EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Consumer Products

SCCP

Preliminary OPINION ON

Sensitivity to Hair Dyes - Consumer Self Testing

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risk

The SCCP approved for public consultation at its 12th plenary meeting on 19 June 2007

About the Scientific Committees
Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCP
Questions concerning the safety of consumer products (non-food products intended for the consumer).
In particular, the Committee addresses questions related to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.

Scientific Committee members
Claire Chambers, Gisela Degen, Ruta Dubakiene, Ramon Grimalt, Bozena Jazwiec-Kanyion, Vassilios Kapoulas, Jean Krutmann, Carola Lidén, Jean-Paul Marty, Thomas Platzek, Suresh Chandra Rastogi, Jean Revuz, Vera Rogiers, Tore Sanner, Günter Speit, Jacqueline Van Engelen, Ian White

Contact:
European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels
Sanco-Sc6-Secretariat@ec.europa.eu

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Dr. C. Chambers
Prof. V. Kapoulas
Prof. C. Lidén (rapporteur)
Prof. J.-P. Marty
Prof. T. Platzek (chairman)
Dr. S.C. Rastogi
Prof. T. Sanner
Dr. J. van Engelen

External experts

Dr. M.-L. Binderup	National Food Institute, Technical University of Denmark
Dr. H. Norppa	Finnish Institute of Occupational Health, Finland
Prof. K. Peltonen	Finnish Food Safety Authority, EVIRA, Finland
Dr. J. van Benthem	RIVM, the Netherlands

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1. BACKGROUND

Some hair dyeing products placed on the Community market contain the advice to assess skin sensitisation by performing a user test before dyeing the hair ("**self tests**"). To this end, the labelling advises to apply a small quantity of the hair dye on the skin.

COLIPA[1], in a "recommendation" on "Warnings on oxidising hair colouring product for consumer use" recommends a leaflet with the following 'safety instructions': "Perform a skin allergy test 48 hours before each product use" (full text of the recommended safety instruction in Annex I).

Some Member States have concerns and point at possible risks stemming from self tests.

The Cosmetics Directive does not contain an obligation for manufacturers/importers to provide for self-tests. Rather, Commission Directive 92/86/EEC of 21 October 1992 *lifted* the obligation to label the warning "sensitivity test advisable before use" for certain hair dyes[2].

This was a consequence of opinion SPC/54/92 of the Scientific Committee of Cosmetology (SCC) concerning current requirements for requesting user test for allergy before use of some hair dyes of 10 February 1992.

In this opinion, the SCC stated the following:

- Sensitivity testing "*should be performed by adequately trained dermatologists who will be medico-legally responsible for any problems related to false negative results and active sensitisation, and who are trained to evaluate any response and can give advice accordingly* "(p. 3)

- In particular, there is the risk that the consumer uses an "*unstandardised amount of dye to an unstandardised area of skin and that there is no occlusion*". As a consequence, "*although some PPD[3] allergic individuals will develop an easily observable reaction, an unknown number of individuals who are PPD[3] hair dye allergic will develop no reaction i. e. a false negative result, and some will be actively sensitised by the procedure*" (p. 4)

- The SCC concluded that "*the 'sensitivity testing' procedures suggested by manufacturers have to be considered as diagnostic tests. There is no published evidence of how helpful such non-standardised tests are in detecting PPD[3] sensitivity. There are numerous anecdotal reports of individuals who claim to have been tested with a hair dye as recommended by manufactures but who develop an allergic contact reaction when their hair is dyed. There are medico-legal implications in suggesting a test with an unknown sensitivity for detection and with poor standardisation. Further, such tests may be performed before a first hair dye, when allergy to PPD should not be present (no previous exposure) but not before subsequent colourings when allergy may have been acquired (because of ignorance)*" (p. 4)

However, since 1992, different views have been voiced on this issue. It has also been argued that self-test are beneficial to the consumer as they provide for a pre-screening of sensitisation (which may be followed-up by patch testing by a professional).

