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
9TH PLENARY MEETING

Held on 10 October 2006 in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Dr. C. Chambers, Prof. R. Dubakiene, Prof. G. Degen, Prof. J. Krutmann, Dr. R. Grimalt and Prof. C. Lidén.

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 draft agenda was approved.

4. APPROVAL OF THE MINUTES OF THE 8TH PLENARY MEETING

Minutes of the 8th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. I.R. White, who is also the chairman of the working group on nano-substances, reminded that it was agreed earlier to invite two experts, in spite of their conflict of interest, to contribute in the scientific discussion due to their in-depth knowledge of the current industrial applications. The Committee concluded that the experts have made a very useful contribution to the scientific discussion, but should not participate in the forthcoming formulation of the scientific opinion.

6. EMERGING ISSUES

No issued 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. Rogiers presented the 6th revision of the Notes of Guidance. However, the adoption was postponed to the next plenary meeting of 19 December 2006 because the methods to calculate the Margin of Safety should be further discussed by the Working Group.

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 20 June 2006.

Draft opinions were prepared on:

A7, para-Phenylenediamine, doc. n° SCCP/0989/06

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider p-Phenylenediamine 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 of p-Phenylenediamine in any oxidative hair dye formulations?*

For the final safety assessment of PPD several aspects have to be taken into account:

- The SCCP considers PPD alone as being not genotoxic. But, positive findings from genotoxicity studies *in vivo/in vitro* of PPD in combination with couplers and /or hydrogen peroxide as well in a carcinogenicity study were reported.
- The generally accepted approach (MOS approach) according to the Notes of Guidance results in a Margin of Safety (MoS) of 77. However, when toxicokinetic studies are considered, a minimum MoS of 25 can be set. A number of toxicokinetic studies were performed and the applicant proposed to base the safety on the comparison of AUCs (area under curve). In this approach, the AUC in rats following a per-oral dosage of 4 mg/kg (corresponding to the NOAEL) was compared to the AUC in humans following

application of a hair dye containing ^{14}C-labeled PPD. In this case a safety margin of 16.3 was obtained which is not considered sufficient by the SCCP.

- On the other hand, experimental evidence was provided that PPD is metabolised in the skin to acetylated (i.e. detoxified) derivatives and, furthermore, that presumably activation of PPD (formation of mono-oxygenated derivatives) does not occur.

The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out. Before any further consideration, additional data would be required on *in vivo* genotoxicity and/or carcinogenicity of PPD in combination with hydrogen peroxide and couplers (to simulate consumer exposure). Further information is needed in supporting the applicant's view that the MoS was sufficiently high.

There is an increasing use of hair dyes by young people and additional exposure to PPD-related substances from temporary tattoos and clothing textiles. PPD is an extreme sensitiser and the risk of allergy occurring in the consumer should be realised.

The opinion was adopted.

A27, 4-Amino-2-hydroxytoluene, doc. n° SCCP/1001/06

The SCCP was asked to answer the following questions:

Does the Scientific Committee on Consumer Products (SCCP) consider 4-amino-2-hydroxytoluene safe for consumers, when used in oxidative hair dye formulations with a concentration on the scalp of maximum 1.5% taking into account the scientific data provided?

The SCCP concluded that the use of 4-amino-2-hydroxytoluene itself as an oxidative hair dye substance 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.

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.

A44, 2-Methylresorcinol, doc. n° SCCP/1002/06

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-Methylresorcinol safe for use in oxidative and non-oxidative hair dye formulations up to an on-head concentration of 1.8% taken into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of 2-Methylresorcinol in any oxidative and non-oxidative hair dye formulations?*

The SCCP concluded that the use of 2-methylresorcinol itself as an oxidative hair dye ingredient at a maximum concentration of 1.8% in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer.

Studies on the genotoxicity/mutagenicity of 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.

B48, HC Red n° 1, doc. n° SCCP/0981/06

The SCCP was asked to answer the following questions:

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

2. *Does the SCCP recommend any further restrictions with regard to the use of HC Red n° 1 in any non-oxidative hair dye formulations?*

The SCCP concluded that the use of HC Red n° 1 in semi-permanent hair dye formulation at a maximum final concentration of 1.0% does not pose a risk to the health of the consumer, apart from its sensitising property.

Studies on the genotoxicity/mutagenicity of 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.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

P32, Triclosan, doc. n° SCCP/1040/06

The SCCP was asked to answer the following questions:

1. *Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe taking into account the new provided documentation of resistance development by certain micro-organisms and cross-resistance?*

2. Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe for the consumer at the current concentration limit of maximum 0.3% taking into account the provided toxicological data?

