



Scientific Committee on Consumer Safety (SCCS)

PLENARY

Venue: Luxembourg

Meeting date: 19 September 2013

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed the participants and took note of one apology. One external expert was also participating as rapporteur to present an opinion for adoption.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 18 JUNE 2013

These minutes were adopted during the summer and published on the website.

4. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No declaration of potential conflict of interest was made.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

- The chair of SCCS has been invited by EPAA for the 9th annual Conference (13/11/2013) and plans to participate.
- The assessment of CMR and the possibility of exchange of exposure data for risk assessment are issues being discussed among Commission services together with the relevant bodies such as EFSA and ECHA. The SCCS may be consulted through the Working Group on Methodology.
- Oral low bioavailability issue may be brought up to the agenda of the next Working Group on Methodology (14/11/2013).
- Industry published a “Guide on inhalation safety assessment for spray products” last June.
- A meeting for the annual review of workshops on allergens (IFRA) has been confirmed in Luxembourg on 13 December 2013. All SCCS members are invited by the Commission.

6. NEW MANDATES

Cosmetic Ingredients

- *METHYLISOTHIAZOLINONE II*: the members were informed about the Rapporteur appointed during the WG meeting on Cosmetic Ingredients.
- *ALUMINIUM IN COSMETIC PRODUCTS*: a Rapporteur was appointed. The dossier will be dealt with by the WG on Cosmetic Ingredients
- *FRAGRANCE VETIVERYL ACETATE*: a Rapporteur was appointed. The dossier will be dealt with by the WG on Cosmetic Ingredients.
- *FRAGRANCE 2-(4-TERT-BUTYLBENZYL)PROPIONALDEHYDE (BMHCA)*: a Rapporteur was appointed. The dossier will be dealt with by the WG on Cosmetic Ingredients.

Hair Dyes

- *Hair Dye Disperse Red 17 (B005)*: the members took note of the Rapporteur appointed during the WG meeting on hair dyes.
- *3-AMINO-2,6-DIMETHYLPHENOL (A 162)*: the members took note of the Rapporteur appointed during the WG meeting on hair dyes.

Nano

The SCCS was informed on the forthcoming submission through the new portal CPNP of the following mandate:

- Silica (nano) CAS n.112945-52-5; Hydrated Silica(nano) CAS n. 112926-00-8; Silica Silylate CAS n. 68909-20-6; Silica Dimethyl silylate (nano) CAS n. 68611-44-9 - the members decided that the Rapporteur will be appointed during the next WG meeting on nano (28/10).

A draft Memorandum on submission of data and quality of data will be finalised at the next nano working group and adopted through a written procedure.

7. DRAFT OPINIONS ON

Cosmetic Ingredients

- **PRESERVATIVE ETHYL LAUROYLARGINATE HCL (P95 - SUBMISSION IV)**
SCCS/1519/13

The SCCS was asked to answer the following questions:

1. In the light of the data provided, does the SCCS consider that Ethyl lauroylarginate HCl is safe for the consumers, when used as preservative up to a maximum concentration of 0.15 % in oral cosmetic products?
2. Does the SCCS have any further scientific concerns with regard to the use of Ethyl lauroylarginate HCl in cosmetic products?

The SCCS considers Ethyl lauroylarginate HCl safe for use as a preservative, when used up to a maximum concentration of 0.15% in mouthwashes, though not in oral cosmetic products as a whole.

As no human data concerning local toxicity of Ethyl lauroylarginate HCl in toothpaste are available, the safety of Ethyl lauroylarginate HCl in toothpaste cannot be assessed.

The opinion was adopted. Editorial work is still needed prior to publication.

- **TGA- THIOGLYCOLIC ACID AND ITS SALTS**

The opinion has been discussed. The work is planned to be finished by end of October before going through written procedure for adoption.

Hair Dyes

- **A8, 2-Chloro-p-phenylenediamine SCCS/1510/13**

The SCCS was asked to answer the following questions:

1. Does SCCS consider 2-chloro-p-phenylenediamine safe for use as oxidative hair dye for eyebrows and eyelashes in a concentration of maximum 4.6 % taken into account the scientific data provided?
2. And/or does the SCCS recommend any further restrictions with regard to the use of 2-chloro-p-phenylenediamine in any hair dye formulations for eyebrows and eyelashes?

The SCCS considers that no sufficient margin of safety could be deduced for the use of 2-chloro-p-phenylenediamine in oxidative hair dye formulations for eyebrows and eyelashes in a concentration of maximum 4.6 % taking into account the scientific data provided.

2-Chloro-p-phenylenediamine is categorised as at least a 'strong' sensitiser.

A complete chemical characterisation of 2-chloro-p-phenylenediamine is needed.