[1] COLIPA - European Cosmetics Toiletry and Perfumery Association
[2] Substances with reference numbers 8, 9 and 10 of Annex III
[3] p-Phenylenediamine

Therefore, the Commission deems it necessary to seek clarification from the Scientific Committee on Consumer Products (SCCP) on the risks and benefits of self-tests.

2. TERMS OF REFERENCE

In the light of the data available,

1. *Does the SCCP consider that there is a risk that:*

   - *Self-tests lead to false-negative results?*
   - *Self-tests lead to induction of contact allergy?*

2. *Does the SCCP consider that self-tests are beneficial for a specific population of hair dye users in order to detect existing sensitisations?*

3. ASSESSMENT

3.1. Introduction

Contact allergy and allergic contact dermatitis caused by hair dyes is an important and increasing health problem to consumers, hairdressers and society. Hair dyes are causing acute and severe dermatitis on the face, scalp and neck in consumers, and hand eczema in hairdressers. Several studies in Europe and in Asia show that contact allergy to p-phenylenediamine (PPD) has increased significantly in the general population, in dermatitis patients, and in hairdressers over the last decades (13, 14, 18, 24, 27). Positive patch test reactions to PPD were found in 3% of dermatitis patients in Europe and North America (4), in 4.8% of dermatitis patients in Germany (8), in 2.3% of the general population in Thailand (3), in 22% of hairdressers (dermatitis patients) in Germany (24) and 37% in Italy (9), and in 6% of hairdressers (non-patients) in the Netherlands (25).

The SCCP and the former SCCNFP have recently assessed the dossiers of 46 of the 117 hair dye substances of interest to industry regarding their skin sensitising property. In a memorandum on hair dye substances and their skin sensitising properties, based on adopted opinions on these 46 hair dye substances, 10 were categorised as extreme, 13 as strong and 4 as moderate skin sensitisers, all fulfilling the EU criteria for classification as a skin sensitiser (R43) (19).

Among the extremely potent skin sensitisers are PPD and related compounds that have been used for more than 100 years. More than two thirds of hair dyes currently used contain PPD. Other examples of much used hair dyes, known to be strong or extreme skin sensitisers, are Toluene-2,5-diamine (TDA), 4-Amino-2-hydroxytoluene, and p-Aminophenol (19, 21).

3.1.1. Diagnostic patch testing

Diagnostic patch testing is the procedure used for detection of contact allergy to substances. The test procedure is standardised with regard to test substances (European standard series, and other series), concentrations and vehicles, amount of test substance applied, test systems (occlusion), application site (upper back), application time (2 days), reading time (recommended on approximately 2, 4 and 7 days after application), and

grading scale for assessment of test reactions. When substances outside the standard series are tested, special care has to be taken not to cause harm to the patient by inducing allergy, irritation, scarring, pigmentation or other local effects, systemic effects, or by false-negative test results. Patch testing requires experience and should be performed by dermatologists with adequate training. (2, 12, 26)

The only hair dye substance in the European standard series for patch testing is PPD (at 1% in petrolatum). The preferred test concentration has varied over time and between authors, considering the risk of inducing allergy by patch testing versus the risk of false-negative result. The concentration has been lowered in some clinics (1), while other experts recommend that the current 1% PPD should be kept (7, 15). PPD has recently been deleted from the standard series in Germany because of the risk of active sensitisation observed from clinical data generated from a number of departments (20), however, active sensitisation has not been considered to be a problem elsewhere (6, 7).

