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
17TH PLENARY MEETING

Held on 30 September 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 and Prof. J.-P. Marty.

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 16TH PLENARY MEETING

The Minutes of the 16th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White reported on the following issues:

- Transatlantic Risk Assessment Dialogue: Representatives of the Commission, the Commission Scientific Committees and other EU risk assessment bodies attended a meeting in Washington on 10 and 11 July 2008, aimed to launch a structured transatlantic dialogue on risk assessment. It emerged from the discussion that many aspects of the subjects on the agenda of this meeting were of common interest.

- International Risk Assessment Conference in Brussels on 13 and 14 November 2008: The Conference is intended to be the first of regular, international and bi-annual conferences on risk assessment. It is aimed at facilitating a global dialogue amongst risk assessment bodies

and agencies in the EU and globally on both methodological and specific risk assessment issues, as well as on risk assessment policy matters.

- Renewal of the Scientific Committees: interested scientists may submit an application until 31 October 2008.

- Special Working Group meeting on *in vitro* mutagenicity testing: the current testing strategy is based on the possibility of a follow-up test *in vivo* when the *in vitro* tests are equivocal. The state of the art was discussed in the light of the *in vivo* testing ban which enters into force on 11 March 2009.

6. INFORMATION ON FOLLOW-UP ON OPINIONS

Mrs Orloff said that the next meeting of the Standing Committee on Cosmetic products would take place on 22 October 2008 during which draft Commission Directives to regulate toluene, vitamin K1, diethylene glycol, 4-aminobenzoic acid (PABA), diethylamino hydroxybenzoyl hexyl benzoate and tooth whitening products would be discussed.

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 reported on the following:

- ECVAM - validation of chemicals for HRT eye irritation assays: the assistance of the SCCP is 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.
For cosmetic ingredients, *in vivo* data exist on 77 non- or mild, on 33 moderate and on 22 severe eye irritants.
As about 30 compounds will be taken up in the pre-validation study, the Committee is asked to indicate how many and which (chemical class) substances should be included in the list.

- Next WG meeting is planned on 7 October 2008. The aim of the meeting is to discuss the issue of dermal absorption with external experts.

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 24 June 2008.

Draft opinions were prepared on:

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

The adoption of the opinion was postponed.

A80, Hydroxyethyl-p-phenylenediamine sulfate, doc. n° SCCP/1124/07

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider hydroxyethyl-p-phenylenediamine 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 hydroxyethyl-p-phenylenediamine sulphate in oxidative hair dye formulations?*

The SCCP concluded that:

- Based on the information provided, a margin of safety of 74 has been calculated suggesting that the use of hydroxyethyl-p-phenylenediamine sulphate as an oxidative hair dye at a maximum concentration of 1.5% in the finished cosmetic product (after mixing with hydrogen peroxide) poses a risk to the health of the consumer.

- The *in vitro* dermal absorption study was not carried out according to the basic criteria for dermal absorption of the SCCP (SCCP 0970/06). Therefore, for the safety assessment, the absorption as determined in the *in vivo* ADME study was used in the calculation of the MOS. It is known that dermal absorption through rat skin is higher than that through human skin.

The conclusion may be re-evaluated if an adequately performed *in vitro* dermal absorption study is available.

Hydroxyethyl-p-phenylenediamine sulfate is a strong sensitiser.

The opinion was adopted.

A143, 2,5,6-Triamino-4-pyrimidinol sulfate, doc. n° SCCP/1122/07

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider 2,5,6-triamino-4-pyrimidinol sulfate safe for use as an oxidative hair dye with a concentration of 0.5% on the head taken into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of 2,5,6-triamino-4-pyrimidinol sulfate in oxidative hair dye formulations?*

The SCCP concluded that that the safe use of 2,5,6-triamino-4-pyrimidinol sulfate as an ingredient in oxidative hair dye formulations at a maximum concentration of 0.5% on the head cannot be assessed.

The potential for induction of gene mutations has to be clarified.

A skin sensitising potential of 2,5,6-triamino-4-pyrimidinol sulfate cannot be excluded.

The opinion was adopted.

B7, Basic Brown 17, doc. n° SCCP/1173/08

The SCCP was asked to answer the following question:

Does the Scientific Committee on Consumer Products (SCCP) consider Basic Brown 17 safe for use as a non-oxidative hair dye with a concentration of maximum 2.0% taking into account the scientific data provided?

