



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C – Public Health and Risk Assessment
C7 Risk assessment
Scientific Committee on Consumer Products

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS
7TH PLENARY MEETING

Held on 28 March 2006 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Dr. R. Grimalt, Prof. C. Lidén and Prof. J. Revuz.

2. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof. T. Platzek declared a conflict of interest in relation to the “Review of the SCCNFP opinion on hair dye strategy in the light of additional information”, point 7.2 of the agenda, due to his participation in the preparation of the dossier submitted for evaluation.

Taking into account the nature of the declaration, committee decided that Prof. Platzek could participate in the discussion, but could not be nominated as Rapporteur of the issue.

3. APPROVAL OF THE AGENDA

The draft agenda was approved.

4. APPROVAL OF THE MINUTES OF THE 6TH PLENARY MEETING

Minutes of the 6th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White informed the members about the work in the WG on the use of nano-substances/technologies in cosmetic products. He illustrated the mandate and the need for the expertise outside the SCCP.

Although only cosmetic ingredients are mentioned in the terms of reference, the Scientific Committee can draw the attention of the Commission on other relevant issues.

6. EMERGING ISSUES

Mrs A. Orloff (DG ENTR) mentioned the issue, raised in the USA, regarding allergic reaction from carmine. She said that the European Food Safety Authority (EFSA) is also aware of the problem and that DG ENTR will decide soon whether the SCCP will be asked for its opinion on the use of carmine in cosmetic products.

7. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

The adopted opinions will be published at:

http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm

7.1. ALTERNATIVES

Report of the Co-ordinator

Prof. Rogiers said that the following draft opinions were prepared:

Basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients, updated March 2006, doc. n° SCCP/0970/06

The SCCP has noticed that several dossiers have failed to fulfil the requirements as described in document SCCNFP/0750/03. In particular, a revision of hair dye dossiers revealed a number of problems.

The document is the result of the work of the expert group, SCCP members and external experts in the field of dermal absorption, whose task was to reach a consensus concerning a revision of the "SCCNFP basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients".

In order to make these criteria more widely known, it is intended to expand the chapter on dermal absorption in the SCCP Notes of Guidance, 6th revision.

A chapter related to specific aspects on nano-substances/technologies will be added as a separate annex to the document as soon as the opinion on "Nanosubstances in cosmetics" is adopted.

The paper was adopted.

Updated recommended strategy for testing oxidative hair dye substances for their potential mutagenicity / genotoxicity (SCCP'S Notes of Guidance), doc. n° SCCP/0971/06

In the 3rd plenary SCCP meeting of 15 March 2005, a temporary working group on mutagenicity/genotoxicity was established to update the existing opinion on "Recommended strategy for testing hair dyes for their potential genotoxicity/mutagenicity/carcinogenicity" [SCCNFP/0720/03].

The resulting final opinion will subsequently be taken up in the updated Notes of Guidance of the Committee, 2006.

It was agreed that the “study day” for the industry should be organised in the first quarter of 2007 in order to explain the requirements for all stakeholders.

Document was adopted.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof. T. Platzek reported on the work done during the 4 meetings of the WG that had taken place since the last plenary of 13 December 2005.

Draft opinions were prepared on:

A22, p-Methylaminophenol sulphate, doc. n° SCCP/0963/05

The SCCP was asked to answer the following questions:

- 1. Does the Scientific Committee on Consumer Products (SCCP) consider p-Methylaminophenol sulphate safe for use as an oxidative hair dyes with an on-head concentration of maximum 0.68% taken into account the scientific data provided?*
- 2. Does the SCCP recommend any restrictions with regard to the use of p-Methylaminophenol sulphate in oxidative hair dye formulations?*

The SCCP concluded that the use of p-methylaminophenol sulphate itself as an oxidative hair dye at a maximum concentration of 0.68% in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.

However, p-Methylaminophenol sulphate is a secondary amine, and thus is prone to nitrosation. It should therefore not be used in combination with nitrosating substances and the nitrosamine content should be < 50 ppb.

Also, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A31, 2-Methyl-5-hydroxyethylaminophenol, doc. n° SCCP/0957/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-Methyl-5-hydroxyethylaminophenol safe for use as an oxidative hair dye with an on-head concentration of maximum 1.5 % taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use of 2-Methyl-5-hydroxyethylaminophenol in oxidative hair dye formulations?*

The SCCP concluded that the use of 2-methyl-5-hydroxyethylaminophenol itself as an oxidative hair dye at a maximum concentration of 1.5 % in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer.

