



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
18TH PLENARY MEETING

Held on 16 December 2008 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Prof. J. Krutmann, Prof. J.-P. Marty and Prof. G. Speit.

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 as proposed.

4. APPROVAL OF THE MINUTES OF THE 17TH PLENARY MEETING

The minutes of the 17th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

No items were raised.

6. INFORMATION ON FOLLOW-UP ON OPINIONS

No items were raised.

7. NEW REQUEST / MANDATES AND OTHER EMERGING ISSUES

No issued were raised.

8. 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

8.1. ALTERNATIVES

Report of the Co-ordinator

Prof. V. Rogiers reminded the Committee about the ECVAM - validation of chemicals for HRT eye irritation assays: the assistance of the SCCP was sought regarding the generation of an inventory of reference chemicals with a potential for coded testing in prospective validation studies of HRT models for eye irritation assays.

She said that, at present, no decision is taken yet on the number and identity of the cosmetic ingredients that should be taken up in this pre-validation study.

8.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

There was a report on the work done during the meetings of the WG that had taken place since the last plenary of 30 September 2008.

Draft opinions were prepared on:

A53, tetra-Aminopyrimidine sulfate, doc. n° SCCP/1118/07
--

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2,4,5,6-Tetraaminopyrimidine sulphate safe for use in any hair dye formulation with an on-head concentration of maximum 2.0 % (as the free base) taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of 2,4,5,6-Tetraaminopyrimidine sulphate in any hair dye formulations?*

The SCCP concluded that the use of 2,4,5,6-tetraaminopyrimidine sulfate as an ingredient in oxidative and non-oxidative hair dye formulations with a maximum on-head concentration of 3.4% (2.0% free base) does not pose a risk to the health of the consumer.

A possible sensitising potential of 2,4,5,6-tetraaminopyrimidine sulfate cannot be excluded.

2,4,5,6-Tetraaminopyrimidine sulphate 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.

A155, 2,2'-Methylenebis-4-aminophenol HCl, doc. n° SCCP/1142/07

The SCCP was asked to answer the following questions:

1. *Does SCCP consider 2,2'-methylenebis-4-aminophenol HCl safe for consumers when used as an ingredient in oxidative and non-oxidative hair dye products with a maximum concentration of 2.0% on the scalp, taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use of 2,2'-methylenebis-4-aminophenol HCl in oxidative and non-oxidative hair dye formulations?*

The SCCP concluded that, because of the low margin of safety for the use in both oxidative and non-oxidative hair dye formulations, 2,2'-methylenebis-4-aminophenol HCl as a hair dye ingredient up to a final on-head concentration of 2.0% in the presence or absence of a developer-mix, poses a risk to the health of the consumer.

In addition, a gene mutation potential of 2,2'-methylenebis-4-aminophenol HCl cannot be excluded.

The opinion was adopted.

A156, 2-Methyl-1-naphthol, doc. n° SCCP/1163/08

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-methyl-1-naphthol safe for use in oxidative hair dye formulations with a concentration on-head of maximum 2.0% taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to ensure the complete hydrolysis of 1-acetoxy-2-methoxynaphthalene into 2-methyl-1-naphthol in oxidative hair dye formulations?*

Based on the chemistry of 1-acetoxy-2-methylnaphthalene (A153) and its *in situ* conversion to 2-methyl-1-naphthol, the relevant material for consideration in the context of the consumer risk assessment for hair dye products is 2-methyl-1-naphthol. Therefore, the toxicological evaluation only of 2-methyl-1-naphthol is relevant.

The physicochemical properties of 1-acetoxy-2-methylnaphthalene (A153) as well as the evaluation of the tests performed with this substance are reported in the Annex 1 to this opinion.

Assuming a complete hydrolysis of 1-acetoxy-2-methylnaphthalene, the SCCP concluded that, apart from the risks associated with the use of a strong sensitiser, the use of 2-methyl-1-naphthol as an ingredient in oxidative hair dye formulations at a maximum concentration of 2.0% on the head, does not pose a risk to the health of the consumer.