The SCCP concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

Before any further consideration:

- complete physico-chemical data must be submitted
- an *in vitro* percutaneous absorption study has to be performed following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance;
- the equivocal findings in the *in vitro* micronucleus test have to be clarified to exclude a genotoxic potential of Basic Brown 17.

A skin sensitising potential of Basic Brown 17 cannot be excluded.

The opinion was adopted.

B47, HC Orange n° 1, doc. n° SCCP/1164/08

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Orange n° 1 as safe for use as an ingredient in non-oxidative hair dye formulations with an on-head concentration of 1% taking into account the scientific data provided?*

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

The SCCP concluded that the use of HC Orange n° 1 as an ingredient in non-oxidative hair dye formulations with an on-head concentration of 1% (assuming 100% absolute dye content), does not pose any risk to the health of the consumer.

A skin sensitising potential of HC Orange n° 1 cannot be excluded.

The opinion was adopted.

C9, Basic Brown 16, doc. n° SCCP/1165/08

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider the use of Basic Brown 16 safe for consumers, when used as an ingredient in non-oxidative hair dye formulations with a concentration on the scalp of maximum 2.0% taking into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of Basic Brown 16 in non-oxidative hair dye formulations?*

The SCCP concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

To reach a definitive conclusion on the genotoxicity of Basic Brown 16, the potential to induce gene mutations has to be excluded.

Basic Brown 16 is a skin sensitiser.

The opinion was adopted.

Basic Orange 69, doc. n° SCCP/1116/07

The SCCP was asked to answer the following questions:

1. *Does SCCP consider Basic Orange 69 safe for consumers when used as a hair dye substance in semi-permanent hair dye formulations with a maximum 2.0% in the finished cosmetic product taken into account the scientific data provided.*

2. *Does SCCP consider Basic Orange 69 safe for consumers when used as a hair dye in oxidative hair dye formulations with a concentration of maximum 1.0% on the scalp taken into account the scientific data provided?*

The SCCP concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

Before any further consideration, the following information must be submitted:

- complete physico-chemical characterisation of Basic Orange 69 and its Zinc-Chloride salt;
- a repeated dose oral toxicity study;
- an *in vitro* dermal absorption study in accordance with the SCCP Notes of Guidance;
- an *in vitro* mammalian cell gene mutation assay was performed to exclude the potential to induce gene mutations.

The sensitising potential of Basic Orange 69 could not be excluded.

The opinion was adopted.

8.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that no opinions had been prepared by the Working Party since the plenary meeting of 24 June 2008.

8.4. UV FILTERS AND AD HOC SUBSTANCES

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

Kojic acid, doc. n° SCCP/1182/08

The SCCP was asked to answer the following question:

1. Does the SCCP consider the use of Kojic acid as a skin whitening or depigmenting agent in cosmetic products safe for the consumer?

2. Does the SCCP foresee any other concerns to the safe use of Kojic acid?

The SCCP concluded that:

Based on the information provided, margins of safety of respectively 35 (face and hands), 58 (hands) and 88 (face) have been calculated suggesting that the use of Kojic acid at a maximum concentration of 1.0% in skin care formulations poses a risk to the health of the consumer. In addition, other parts of the skin might be exposed to Kojic acid.

Kojic acid has the potential to induce skin sensitisation.

Relevant data on kinetics of Kojic acid after dermal application may be submitted to refine the MOS approach.

The opinion was adopted.

Tea Tree Oil, doc. n° SCCP/1155/08

The adoption of the opinion was postponed.

9. NEW REQUESTS FOR OPINION

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10. ANY OTHER BUSINESS

- Dates of meetings:

7 October	WG "Alternatives"
21 October	WG "ad hoc Substances" + "Fragrances & Preservatives"
29 October	WG "TTC (Threshold of Toxicological Concern)"
11 November	WG "Hair Dyes"
18 November	WG "ad hoc Substances" + "Fragrances & Preservatives"
25 November	WG "Hair Dyes"
10 December	WG "ad hoc Substances" + "Fragrances & Preservatives"
16 December	18th plenary meeting

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
17th Plenary Meeting

Held on 30 September 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