reaction, the hairdresser is obliged to send the customer away.

They simply go to another salon where no test is carried out. Thus encouraging the black economy!

- If hairdressers don't follow the instructions of manufacturers, they could be taken to court.



Option CEU: Abolish the self-test and replace it by questionnaires

- **Swedish Medical Agency Products** recommends that consumers do not carry out the test (unreliable, may cause sensitization/allergy)
- **COST Action StanDerm (150 scientific experts from 29 EU countries)**
Prof. Swen Malte John: “All scientific findings point in the same direction - the self-test is a tremendous and completely unrectified action leading consumers towards avoidable risks”
- **The paper ‘Issues that arise’ (2001):** the 30-month Irish research programme into the effects/results of following the testing procedures recommended by manufacturers. This report also questions the use of such tests.



Option CEU: Abolish the self-test and replace it by questionnaires

- **Scientific Committee on Consumer Safety (SCCS) and the former European Commission's Scientific Committee on Consumer Products (SCCP) share the opinion of the former Scientific Committee on Cosmetic Products and Non-food products intended for Consumers (SCCNFP):**
Predictive tests of potentially cutaneous sensitizing cosmetic ingredients or mixtures of ingredients should not be undertaken.
“Repeated hair dye application on the skin with the self-test could, in its current form, be compared with experimental human sensitization tests”



Cosmetic Forum (Ueapme) 14 January 2016

- CEU: FR, IRL, A, M, UK, B + Prof An Goossens KU Leuven
- Cosmetic industry: ICADA, COSMED, CNAIB, STANPA
- Conclusions of the discussion:
 - Cosmetic industry: rather convinced about our points of view
 - Main concern: PPD, at present : no alternative
 - Short term: Cosmetic Forum (Ueapme) with Cosmetic Europe



Thank you for your attention!

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