However, 2-methyl-5-hydroxyethylaminophenol is a secondary amine, and thus is prone to nitrosation. It should therefore not be used in combination with nitrosating substances and the nitrosamine content should be < 50 ppb.

Also, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A33, 1,2,4-Trihydroxybenzene, doc. n° SCCP/0962/05

The SCCP was asked to answer the following questions:

1. *Is 1,2,4-Trihydroxybenzene safe for use in hair dye formulations taken into account the data provided ?*
2. *Does the SCCP recommend any restrictions with regard to the use of 1,2,4-Trihydroxybenzene in hair dye formulations?*

The SCCP concluded that the information submitted is inadequate to assess the safe use of the substance.

Before any further consideration, the following information is required:

- Characterisation of the reaction product(s) to which the consumer is exposed, because of the reported instability of 1,2,4-trihydroxybenzene in aqueous systems.
- An *in vivo* micronucleus test to exclude the clastogenic potential.
- A thorough interpretation of the literature data should be done.
- Further testing on the potential to induce gene mutation is required.

This hair dye, like many other hair dyes, is a skin sensitiser.

The opinion was adopted.

A42, 2,4-Diaminophenoxy ethanol and its salts, doc. n° SCCP/0979/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2,4-Diaminophenoxyethanol in the form of its either dihydrochloride or sulphate salt safe for use as an oxidative hair dye with a concentration on-head of maximum 2.0 % taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use 2,4-Diaminophenoxyethanol in the form of its either dihydrochloride or sulphate salt in any oxidative hair dye formulations?*

The SCCP concluded that the use of 2,4-diaminophenoxyethanol HCL itself as an oxidative hair dye at a maximum concentration of 2.0 % in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.

However, no data were submitted on 2,4-diaminophenoxyethanol sulphate.

Also, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A84, 2-Amino-4-hydroxyethylamino-anisole sulfate, doc. n° SCCP/0958/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-Amino-4-hydroxyethylaminoanisole sulphate safe for use as an oxidative hair dye with a concentration on-head of maximum 1.5 % taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use 2-Amino-4-hydroxyethylaminoanisole sulphate in oxidative hair dye formulations?*

The SCCP concluded that 2-amino-4-hydroxyethylamino-anisole and its sulfate is not safe for use as a hair dye and should not be present in hair dyes or other cosmetic products.

A margin of safety of 65 has been calculated using data that was provided for an *in vivo* test in rat skin

As the value of the percutaneous absorption is critical to the calculation of the MOS, a skin penetration test using 2-amino-4-hydroxyethylamino-anisole sulfate and conforming to current Notes of Guidance for Safety Evaluation would be required before any re-evaluation of the substance.

The opinion was adopted.

A98, Hydroxyethyl-3,4-methylenedioxyaniline HCl, doc. n° SCCP/0951/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Hydroxyethyl-3,4-methylenedioxyaniline hydrochloride safe for use as an oxidative hair dye with an on-head concentration of maximum 1.5% taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use of Hydroxyethyl-3,4-methylenedioxyaniline hydrochloride in any oxidative hair dye formulations?*

The SCCP concluded that the information submitted is insufficient to assess the safe use of the substance. Hydroxyethyl-3,4-methylenedioxyaniline HCl is a secondary amine and thus prone to nitrosation. It should therefore not be used in combination with nitrosating substances.

Before any further consideration, the following information is required:

- The nitrosamine content should be given.
- Clarification on the problems with the stability of the test substance used in the prenatal developmental toxicity study (ref. 31).
- Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

This hair dye, like many other hair dyes, is a skin sensitiser.

The opinion was adopted.

A111, Dihydroxyindole, doc. n° SCCP/0952/05

The SCCP was asked to answer the following questions:

1. *Is Dihydroxyindole safe for use in hair dye formulations taken into account the data provided?*
2. *Does the Scientific Committee on Consumer Products (SCCP) recommend any restrictions with regard to the use of Dihydroxyindole in hair dye formulations?*

The SCCP concluded that the use of dihydroxyindole itself as a hair dye at a maximum concentration of 0.50% in the finished cosmetic product does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

A128, 6-Hydroxyindole, doc. n° SCCP/0947/05

The SCCP was asked to answer the following questions:

1. *Is 6-hydroxyindole safe for use in hair dye formulations taken into account the data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of 6-hydroxyindole in hair dye formulations?*

The SCCP concluded that the use of 6-hydroxyindole itself as an oxidative hair dye at a maximum concentration of 0.5 % in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.