The SCCS is of the opinion that, based on the available data and the lack of a proper in vivo test for gene mutation induction, it is not possible to give a conclusion on the genotoxic potential of 2-chloro-p-phenylenediamine.

Therefore, the use of 2-chloro-p-phenylenediamine cannot be considered safe for the consumer.

The opinion was adopted. Editorial work is still needed prior to publication.

- **C169, *Lawsonia inermis* (Henna) SCCS/1511/13**

The SCCS was asked to answer the following questions:

1. Does the SCCS consider that the safe use of henna (*Lawsonia inermis*) in cosmetics, especially as a hair dye, can be established based on the available scientific data? Would the SCCS suggest concentration limits for the use of henna (*Lawsonia inermis*) in cosmetic products?
2. In case the safe use of henna (*Lawsonia inermis*) cannot be established based on the available scientific data, does the SCCS consider that the proposed in vivo testing following test guideline OECD 474 on batch 1271 is necessary and appropriate to obtain the data that will allow a conclusive safety assessment?
3. In addressing the necessity and appropriateness of the proposed in vivo test, could the SCCS in particular address the following questions:
 - is there a need for confirmatory animal testing given that there is already animal data available from two earlier in vivo tests?
 - could the additional required data be obtained based on non-animal approaches?
 - will the proposed testing of batch 1271 provide the necessary data to allow a subsequent safety assessment of henna (*Lawsonia inermis*)?

The SCCS is of the opinion that the information provided is sufficient to assess the safe use of Henna as a hair dye. The assessment is based on the Henna batches 1271 and 830.72 and relates to a Lawsone content of max. 1.4%. When formulated and applied as indicated under functions and uses, e.g. 100 g Henna powder mixed with 300 ml boiling water Henna is considered safe for the consumer.

Other kinds of extracts of Henna that may have different compositions are not covered by this assessment.

The traditional and current expanding use of Henna Rot (*Lawsonia inermis*) as a body-paint has not been assessed.

Additionally, a reassessment of the genotoxicity of Lawsone by the SCCS is desirable.

The opinion was adopted. Editorial work is still needed prior to publication.

Methodology

The chair of that Working Group reported briefly on the content of the meeting held on 18 September focusing on genotoxicity. Minutes will be published.

The nano Working Group will discuss this issue further in order to propose some guidance for nano materials.

8. COMMENTS ON OPINIONS FROM PLENARY IN 2013

• PARABENS

(SCCS/1514/13)

The members agreed with the reply to the different questions that are not amending the opinion.

- **ACID BLACK - B15** (SCCS/1492/12)

The members postponed the discussion to the next Hair Dye working group meeting (11/10).

- **TiO2** (SCCS/1516/13)

The draft replies to the different questions that are not amending the opinion will be finalised during the next nano Working Group meeting (28/10) and be adopted through a written procedure.

(SEE ALSO POINT 6. NANO: cf. DRAFT MEMORANDUM)

9. DISTRIBUTION OF TASKS

Tasks were distributed among SCSS members.

10. ANY OTHER BUSINESS

Next **Plenary meeting: 12 December 2013**

THURSDAY 27 MARCH 2014

WEDNESDAY 18 JUNE 2014

Next WG meetings for information:

08 October 2013: WG on Cosmetic Ingredients

11 October 2013: WG on Hair Dyes

28 October 2013: WG on Nanomaterials in cosmetic products

29 October 2013: WG on Cosmetic Ingredients

14 November 2013: WG on Methodology: oral low bioavailability

22 November 2013: WG on Cosmetic Ingredients

25 November 2013: WG on Nanomaterials in cosmetic products

26 November 2013: WG on Hair Dyes

04 December 2013: WG on Nanomaterials in cosmetic products

13 December 2013: IDEA review of workshops on allergens (IFRA)

11. ANNEX : LIST OF PARTICIPANTS

Annex

List of Participants

Members of the SCCS

Dr Ulrike Bernauer, Dr Qasim Chaudhry, Prof. Gisela Degen, Dr Elsa Nielsen, Prof. Thomas Platzek (Chair), Dr Suresh Chandra Rastogi (Vice-Chair), Dr Christophe Rousselle, Dr Jan van Benthem, Prof. Pieter-Jan Coenraads, Dr Maria Dusinska, Dr Werner Lilienblum, Prof. David Gawkrödger (Vice-Chair), Prof. Andreas Luch, and Prof. Manfred Metzler

Apology

Prof. Nancy Monteiro- Rivière

SCCS Secretariat (DG SANCO C2)

Mrs Donata Meroni, Ms Natacha Grenier, Ms Diana Herold

DG SANCO B2

Mrs Federica de Gaetano