



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
11TH PLENARY MEETING

Held on 21 March 2007 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Dr. R. Grimalt, Prof. V. Kapoulas, Prof. J. Krutmann and Dr. S.C. Rastogi.

2. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

3. APPROVAL OF THE AGENDA

The agenda was approved.

4. APPROVAL OF THE MINUTES OF THE 10TH PLENARY MEETING

Minutes of the 10th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

No issues were raised.

6. EMERGING ISSUES

No issues were raised.

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. V. Rogiers said that no meetings of the Working Party have taken place since the last plenary meeting. However, a meeting will take place on 5 June 2007 to discuss the actual status of alternative methods and in particular regarding cosmetic ingredients testing.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof. T. Platzek reported on the work done during the meetings of the WG that had taken place since the last plenary of 19 December 2006.

Draft opinions were prepared on:

A18, 1,5-Naphthalenediol, doc. n° SCCP/1060/06
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The SCCP was asked to answer the following questions:

Does the Scientific Committee on Consumer Products (SCCP) consider 1,5-naphthalenediol safe for use as an ingredient in both oxidative and non-oxidative hair dyes formulations with a concentration on the scalp of maximum 1.0% taking into account the scientific data provided?

The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out. Before any further consideration, an *in vitro* percutaneous absorption study should be performed following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The results from a LLNA study indicated that 1,5-naphthalenediol is a skin sensitiser.

1,5-Naphthalenediol itself has no mutagenic potential *in vivo*. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A19, 1,7-Naphthalenediol, doc. n° SCCP/1061/06
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The SCCP was asked to answer the following questions:

Does the Scientific Committee on Consumer Products (SCCP) consider the extension in the use of 2,7-naphthalenediol safe for consumers, when used as an ingredient in oxidative and non-oxidative hair dye formulations with a concentration on the scalp of maximum 1.0% taking into account the scientific data provided?

The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out. Before any further consideration, an *in vitro* percutaneous absorption study should be performed following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

2,7-naphthalenediol is a moderate sensitizer.

2,7-naphthalenediol itself has no mutagenic potential *in vivo*. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A43, 3-Amino-2,4-dichlorophenol HCl, doc. n° SCCP/1074/07

The SCCP was asked to answer the following questions:

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

The SCCP concluded that the use of 3-amino-2,4-dichlorophenol HCl 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, apart from its sensitising potential.

3-Amino-2,4-dichlorophenol HCl itself has no mutagenic potential *in vivo*. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

B51, 4-Amino-3-nitrophenol, doc. n° SCCP/1059/06
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The SCCP was asked to answer the following questions:

- 1. Does the Scientific Committee on Consumer Products (SCCP) consider 4-Amino-3-nitrophenol safe for use as non-oxidative hair dye with an on-head concentration of maximum 1.0% taken into account the scientific data provided?*

2. *Does the SCCP consider 4-Amino-3-nitrophenol safe for use as an oxidative hair dye with an on-head concentration of maximum 1.5% taken into account the scientific data provided?*
3. *Does the SCCP recommend any further restrictions with regard to the use of 4-Amino-3-nitrophenol in any non-oxidative or oxidative hair dye formulations?*

The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out. Before any further consideration:

- an *in vitro* percutaneous absorption study should be performed following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.
- an additional mutagenicity / genotoxicity test should be performed following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance in order to exclude a gene mutation potential.

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

4-Amino-3-nitrophenol is an extreme sensitiser.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

P72, Alkyl (C16, C18, C22) trimethylammonium chloride, doc. n° SCCP/1087/07

On 17 March 2006, the SCCP adopted an opinion on Alkyl (C16, C18, C22) trimethylammonium chloride, based on the safety dossier submitted by EFfCI/COLIPA.

On 28 June 2006, the EFfCI/COLIPA Consortium sent a letter requesting the European Commission to forward to the SCCP their comments on the opinion as well as to inform the SCCP of a testing strategy developed in response to the requests formulated by SCCP.

On the basis of these comments, the SCCP decided to re-evaluate the safety data and concluded that:

As far as systemic and local toxicity are concerned, the chemical analogy between the three compounds seems to permit a read-across approach for *cetrimonium chloride*, *steartrimonium chloride* and *behentrimonium chloride*.

The calculation of the Margin of Safety under 3.3.13 leads to a value of 192. Nevertheless, this value does not apply in cases where the final formulation (finished cosmetic products) containing

cetrimonium chloride, *steartrimonium chloride* and/or *behentrimonium chloride* is irritating to the skin and thus may increase the dermal absorption of the ingredient(s). Moreover, single human patch tests clearly showed that all combinations of quaternary ammonium compound concentrations and formulations lead to diverging results.

Considering the fact that quaternary ammonium compounds are known to be irritating, combination effects should also be taken into account. Therefore the following concentration limits should apply for rinse-off cosmetic products:

- the sum of the *cetrimonium* and *steartrimonium chloride* concentrations should not exceed 0.5%, and
- the total sum of *behentrimonium*, *cetrimonium* and/or *steartrimonium chloride* should not exceed a maximum level of 3%.

The submission requests evaluation of the use of these quaternary ammonium derivatives in leave-on (face)-cream products.

This dossier only allows the safety evaluation of quaternary ammonium compounds in leave-on cosmetic products when present in a maximum level of 0.1% (preservative or non-preservative).

The safety evaluation of the leave-on (face)-cream products containing these substances needs to be assessed on a case by case basis.

The opinion was adopted.

