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
13TH PLENARY MEETING

Held on 2 October 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. J. Krutmann, Prof. C. Lidén, Prof. J.-P. Marty and Prof. J. Revuz.

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 12TH PLENARY MEETING

The Minutes of the 12th plenary meeting were approved without changes.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White I.R. reported on his meeting with the members of EP IMCO Committee on 12 September 2007.

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. V. Rogiers said that no meetings of the Working Group had taken place since the last plenary meeting of 19 June 2007. However, a meeting is planned on 27 November 2007, during which the work of the EPAA will be discussed.

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 21 March 2007.

Draft opinions were prepared on:

A5, Toluene-2,5-diamine, doc. n° SCCP/1084/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Toluene-2,5-diamine and its sulfate salt safe for use as an oxidative hair dye with a concentration on-head of maximum 4.0 % taken into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of Toluene-2,5-diamine and its sulfate salt in oxidative hair dye formulations?*

The SCCP concluded that the use of toluene-2,5-diamine cannot be considered safe based on the available data. This conclusion may be re-evaluated if human toxicokinetic data were to become available in which dosages used more closely approximate the intended use of the substance.

Clarification must be given on the myocyte degeneration in the dose range finding study of the 90 day study.

Toluene-2,5-diamine is an extremely potent skin sensitiser.

Toluene-2,5-diamine sulfate 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.

B52, 2-Hydroxyethylamino-5-nitroanisole, doc. n° SCCP/1099/07

The SCCP was asked to answer the following questions:

1. *Does Scientific Committee on Consumer Products (SCCP) consider 2-Hydroxyethylamino-5-nitroanisole safe for use as a non- oxidative hair dyes with a concentration of maximum 0.2 % taken into account the scientific data provided?*

2. *Does the SCCP recommend any further restrictions with regard to the use of 2-Hydroxyethylamino-5-nitroanisole in non-oxidative hair dye formulations?*

The SCCP concluded that, since 2-hydroxyethylamino-5-nitroanisole was positive in a gene mutation tests in bacteria, a proper genotoxicity test covering *in vivo* gene mutations was essential to definitively conclude on the genotoxicity of 2-hydroxyethylamino-5-nitroanisole.

2-Hydroxyethylamino-5-nitroanisole is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

This risk assessment relates to the use of 2-hydroxyethylamino-5-nitroanisole in non-oxidative hair dye formulations only.

The opinion was adopted.

B58, 3-Methylamino-4-nitrophenoxy ethanol, doc. n° SCCP/1089/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 3-methylamino-4-nitrophenoxyethanol safe for use as a non-oxidative hair dye with a concentration of maximum 0.15 % taken into account the scientific data provided?*

2. *Does the SCCP recommend any further restrictions with regard to the use of 3-methylamino-4-nitrophenoxyethanol in any non-oxidative hair dye formulations?*

The SCCP concluded that the use of 3-methylamino-4-nitrophenoxy-ethanol as a non-oxidative hair dye at a maximum concentration of 0.15% on the head does not pose a risk to the health of the consumer.

3-Methylamino-4-nitrophenoxy-ethanol is a secondary amine and should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

This risk assessment relates to the use of 3-methylamino-4-nitrophenoxy-ethanol in non-oxidative hair dye formulations only.

The opinion was adopted.

B77, HC Blue n° 11, doc. n° SCCP/1079/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Blue n° 11 safe for use as an ingredient in direct hair dye formulation with an on-head concentration of maximum 2.0 % taking into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of HC Blue n° 11 in non-oxidative hair dye formulations?*

The SCCP concluded that the use of HC Blue n° 11 as a non-oxidative hair dye at a maximum concentration of 2.0% on the head does not pose a risk to the health of the consumer, provided that the nitrosamine content is < 50 ppb.

The nitrosamine content in the test substance used in submission III was 1600 ppb. HC Blue n° 11 is both a secondary and a tertiary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

This risk assessment relates to the use of HC Blue n° 11 in non-oxidative hair dye formulations only.

The opinion was adopted.

B98, HC Violet n° 2, doc. n° SCCP/1081/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Violet No. 2 safe for use as a non-oxidative hair dye with a concentration 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 HC Violet No. 2 in any non-oxidative hair dye formulations?*

The SCCP concluded that the use of HC Violet n° 2 as a non-oxidative hair dye at a maximum concentration of 2.0% on the head does not pose a risk to the health of the consumer, apart from its moderate sensitising potential.

HC Violet n° 2 is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

This risk assessment relates to the use of HC Violet n° 2 in non-oxidative hair dye formulations only.

The opinion was adopted.

7.3. 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 21 March.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

Polidocanol, doc. n° SCCP/1130/07

The SCCP was asked to answer the following questions:

1. *Does SCCP consider the use of laureth-9 or polidocanol safe for consumers when used in rinse-off products at a maximum concentration of 4% or when used in leave-on products at a maximum concentration of 3% taken into account the scientific data provided?*

2. *And/or does the SCCP have any further concerns regarding the use of laureth-9 or polidocanol in cosmetic products?*

The SCCP concluded that the data included in this dossier demonstrate that polidocanol is of low toxicity and does not pose a risk to the health of the consumer when used up to 3% in leave-on and up to 4% in rinse-off cosmetic products.

Recent scientific evidence does not confirm the assumed local-anaesthetic effect of polidocanol. Thus, its presence in cosmetics and skin care products will not affect cutaneous sensation.

The opinion was adopted.

8. NEXT PLENARY MEETING

The 14th plenary meeting of the SCCP will take place on 18 December 2007.

9. ANY OTHER BUSINESS

Presentations were given on:

- Follow-up on the SCCP opinion on biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes.
  D. Eardley, DG ENTR and G. Straszburger, DG SANCO

- Information on Working Group 4 "Implementation of the 3Rs in regulation and decision-making" of the European Partnership for Alternative Approaches to Animal Testing (EPAA)
  C. Brekelmans, DG ENTR, Mrs. J. Scheel, EPAA

- Information on the planned recast of the Cosmetics legislation
  S. Fuehring, DG ENTR

- **Dates of WG meetings:**

19 October	Nano-substances in Cosmetics
23 October	ad hoc substances + Fragrances & Preservatives
30 October	Hair Dyes
13 November	ad hoc substances + Fragrances & Preservatives
21 November	Hair Dyes
27 November	Alternatives
11 December	ad hoc substances + Fragrances & Preservatives

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
13th Plenary Meeting

Held on 2 October 2007
in Brussels

List of Participants

Members of the SCCP
Dr. C.M. CHAMBERS, Prof. G. DEGEN, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. T. PLATZEK, Dr. S.C. 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. K. KILIAN, Mrs. G. STRASZBURGER, Mr. A. VAN ELST

DG ENTR F3
Mr. C. BREKELMANS, Mr. D. EARDLY, Mr. S. FUEHRING, Mrs. A. ORLOFF

EPAA (European Partnership for Alternative Approaches to Animal Testing)
Mrs. J. SCHEEL