When both 2-methyl-1-naphthol and 1-acetoxy-2-methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-methyl-1-naphthol should not exceed 2.0%.

2-methyl-1-naphthol 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.

B1, Acid Yellow 1, doc. n° SCCP/1160/08

The SCCP was asked to answer the following question:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Acid Yellow 1 safe for consumers when used in oxidative hair dye formulations with a concentration on the scalp of maximum 1.0% taking into account the scientific data provided?*
2. *Does the SCCP consider Acid Yellow 1 safe for consumers when used in non-oxidative hair dye formulation with a concentration on the scalp of maximum 0.2% taken into account the scientific data provided*
3. *And/or does the SCCP recommend any restrictions with regard to the use of Acid Yellow 1 in any hair dye formulations?*

The SCCP concluded that, apart from the risks associated with the use of a sensitiser, the use of Acid Yellow 1 as an ingredient in oxidative hair dye formulations at a maximum on-head concentration of 1.0% and in non-oxidative hair dye formulations at a maximum on-head concentration of 0.2% does not pose a risk to the health of the consumer.

The stability of Acid Yellow 1 in oxidative hair dye formulations has not been demonstrated.

The opinion was adopted.

B5, Disperse Red 17, doc. n° SCCP/1161/08

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Disperse Red 17 safe for consumers, when used as an ingredient in non-oxidative hair dye formulations with a concentration on the scalp of maximum 0.2% taking into account the scientific data provided?*
2. *Does the SCCP consider Disperse Red 17 safe for consumers, when used as an ingredient in oxidative hair dye formulations with a concentration on the scalp of maximum 2.0% taken into account the scientific data provided*

The SCCP concluded that the safety of Disperse Red 17 can not be assessed based on the data submitted. Before any further consideration, an additional *in vivo* mutagenicity test should be performed to exclude the gene mutation potential of Disperse Red 17.

The stability of Disperse Red 17 in oxidative hair dye formulations has not been demonstrated.

A sensitising potential of Disperse Red 17 could not be excluded.

The opinion was adopted.

B60, 2-Nitro-5-glyceryl methylaniline, doc. n° SCCP/1162/08

The adoption of the opinion was postponed.

Intermediates and reaction products of oxidative hair dye ingredients, doc. n° SCCP/1198/08

The adoption of the opinion was postponed.

Updates

The following opinions were updated:

A43, 3-amino-2,4-dichlorophenol HCl, doc n° SCCP/1205/08

A44, 2-methylresorcinol, doc n° SCCP/1206/08

B51, 4-amino-3-nitrophenol, doc n° SCCP/1207/08

B72, 2-hydroxyethyl picramic acid, doc n° SCCP/1208/08

B73, HC Blue n° 12, doc n° SCCP/1209/08

8.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

Citric acid and silver citrate, doc. n° SCCP/1196/08

The adoption of the opinion was postponed.

P32, Triclosan, 1192/08

The adoption of the opinion was postponed.

P64, Climbazole, doc. n° SCCP/1204/08

The adoption of the opinion was postponed.

8.4. UV FILTERS AND AD HOC SUBSTANCES

Prof. Sanner said

DEGEE, diethyleneglycol monoethylether, doc. n° SCCP/1200/08

The SCCP was asked to answer the following question:

1. *Does the SCCP consider that an additional use of the substance DEGEE as solvent in an on-head concentration up to 7.0% in oxidative hair dye formulations and in an on-head concentration up to 5.0% in non-oxidative hair dye formulations is safe, taken into account the provided data?*
2. *And/or, does the SCCP have any further scientific concerns with regard to the overall use of DEGEE in cosmetic products in a concentration up to 1.5% and the additional use with an on-head concentration up to 7.0% in hair dyeing formulations?*

The SCCP concluded that the use of diethylene glycol monoethyl ether (DEGEE) as a solvent in an on-head concentration of up to 7.0% in oxidative hair dye formulations and in an on-head concentration of up to 5.0% in non-oxidative hair dye formulations in addition to the use of DEGEE at concentrations up to 1.5% in all cosmetic products except products for oral hygiene and eye products does not pose a risk to the health of the consumer, provided that the level of ethylene glycol in DEGEE used is < 0.2%.