However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

B99, 2-Amino-6-chloro-4-nitrophenol, doc. n° SCCP/0948/05

The SCCP was asked to answer the following questions:

1. *Is 2-Amino-6-chloro-4-nitrophenol safe for use in hair dye formulations taken into account the data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use 2-Amino-6-chloro-4-nitrophenol in hair dye formulations?*

The SCCP concluded that the use of 2-Amino-6-chloro-4-nitrophenol itself as a semi-permanent hair dye, or as a non-reactive colorant in oxidative hair dye formulations (after mixing with hydrogen peroxide at a ratio between 1:1 and 1:3) at a maximum concentration of 2.0 % in the finished cosmetic product does not pose a risk to the health of the consumer.

However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

This hair dye, like many other hair dyes, is a skin sensitiser.

The opinion was adopted.

C63, Acid Violet 43, doc. n° SCCP/0964/05

The SCCP was asked to answer the following questions:

1. *Is Benzenesulfonic acid, 2-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-, monosodium salt safe for use in hair dye formulations taken into account the data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of Benzenesulfonic acid, 2-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-, monosodium salt in hair dye formulations?*

The SCCP concluded that the information submitted is inadequate to assess the safe use of the substance as a hair dye.

Before any further consideration, the following information is required:

- Complete physico-chemical characterisation of the test substances;
- Further data to exclude the clastogenic potential.

The opinion was adopted.

Review of the SCCNFP opinion on hair dye strategy in the light of additional information, doc. n° SCCP/0959/05

The SCCP was requested to review, and if appropriate, to amend the overall assessment of the use of hair dyes and cancer risk as stated in the opinion SCCNFP/0484/01, 0797/04 and 0807/04 on the basis of currently available scientific information and taking into account the attached opinion of the Bundesinstitut für Risikobewertung, ‘‘Hair dyes on the Test Bench: Their Regulation at European level’’ (14 September 2004), in particular with regard to non-permanent hair dyes?

The SCCP concluded that, due to differences in technology of hair dye formulations, as well as in view of the epidemiological findings concerning various cancers, it supports differentiated approaches for the different types of hair dyes and that priority should be given to the evaluation and regulation of oxidative hair dyes.

The issue of sensitisation has not been addressed in this opinion.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that the following opinions had been prepared:

P97, Cetylpyridinium chloride, doc. n° SCCP/0985/06

The SCCP was asked to answer the following questions:

1. *Is the SCCP of the opinion that the information submitted is sufficient to allow an adequate risk assessment of cetylpyridinium chloride to be carried out?*
2. *If yes, is cetylpyridinium chloride safe when used as a preservative:*
 - a) *in mouthwashes cosmetic products up to the maximum authorised concentration of 0.1 %?*
 - b) *in all other oral hygiene cosmetic products up to the maximum authorised concentration of 1.0 %?*
 - c) *in skin lotions and creams up to the maximum authorised concentration of 0.2 %?*
 - d) *in anti-prespirant deodorants up to the maximum authorised concentration of 2.0 %?*
3. *Does the SCCP recommend any further restrictions on the conditions of use and a maximum authorised concentration for cetylpyridinium chloride when used as a preservative in cosmetic products?*

The SCCP concluded that the dossier is another example of an inadequate and poor submission provided by industry. It is impossible for the SCCP to assess whether cetylpyridinium chloride is safe for use in cosmetic products for the requested function and uses.

In view of the poor quality of the toxicological data presented in the dossier, a new dossier should be submitted in which data is provided to all relevant toxicological end-points and conforming to currently accepted standards.

The opinion was adopted.

Peru balsam, doc. n° SCCP/0988/06

The SCCP was asked to answer the following questions:

1. *Does the SCCP confirm that the ban proposed in the opinion SCCNFP/0771/03 and set out in the directive 2005/42/EC is restricted to the crude Peru Balsam only?*
2. *Does the SCCP confirm that the use for the consumers of Peru Balsam extracts and distillates are safe under the restrictions as proposed in the SCCNFP/0392/00?*

The SCCP concluded that the sentence “Peru Balsam (Myroxylon pereirae Klotzsch) CAS n° 8007-00-9: Peru balsam (the exudation from Myroxylon pereirae (Royle) Klotzsch) should not be used as a fragrance ingredient” in opinion n° SCCNFP/0771/03 of 9 December 2003 relates to the crude exudates only.

