



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Allergy Alert Test (AAT) as a proof-of-concept study.

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

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Some hair dyeing products placed on the EU market contain the advice to assess skin sensitisation by performing a user test before dyeing the hair (“self-tests”). The exact protocol depends on the producer. In principle, the user applies the product to a small area of their skin and observes any signs of abnormal effects in the next 48 hours. Should they notice any such effects, they are advised to avoid using the hair dye and consult a medical professional.

In its opinion, SCCP/1104/07 - “Sensitivity to hair dyes-consumer self-testing”, the SCCP concluded the following:

- “There is a risk that “self tests” with hair dye products and with separate kits lead to misleading and false-negative results, thus giving individuals who are allergic to hair dye substances the false impression that they are not allergic or not at risk of developing an allergic reaction by dyeing their hair.*
- There is potential risk that “self tests” result in induction of skin sensitisation to hair dye substances.*
- Self-testing may offer protection to those individuals who perform the recommended test and develop a positive reaction. However, the proportion of hair dye chemical allergic individuals who do produce a positive reaction from this in vivo diagnostic test is unknown.”*

According to the applicant, so far no standardised approach to this type of test is in place. There is variation in the dose, site and duration of exposure. In addition, the consumer is expected to be able to perform the test and understand the alert signs.

The aim of the study in the current submission is to assess whether a defined self-test, referred to as Allergy Alert Test (AAT), can elicit a self-noticeable alert signal to a hair dye when performed by a layperson. Based on the study, the applicant recommends the following conditions for the AAT:

- Site of application: forearm
- Product: hair colouring product mixed with the developer in equal volumes (1:1 ratio), whenever relevant
- Amount of product applied: pea-size, spread evenly in a thin layer across a 2x2 cm skin area
- Application condition: open (not occluded)
- Duration of application: 45 minutes, followed by rinsing
- Self-evaluation period: 2 days (48 hours)

The applicant does not intend the AAT to be used for diagnosis of contact allergy.

2. Terms of reference

(1) In light of the study provided and the SCCP/1104/07 opinion, does the SCCS consider the new harmonized Allergy Alert Test (AAT), with the conditions listed above, a suitable test to provide a signal indicative of an allergic reaction to hair dyes when used by laypersons?

(2) Does the SCCS have any further scientific concerns regarding the AAT?

3. Deadline: June 2019

4. Supporting documents:

Cosmetic Europe's Dossier

The SCCS approved this mandate by written procedure on 21 December 2018.