3.1.2. "Self test" in relation to medicinal products

The Danish Medicines Agency has determined that the product "Colourstart" is a medicinal product according to section 2, n° 2 in the Danish Medicinal Products Act (5), as the product is meant to make a medical diagnosis. The decision for this was that "Colourstart" is a patch testing preparation containing PPD and intended for the purpose of identifying individuals who have an allergy to PPD. "Colourstart" is marketed to hairdressing salons in order to make it possible for the hairdresser to test people before permanent hair colour treatment. According to the Danish Medicinal Products Act, medicinal products must not be manufactured, imported, exported, stored, sold, supplied, dispensed or packed without authorisation from the Danish Medicines Agency, and no medicinal product may be distributed unless a marketing authorisation has been granted by the Danish Medicines Agency or granted according to regulation laid down by the Council of the European Union.

In a note on the question whether and under what circumstances allergy self-tests for hair dyeing products are medicinal products, it was stated by DG Enterprise and Industry, Consumer Goods, Pharmaceuticals (ENTR F/2), that devices for allergy self testing fall under the pharmaceutical legislation as defined in Directive 2001/83/EC, and that a product intended for the diagnosis of allergic reactions is to be authorised according to Directive 2001/83/EC (16).

In a second note on the question of whether hair dyeing products and related testing kits are to be classified as medicinal products, the view of DG Enterprise and Industry, Consumer Goods, Pharmaceuticals (ENTR F/2) was summarised (17):

1. Hair dye products with safety instructions including advice to test the product beforehand are not medicinal products, as they are presented as intended for hair dyeing and the function is to dye the hair.
2. Autonomous testing devices in order to assess the sensitivity to some components of hair dye fall under the pharmaceutical legislation as defined in Directive 2001/83/EC as they are devices for allergy self testing with the purpose to establish a diagnosis.
3. In kits containing hair dye and an additional testing device, the separate testing device is considered as a medicinal product, while the hair dye is not a medicinal product.

3.2. "Self test" recommended by industry

In a submission by COLIPA, it is stated that: "Some differences exist in the methodology recommended by individual hair colorant manufacturers. Recommended application sites include the scalp area close to the ear or the fold of the elbow. Some manufacturers

recommend application of the neat hair colorant or after mixing with hydrogen peroxide. The product may be rinsed after 45 minutes or left on the application site for 48 hours. These somewhat different methodologies reflect different regulatory requirements by non-European authorities specifying different test conditions." Examples of "self test" instructions by industry are given below.

> *"Carry out a sensitivity test 48 hours before the use of this product, even if you have previously used a hair colour product from this brand or any other brand.*
> *Sensitivity test: With surgical spirit clean an area of 1 cm^2 behind your ear and apply a small amount of the Nourishing Colour Cream contained in tube B with a cotton tip to the cleaned area; reapply 2 or 3 times and let dry in between. Carefully close the colorant tube again. Wait for 48 hours without washing. If during this period you notice itching or reddening do not use this product.*
> *In the case of an intense tingling sensation, a rash, or a burning sensation on the scalp rinse immediately with lukewarm water and discontinue use. Before attempting to use a hair colour product again consult your doctor." (Garnier Nutrisse)*

> *"Conduct a skin allergy test 48 hours before each product use even if you have already used colouring products before. This should be done like this:*
> *Sensitivity test: Perform the skin test on an area of skin sized approximately 1 cm x 1 cm on the inside of the elbow. Apply a small amount of the colour gel in a thin layer on the inside of the elbow with a cotton bud and leave uncovered for 45 minutes. Avoid contact with clothes. Close bottle again carefully. After 45 minutes, wash off the colour gel carefully with lukewarm water. If any reaction occurs during the processing time or during the following 48 hours, you should rinse immediately and not use this colorant.*
> *The absence of reaction to this test is no guarantee that an allergic reaction may not occur as a result of a future hair colouring process. However, this test is an important precaution. Please consult a doctor, if you have any doubts." (Schwarzkopf)*

Comments
The examples of "self test" instructions show that the procedure allows for large variation of crucial factors that are carefully standardised in clinical diagnostic patch testing.