In response to questions 2, the SCCP concluded that opinion SCCNFP/0392/00 of 25 September 2001 clearly proposes that Peru Balsam extracts and distillates may be used as fragrance ingredients of cosmetic products up to a maximum concentration of 0.4 % in the finished cosmetic product.

The opinion was adopted.

Sclareol, doc. n° SCCP/0986/06

The SCCP was asked to answer the following questions:

- 1. On the basis of currently available information, the SCCP is asked to assess the risk to consumers when sclareol is present in cosmetic products, and if necessary, to revise the maximum concentration in fragrances used in cosmetic products considering the concentration limits or other restrictions suggested by industry.*
- 2. And/or does the SCCP recommend any further restrictions with regard to the presence of sclareol as an ingredient of fragrances used in cosmetic products?*

The SCCP concluded that the information submitted is inadequate to assess the safe use of the substance.

Before any further consideration, the following information is required:

- Characterisation of the test substance; clarification on purity and impurities.
- Data on sensitisation conforming to modern standards and guidelines.
- Appropriate information on all relevant toxicological endpoints as required to assess the safe use of the substance when used in cosmetic products.

The opinion was adopted.

Vetiveryl acetate, doc. n° SCCP/0984/06

The SCCP was asked to answer the following questions:

- 1. On the basis of currently available information, the SCCP is asked to assess the risk to consumers when vetiveryl acetate is present in cosmetic products, and if necessary, to revise the maximum concentration in fragrances used in cosmetic products considering the concentration limits or other restrictions suggested by industry.*
- 2. And/or does the SCCP recommend any further restrictions with regard to the presence of vetiveryl acetate as an ingredient of fragrances used in cosmetic products?*

The SCCP concluded that the information submitted is inadequate to assess the safe use of the substance.

Before any further consideration, the following information is required:

- Characterisation of the test substance; clarification on purity and impurities;
- Data on sensitisation conforming to modern standards and guidelines;
- Appropriate information on all relevant toxicological endpoints, as required, to assess the safe use of the substance when used in cosmetic products.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

Prof. Sanner said that the following opinions had been prepared:

Guidance document on epidemiological and clinical studies on Tooth Whitening Products, doc. n° SCCP/0974/06

On the basis of the data gaps identified in the SCCP opinion SCCP/0844/04 of 15 March 2005 concerning clinical data and long term epidemiological data to assess effects in the oral cavity the SCCP prepared a guidance document concerning the methodology of studies to be considered including product application, end points, size and definition of the study population(s) including subgroups, study duration and possibly other aspects.

The document was adopted.

Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes, doc. n° SCCP/0949/05

Prof. Sanner said that 26 comments were received in response to the public consultation on sunbeds, published on the SCCP web page and ending on 17 March 2006.

Comments were received from Public Health authorities (10), individuals (10), Medical Associations and Academia (2) and from industry and NGO (1).

The majority of the comments, especially from public health institutes, academia and health care professionals said that even more emphasise should be put on the negative effects of UV-radiation. Especially as the life-time cancer risk from UVR is quite high in comparison with some substances which have been banned. Other comments recommended to establish restrictions for people under the age of 18 and/or for people with skin types I and II. It was also said that the role of vitamin D is not enough understood to be mentioned as a positive effect. Other comments said that the positive effects of UV radiation are not sufficiently covered.

WG Meetings will be organised to consider all the comments received and to draft prepare the final opinion.

8. NEXT PLENARY MEETING

The 8th plenary meeting of the SCCP will take place on 20 June 2006.

9. ANY OTHER BUSINESS

- Exposure data: the secretariat will send a reminder to COLIPA regarding the exposure data. As agreed during a meeting with representatives from three companies, COLIPA would submit to the SCCP the individual data from these companies. Unfortunately, data provided by COLIPA concerned only the average exposure.

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products 7 th Plenary Meeting

Held on 28 March 2006
in Brussels

List of Participants**Members of the SCCP**

Dr. C. CHAMBERS, Prof. G. DEGEN, Prof. R. DUBAKIENE, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. J. KRUTMANN, Prof. J.-P. MARTY, Prof. T. PLATZEK, Dr. S. RASTOGI, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Prof. G. SPEIT, Dr. J. van Engelen, Dr. I.R. WHITE (Chair)

SCCP Secretariat (DG SANCO):

Mrs. C. DEKINDT, Mrs. T. PEETSO, Mrs M. PUOLAMAA, Mr. A. VAN ELST

DG ENTR F3: Mrs. B. MENTRE, Mrs. A. ORLOFF