The opinion relates to the dermal application of cosmetic products only and does not include any other cosmetic exposure, such as exposure from possible aerosol/spray products. Aggregate exposure to diethylene glycol monoethyl ether (DEGEE) from non-cosmetic sources has not been considered.

The opinion was adopted.

S38, Benzophenone-3, doc. n° SCCP/1201/08

The SCCP was asked to answer the following question:

1. *Does the SCCP consider Benzophenone-3 safe for use as an UV-filter in cosmetic products in a concentration up to 6.0% taken into account the scientific data provided?*
2. *And/or does the SCCP have any further scientific concerns with regard to the use of Benzophenone-3 as an UV-filter in cosmetic products?*

The SCCP concluded that the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation

does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential.

The opinion was adopted.

S57, camphor benzalkonium methosulfate, doc. n° SCCP/1202/08

The adoption of the opinion was postponed.

Tea Tree Oil, doc. n° SCCP/1155/08

The SCCP was asked to answer the following question:

1. *On the basis of the data provided, does the SCCP consider the use of Tea Tree Oil safe for the consumers when used in cosmetic products in concentrations as mentioned above?*
2. *Does the SCCP have any safety concerns for the use of Tea Tree Oil as an undiluted product?*

The cosmetic function of Tea Tree Oil needs to be indicated, as no clear cosmetic function was given by the applicant and several non-cosmetic applications are known.

When exposed to air and heat, Tea Tree Oil is prone to oxidation, yielding epoxides and further oxidation products which are considered to contribute to the skin sensitising potential of Tea Tree Oil. It is important to consider that certain formulations tend to reduce stability. According to the Code of Practice and the Guidance document introduced by the Australian Tea Tree Oil Association, safe processing and storage may be achieved which can be controlled by the p-cymene content.

Tea Tree Oil is a skin sensitiser. Skin sensitisation may also be enhanced by irritancy. Neat Tea Tree Oil and certain formulations at concentrations of 5% or more can induce skin and eye irritation.

Based on clinical data, the current use levels of TTO are shown to induce contact allergy.

Methyleugenol was reported as a minor constituent of Tea Tree Oil; the content should be indicated. According to the opinion SCCNFP/0373/00 on methyleugenol in fragrances the content in finished leave-on products should not exceed 0.0002 % (2 ppm) and in rinse-off products 0.001 % (10 ppm).

Following topical application of Tea Tree Oil and Tea Tree Oil containing products, percutaneous absorption of some constituents may occur, leading to a considerable systemic exposure, especially from neat oil, body lotion and foot spray/powder (see appendix). Because of inadequate dermal absorption studies available, the magnitude of systemic exposure to Tea Tree Oil from cosmetic products is uncertain. Only worst case estimations for NOAELs for general systemic and reproductive toxicity can be made. A Margin of Safety has not been calculated and the safety of Tea Tree Oil cannot be assessed.

Should there be reliable data on percutaneous absorption covering relevant concentrations and cosmetic formulations, a reassessment of the safety of Tea Tree Oil is envisaged by the SCCP.

The opinion was adopted.

9. NEW REQUESTS FOR OPINION

10. ANY OTHER BUSINESS

- Dates of meetings:

12 January 2009	WG "TTC"
21 January 2009	19 th plenary meeting

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products 18 th Plenary Meeting

Held on 16 December 2008
in Brussels

List of Participants**Members of the SCCP**

Dr. C.M. Chambers, Prof. G. Degen, Dr. B. Jazwiec-Kanyion, Prof. V. Kapoulas, Prof. C. Lidén, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. J. Revuz, 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. Istoc, Mrs. K. Kilian, Mr. A. Van Elst

DG ENTR F3

Mrs. A. Orloff