1. The amount of substance applied is described as "a small amount" by 1, 2, or 3 applications.
2. The application time varies from 45 minutes to 48 hours.
3. The concentration of hair dye substance is not known, as the product is tested 'as is'. This may give up to 6% PPD or 10% TDA, the highest allowed concentration of some of the most potent skin sensitisers. Such exposure may induce sensitisation. The concentration may also be much lower than what is known to be relevant in patch testing, and the result may be false negative.
4. The reading time is up to 48 hours. This is known to be too short as patch test reactions may develop up to 7 days after application, and allergy may be missed.
5. It is difficult to understand how the test can be performed behind the ear (retro auricular area), by repeated application onto a 1 cm^2 area and how the reaction other than itching can be assessed by the subject.
6. The application site is either behind the ear or on the arm, while patch testing is done on the upper back for good reproducibility.
7. The application is open, while clinical diagnostic patch testing is performed by occluded application.
8. In clinical diagnostic patch testing, readings are undertaken by trained observers.

Summary
The "self test" gives extremely large and uncontrolled variation in dose, duration of exposure and other factors crucial for the outcome. The validity as a relevant test for contact allergy to hair dye substances is considered very low by the SCCP.

3.3. Human tests

Open tests with hair dyes

The following two experiments describe open testing of hair dye products but performed in a clinical setting.

Method:	Single open application
Subjects:	30 subjects (2 males and 28 females) with positive patch test reaction to PPD at routine investigation. 5 subjects were hairdressers. Allergy to other para-substituted derivatives was established (p-toluenediamine (n=12), disperse orange 3 (n=3), o-nitro-p-phenylenediamine (n=2)) 36 control subjects with a negative patch test to PPD and no history of adverse reactions to hair dyes.
Test product:	a marketed hair colorant containing 1.8% PPD and 6 other hair dye molecules at total concentration below 2% (2,4-Diaminophenoxyethanol HCl, Resorcinol, m-Aminophenol, o-Aminophenol, Hydroxybenzomorpholine, p-Aminophenol), matrix: water, surfactants (<30%), conditioning agents (<5%), alkalizing agents(<3%), antioxidants and stabilizers (<2%), perfume (0.5%)
Dosages:	0.1 ml applied by micropipette and combitips, spread manually over a surface of 1.75 cm^2, actual volume applied: approx. 0.085 ml

The retro-auricular area was wiped with alcohol. Circular adhesive devices (3M) were applied behind each ear. The test product was applied in the centre of one adhesive, the other was left empty as negative control. The adhesives were removed 1 hour after application, the test sites were marked. The test product was left for 48 hours without washing. Reactions were recorded on Day 0 (1 hour after application), Day 2 and Day 4. Recording was made by a scoring method evaluating the "overall clinical impression" as the severity of reaction (five-point grading scale according to Johansen et al. 1997); and by evaluation of parameters including area, erythema, papules/infiltration/oedema, vesicles/erosion, sensory manifestations (maximal total score 19).

Results
16/30 PPD-positive subjects and 13/30 PPD-negative subjects reacted on Day 0 with mild irritant reaction, low grade erythema and/or sensory manifestations. All 30 PPD-positive subjects reacted on Day 2 with erythema and infiltration. In 25/30 vesicles were observed. Sensory manifestations were recorded in 27/30. The reactions in 4/30 were evaluated with the maximal score (19/19). The reactions were evaluated as allergic. Maximal intensity of reactions was recorded on Day 2 in all but 2 subjects. The severity of reactions was reduced in most PPD-positive subjects on Day 4. 3/36 control subjects had mild erythematous reactions on Day 2.