Clarification on conditions of use of 'Verbena', doc. n° SCCP/1073/06

The SCCP was asked to answer the following questions:

1. *Can the SCCP clarify whether the original advice not to use verbena essential oils and derivatives as stated in SCCNFP/0320/00 should not have had included derivatives such as concrete and absolute of verbena, but should solely have covered the crude verbena oil or the exudation of Verbena?*
2. *If yes, does SCCP consider that the restriction of 0.2% in the finished cosmetic product should cover not alone the absolute form of verbena as proposed in SCCNFP/0392/00 but also the concrete form?*

The SCCP recognises contradiction in the entries on 'Verbena (*Lippia citriodora Kunth*)' in the respective opinions.

However, and in order to respond to the questions asked, the following information is required:

- * Clarification of the botanical identity of the entry 'Verbena (*Lippia citriodora Kunth*)' as listed in the opinions SCCNFP/0320/00 and SCCNFP/0392/00, which were taken from the IFRA Guidelines;
- * Chemical identification/characterisation of fragrance ingredients derived from 'Verbena (*Lippia citriodora Kunth*)';

- * Sensitisation studies on the fragrance ingredients derived from 'Verbena (*Lippia citriodora Kunth*), conforming to current standards and guidelines.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

EGBE, doc. n° SCCP/1045/06

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider the use of EGBE as solvent in hair dyes in a concentration up to 4% in oxidative hair dyes and up to 2% in non-oxidative hair dyes safe for the consumer taken into consideration the scientific data provided?*
2. *If not, does the SCCP foresee any other restrictions to the safe use of EGBE?*

The SCCP concluded that, based on the information provided, the use of ethylene glycol monobutyl ether (EGBE) as a solvent at a concentration up to 4.0% in oxidative hair dye formulations and up to 2.0% in non-oxidative hair dye formulations, does not pose a risk to the health of the consumer.

The opinion relates to the direct application to the hair/scalp. It does not include any other cosmetic exposure, such as exposure from other type of cosmetics or possible aerosol/spray products.

The opinion was adopted.

Phthalates in cosmetic products, doc. n° SCCP/1016/06

The SCCP was asked to answer the following questions:

1. *Does the SCCP see any need to update its opinion on the safe use of diethyl phthalate (DEP) in cosmetics with the new scientific data provided?
If so, do the data provided by Greenpeace allow an assessment of the level of risk from current use and the determination of a safe consumer exposure from the scientific data provided?*
2. *Do the data provided by Greenpeace, the literature and where available, CSTE/SCHER and EFSA indicate a risk for the consumers from the presence of the following phthalates, (which have so far not been evaluated or regulated under the cosmetics directive), when present at the levels found by Greenpeace in cosmetic products: DMP, DIBP, DCHP, DINP and DIDP?
If so, do the data allow an assessment of the level of risk from current levels and the determination of a safe consumer exposure?*

3. *Do the data provided support the safety of traces of up to 100 ppm total or per substance in cosmetics products of those phthalates (DEHP, DBP and BBP), which are banned in cosmetics products?*

The SCCP concluded that:

- there is no need to update its opinion on the safe use of diethyl phthalate (DEP) (doc. n° SCCNFP/0441/01) in cosmetics on the basis of the new scientific data provided.
- despite there being a lack of adequate toxicological data for some of this group of phthalates, and in view of the low concentrations found in the samples of perfume analysed, there would be no quantifiable risk for the consumer.
- in view of the high Margin of Safety determined for DEHP, DEB and BBP, traces of up to 100 ppm total or per substance do not indicate a risk to the health of the consumer.

The opinion was adopted.

S12, Homosalate, doc. n° SCCP/1086/07

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider the continued use of Homosalate safe for the consumers, when used as an UV-filter in a concentration up to 10% w/w in cosmetic products taken into consideration the provided scientific data?*
2. *Does the SCCP consider the use of homosalate in a concentration up to 10% w/w in other products than sunscreen products safe for the consumer?*
3. *Does the SCCP foresee any other restrictions to the safe use of Homosalate?*

The SCCP concluded that, based on the information provided, the use of homosalate at a maximum concentration of 10% w/w in cosmetic sun screen product does not pose a risk to the health of the consumer.

Uses of homosalate in other types of cosmetic products at concentrations up to 10.0% also does not pose a risk to the health of the consumer.

Only the dermal application of homosalate was considered, not its use in 'spray'-applications.

The opinion was adopted.

Nano-materials in cosmetic products, doc. n° SCCP/1086/07

The draft opinion was discussed and re-addressed to the Working Group 'Nano-materials', asking to reconsider certain chapters, in particular the section on *in vitro* methods.

8. NEXT PLENARY MEETING

The 12th plenary meeting of the SCCP will take place on 19 June 2007.

9. ANY OTHER BUSINESS**- Dates of WG meetings:**

18 April	Hair Dyes
8 May	Hair Dyes
15 May	ad hoc substances + Fragrances & Preservatives
22 May	Hair Dyes
29 May	ad hoc substances + Fragrances & Preservatives
30 May	Nano-substances in Cosmetics
5 June	Alternatives
12 June	Hair Dyes

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products 11 th Plenary Meeting

Held on 21 March 2007
in Brussels

List of Participants**Members of the SCCP**

Dr. C.M. CHAMBERS, Prof. G. DEGEN, Dr. B. Jazwiec-Kanyion, Prof. C. LIDÉN, Prof. J.-P. MARTY, Prof. T. PLATZEK, Prof. J. REVUZ, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Prof. G. SPEIT, Dr. J. VAN ENGELN, Dr. I.R. WHITE (Chair)

SCCP Secretariat (DG SANCO)

Mrs. C. DEKINDT, Mrs. K. KILIAN, Mrs M. PUOLAMAA, Mr. A. VAN ELST

DG ENTR F3: Mrs. A. ORLOFF