Recent scientific papers (1, 7, 13, 14) and European institutions reports (2, 3, 4, 5) have expressed concerns about the indiscriminate use of biocides including triclosan. These concerns have been based on experimental studies and the theoretical association between increased occurrence of antibiotic cross-resistance and the use of biocides, including triclosan. Although probable, this link has not been fully demonstrated (9, 18).

Regarding question 1, the SCCP concluded that, on the basis of the available data, there is presently no evidence of clinical resistance and cross-resistance occurring from the use of triclosan in cosmetic products.
Information is required on consumer exposure to triclosan from all sources, including cosmetic products.

Regarding question 2:
For a toxicological assessment of the safe use of triclosan, the SCCP required a dossier to be submitted in which data is provided to all relevant exposure and toxicological end-points and conforming to currently accepted standards.
This should be regarded as a matter of urgency because triclosan has been identified in human milk of some European populations.

The opinion was adopted.

P82, Parabens, doc. n° SCCP/1017/05

The SCCP was asked to answer the following questions:

Does the SCCP consider the continued use of propyl, isopropyl, butyl and isobutylparaben in a concentration up to the existing 0.4% weight/weight as individuals or 0.8% when used in combination in cosmetic products safe for the consumer?

The SCCP concluded that its opinion n° SCCP/0873/05 of 28 January 2005 remains unchanged.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

S60, 4-Methylbenzylidene camphor, doc. n° SCCP/1042/06

The SCCP was asked to answer the following questions:

1. *On the basis of provided data the SCCP is asked to assess the risk to consumers when 4-MBC is used in sunscreen products?*

2. *Does the SCCP recommend any further restrictions for the use of 4-MBC in cosmetic products based on the provided information?*

The SCCP concluded that the majority of the questions raised by the SCCNFP in its opinion n° SCCNFP/0779/04 of 25 May 2004 were not been addressed. Neither the *in vitro* dermal absorption study nor the exposure data on other uses (cosmetic and non-cosmetic) and on oral intake when used in e.g. lip products were provided.

Consequently, the safe use of a maximum concentration of 4% 4-MBC in sunscreens could not be established.

The opinion was adopted.

Toluene, doc. n° SCCP/1029/06

The SCCP was asked to answer the following questions:

1. *Is toluene safe when used in cosmetic products for all groups of consumers independent of their age, taking into account the data provided?*

2. *Does the SCCP recommend any further restrictions with regard to its presence in cosmetic products or the use by different age (children) of consumers?*

For the present evaluation, measurements for two situations of nail product use were available:

- Home use conditions (non-ventilated rooms): toluene air levels of 1 - 4 ppm
- Client exposure in (ventilated) professional nail studios: 0.26 ppm

The duration of exposure is less than 30 min (typical application times 10-20 min). This exposure situation has been viewed in comparison to:

a) consumer exposure as characterized in the EU report on toluene (for two scenarios [U1 and U3A], for which there are at present no restrictions), and
b) occupational exposure limits (OEL) set for continuous 8 hour exposures where risks from levels of 25 to 50 ppm are considered as acceptable.

This comparison demonstrated that occasional consumer exposure to toluene present in nail cosmetics where the exposure may be within the range of 1 to 4 ppm could be considered as safe.

Although specific information related to the effects in children was limited and because of the low and occasional exposure, the SCCP concluded that the presence of toluene as a solvent in nail cosmetics does not pose a risk to the health of all groups of consumers, independent of their age.

This conclusion was based on an exposure driven evaluation of both, acute inhalation effects and reproductive toxicity.

The opinion was adopted.

DEGBE, DEGEE, EGBE

The adoption of the opinions on DEGBE, DEGEE and EGBE was postponed to the next plenary meeting of 19 December 2006.

The issues raised during the discussion on the 6th revision of the Notes of Guidance regarding the calculation of the Margin of Safety need to be solved before the opinions on these glycol ethers can be adopted.

8. NEXT PLENARY MEETING

The 10th plenary meeting of the SCCP will take place on 19 December 2006.

9. ANY OTHER BUSINESS

- **Dates of WG meetings:**

11 October	Nano-substances in Cosmetics
7 November	ad hoc substances & UV Filters+ Fragrances & Preservatives
14 November	Hair Dyes
22 November	Nano-substances in Cosmetics
28 November	ad hoc substances & UV Filters+ Fragrances & Preservatives
5 December	Hair Dyes
12 December	ad hoc substances & UV Filters+ Fragrances & Preservatives
19 December	Plenary Meeting

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
9th Plenary Meeting

Held on 10 October 2006
in Brussels

List of Participants

Members of the SCCP
Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. J.-P. Marty, Prof. T. PLATZEK, Dr. S. 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. DEKINDT, Mr. B. DELOGU, Mrs. T. PEETSO, Mrs M. PUOLAMAA, Mr. A. VAN ELST

DG ENTR F3: Mrs. A. ORLOFF