Ref.: 11

Method:	Single open application
Subjects:	34 subjects (1 male and 33 females) with positive patch test reaction to PPD (+ to +++) at routine investigation in the last five years. 50 control subjects with a negative patch test to PPD and related allergens and no history of adverse reactions to hair dyes.
Test substances:	Product A: 0.1% PPD and other ingredients Product B: 0.5% PPD and other ingredients Product C: 1.0% PPD and other ingredients Product D: 1.5% PPD and other ingredients

	A, B, C, D contained ingredients such as resorcinol, m-Aminophenol, 2,4-Diaminophenoxyethanol ranging from 0.1% (A) to 1.64% (D) Control product Y: corresponding to A and B, without PPD or other colorant Control product Z: corresponding to C and D, without PPD or other colorant Matrices: water, surfactants (max. 30%), antioxidants, stabilisers (max 1%), perfume (max 0.5%)
Dosages:	0.1 ml applied by micropipette and combitips, spread over a surface of 1.75 cm^2 enclosed by adhesive devise. Actual volume applied: approx. 0.08 ml.

The PPD-positive subjects were tested consecutively with rising concentrations (A through D) and the corresponding control product, and a rest period of 3 to 6 weeks between two consecutive applications. When test products produced a definite allergic reaction (at least erythema with papules or homogenous infiltration/oedema) the subject was classified as SAT-positive (skin allergy test positive) and testing with products containing higher concentrations of PPD was discontinued. The PPD-negative control subjects were designated to testing with one of the products A-D respectively, and with the corresponding control product Y or Z.

The test product and the corresponding control product were applied after placing circular adhesive devices (3M) behind each ear. The adhesives were removed 1 hour after application. The test products were left for 48 hours without washing. Reactions were recorded on Day 0 (1 hour after application), Day 2 (48 ± 2 hours) and Day 4 (96 ± 2 hours). Recording was made by a scoring method including global evaluation of the severity of reaction (five-point grading scale according to Johansen et al. 1997); and by evaluation of parameters including area, erythema, papules/infiltration/oedema, vesicles/erosion, sensory manifestations (maximal total score 19). On day 2, the subjects were requested to report the earliest manifestations they had noted and the time of onset.

Results
27/34 PPD-positive subjects developed positive reaction when tested with product A (containing 0.1% PPD); 3/7 were positive to product B (containing 0.5% PPD); 3/5 were positive to product C (containing 1% PPD); and 1/1 was positive to product D (containing 1.5% PPD). Thus, all 34 PPD-positive subjects reacted positively to PPD-containing products tested.

Apart from one exception, no reaction was graded as positive in PPD-positive or PPD-negative control subjects to control product Y or in PPD-negative control subjects to product A, although several test sites showed low grade erythema which had remained unnoticed by the subjects. All reactions in PPD-negative control subjects tested with B, C or D and corresponding control product were graded negative. A PPD-negative control subject who reacted positively to product A and to the corresponding control Y was found positive to sodium metabisulfite present in A and B, and the subject was excluded from the control group.

The mean severity of reactions (overall clinical impression) to products A-D was strongest on Day 2. The test reactions were generally strong, 27/34 having vesicular reactions. All subjects reported that they had noticed a reaction, pruritus was the first symptom reported by 33/34.

Ref.: 10

Comment
The composition of the test products (A, B, C and D) and the control products (Y and Z) was not specified. The testing was not blind. The test products contained PPD. It is not possible to draw the conclusion that the sensitivity and specificity of the test would be the same, if

performed with other hair dye substances. It is not possible to draw conclusions concerning the performance if the test products are applied and reactions assessed by consumers themselves.

3.4. Discussion

Among dermatologists experienced in contact allergy and clinical diagnostic patch testing, it is well-known and generally agreed that:

- single occupational or non-occupational, open or occluded, exposure to some substances may induce sensitisation;
- patch testing may induce sensitisation to some substances;
- patch test reactions may become positive up to a week after application of the test substance; that it may be difficult to assess reactions to substances beyond the standard series; and that
- care must be taken when testing with substances and products beyond the standard series, due to the risk of causing harm to the patient by sensitisation, irritation, or false positive or false negative results.

These difficulties and concerns are the background to the general recommendation that patch testing (selecting substances for testing, preparing the patch test substances, applying the test, reading and interpreting the result) should be performed by skilled persons. Reading of test reactions should be performed on approximately Day 2, 4 and 7.
Ref.: 2, 12, 26

It is known that different anatomical sites have different sensitivity at patch testing, and the upper back is recommended due to best reproducibility and least false-negatives (26). In a dose-response study with PPD, however, no statistical difference in response was found between the upper back, lateral aspect of the upper arm and behind the ear when read by a skilled observer (22).

The "self test" recommended by COLIPA is not standardised and it is uncontrolled. It allows for very large variations in dose, number of applications, duration of exposure, etc. False-negative, but also false-positive results are expected, and sensitisation may occur as a result of repeated application of high concentrations of hair dyes which are potent skin sensitisers.

False negative results from "self testing" is considered to be the largest problem. False-negative results may cause harm to consumers, as they may lead to severe clinical reactions due to hair dyeing with substances to which the consumer is allergic.

There is a wide range of hair dye formulations. They contain different hair dye substances at different concentration and in combination with other substances, constituting individual hair dye products. The composition, including product matrix and presence of other chemicals, may affect the response at open or closed testing with hair dye products. Thus, it is not possible to extrapolate results from testing with a particular product to all other possible formulations.

The SCCP agrees with the statements in the opinion SPC/54/92 of the Scientific Committee of Cosmetology (SCC) of 10 February 1992 (23).

4. CONCLUSION

When a hair dye product is applied to the skin for the purpose of providing an indication as to whether the individual consumer may or may not have contact allergy to hair dye chemicals(s), the product is being used for *in vivo* diagnostic purposes.

In response to the questions asked, the SCCP is of the opinion that:

- 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.

The SCCP wishes to point out that the use of hair dye products on the skin and for *in vivo* diagnostic purposes is not covered by the current Cosmetics Directive.

5. MINORITY OPINION

Not applicable

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Annex I

Wording recommended by COLIPA for leaflet accompanying hair dyeing products according to "Recommendation to Members n° 17A "warnings on oxidising hair colouring products for consumer use"

LEAFLET

CAUTION:
Can cause an allergic reaction.
Avoid contacts with eyes. Rinse immediately if product comes into contact with them. Do not use to dye eyelashes or eyebrows. Rinse hair well after application. Wear suitable gloves.
Keep out of reach of children.

IMPORTANT: Hair colorants can cause allergic reactions which in rare instances can be severe. Tattoos may increase your risk of allergy. To reduce your risk follow these instructions.

SAFETY INSTRUCTIONS

1. DO NOT USE THE PRODUCT AT ALL IF:
- you have already experienced any reaction to colouring products.
- you have sensitive, irritated or damaged scalp.

In these cases consult a doctor before using any hair colour product.

2. PERFORM A SKIN ALLERGY TEST 48 HOURS BEFORE EACH PRODUCT USE even if you have already used colouring products before.

(Test protocol to be decided by each producer as well as the use of the following sentence:The absence of reaction to this test is no guarantee that an allergic reaction may not occur as a result of future hair colouring process. However, this test represents an important precaution. Please consult a doctor, if you have any doubts).

3. IF DURING COLOURING YOU EXPERIENCE
- any stinging or burning and/or rash, rinse immediately and discontinue use as this may be an indication of more serious reaction. DO NOT colour your hair again before consulting a doctor or seeking medical advice.
- rapidly spreading skin rash, dizziness or faintness, shortness of breath and/or swelling to eyes/face, rinse immediately and SEEK IMMEDIATE MEDICAL ATTENTION.

4. IF AFTER COLOURING OR ON THE FOLLOWING DAYS YOU EXPERIENCE problems such as skin or scalp itching, skin or scalp rash, swelling to eyes/face, blistering and/or skin or scalp weeping SEEK IMMEDIATE MEDICAL ATTENTION.