



Scientific Committee on Consumer Safety (SCCS)

8th PLENARY

Venue: Luxembourg

Meeting date: 16 December 2014

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. There was one apology.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 23 SEPTEMBER 2014

The minutes were adopted on 20/10/2014 through written procedure 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

- SCCS Member Andreas Luch officially resigned due to the heavy workload. His resignation was accepted. The SCCS Secretariat informed about a call for experts in cosmetic risk assessment launched on 27 November with a deadline for applications on 11 January 2015.
- *New Chairs* of working groups (Hair Dyes/Fragrances and Cosming) *were appointed*.
- *P.J. Coenraads* informed about his participation in the IDEA workshop on categorization and characterization of fragrance allergens (September 24-25, 2014).
- *Th. Platzek* informed about his participation in Gastein European Health Forum "fragrances allergens" workshop (2-3 October 2014), in the ICADA event on "endocrine disruptors" (27 November 2014) and about his participation in the European Food Safety Authority (EFSA) and the World Health Organization (WHO) event that have embarked on a project to review the science underlying the concept of the Threshold of Toxicological Concern (TTC) – 2nd December 2014
- *Information about ECHA workshop* on Topical Scientific Workshop on Regulatory Challenges in Risk Assessment of Nanomaterials (23-24 October 2014) will be sent to the members.

- SANCO E3 informed the SCCS about state of play of Roadmap and Impact Assessment *on Endocrine Disruptors*, including on the ongoing public consultation until mid-January. The SCCS is planning to send its contribution via a Memorandum.

6. NEW MANDATES

Mandates were adopted; rapporteurs appointed for:

Cosmetic ingredients

- Dichloromethane (CAS No 75-09-2). Submission IV
- Methylisothiazolinone CAS 2682-20-4 (MI) (P94) - *in rinse-off and leave-on hair products up to concentration limit of 100 ppm*
- S86 UV filter

Hair Dyes

- Hair dye 2,5,6-Triamino-4-pyrimidinol sulfate (CAS 1603-02-7) (A143). Submission III
- Basic Brown 124 – addendum to the mandate only → no oxidative formulation

Nanomaterial in cosmetic ingredients

- *UV-filter:2,2'-methylene-bis-[6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]* - COLIPA S79 (CAS No 103597-45-1). Submission III

7. DRAFT OPINIONS ON

Joint opinion SCCS/SCENIHR/SCHER

• **SYNBIO – OPINION II**

The SCCS adopted the preliminary opinion on Synbio II concerning risk assessment methodologies.

Cosmetic Ingredients

- **ADDENDUM TO OPINION ON PRESERVATIVE ETHYL LAUROYL ARGINATE HCl -P95:** this opinion was adopted and will be published. The SCCS was asked to answer the following questions:

1) In the light of the data provided, does the SCCS consider that Ethyl Lauroyl Arginate HCl is still safe for the consumers at current use in all cosmetic product including oral products, considering the exposure from other sources, such as food?

The SCCS considers Ethyl lauroyl arginate 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.

2) In particular does the SCCS consider that Ethyl Lauroyl Arginate HCl is safe considering the specific age groups who might be particularly susceptible to the effects of total exposure to Ethyl Lauroyl Arginate HCl, used in both cosmetic and food products?

The exposure estimations provided suggest that for the subgroup ‘Children’ the ADI may be exceeded when adding food exposure (using the 95th exposure percentile) and cosmetic exposure. However, the amounts stemming from dermal exposure should not be added when using the ADI based on the low NOAEL used by EFSA. To the

maximum amount of 0.442 mg/kg bw/day (food exposure, 3 year old children, 12 kg body weight, 95th exposure percentile) only 0.29 mg/kg bw/day from oral exposure should be added resulting in a total exposure of 0.73 mg/kg bw/day. In contrast, when considering 9 year old children (body weight 25 kg) the oral exposure from cosmetics would be 0.14 mg/kg bw/day and the sum would be 0.58 mg/kg bw/day. Both of these values (0.58 and 0.73 mg/kg bw/day) are not covered by the ADI. The SCCS considers the use of Ethyl Lauroyl Arginate in mouthwashes for children at the concentration of 0.15% for longer time periods as not safe.

3) Does the SCCS have any further scientific concerns with regard to the use of Ethyl Lauroyl Arginate HCl in cosmetic products?

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

- **SCCS MEMORANDUM ON ENDOCRINE DISRUPTORS:** this Memorandum was adopted. It will be published. It is also planned to introduce this document into the public consultation system of the Commission, as informed above.
- **CYCLOPENTASILOXANE (D5):** this draft opinion was discussed and further contributions from the members are expected by the next WG meeting (20/01/15).

Hair Dyes/Fragrances

- **FRAGRANCE 2-(4-TERT-BUTYLBENZYL) PROPIONALDEHYDE – BMHCA :** this opinion was discussed and SANCO B2 agreed that the adoption is postponed until the SCCS will get some clarification or data by the next WG meeting (21/01/15).
- **FRAGRANCE VETIVERYL ACETATE:** this opinion was adopted. The SCCS was asked to answer the following questions:

The main concern with the safety assessment of the fragrance ‘vetiveryl acetate’ is that it is a mixture of many different constituents and that the composition of the fragrance will vary considerably depending on the origin of the grass *Vetiveria zizanioides* from which the crude vetiver oil is derived, as well as the different manufacturing processes of the fragrance from the vetiver oil.

In the absence of knowledge of the composition of the test substances used in the submitted studies, the relevance of test results is questionable.

1. On the basis of currently available information, does the SCCS consider vetiveryl acetate safe for use as fragrance ingredient in cosmetic leave-on and rinse-off type products in a concentration limit(s) according to the ones set up by IFRA as reported above?

In the previous opinion on vetiveryl acetate the SCCP was of the opinion that the information submitted was inadequate to assess the safe use of the substance. Before further consideration, information such as characterisation of the test substance and clarification on purity and impurities was required (SCCP/0984/06).

Based on the newly submitted studies, the safety of vetiveryl acetate on the market cannot be evaluated as only partial and insufficient information on the composition of vetiveryl acetate on the market is reported and as no information is provided on the composition of the test substances used in the submitted toxicological studies.

Adequate information regarding chemical characterisation and quantification of constituents of 'vetiveryl acetate' on the market, including the concentration range of the constituents, is required. Furthermore, documentation and justification is required allowing judgement whether the test substances used in the submitted toxicological studies can be considered representative for what is considered as 'vetiveryl acetate' on the market.

2. Does the SCCS have any further scientific concerns with regard to the use of vetiveryl acetate as fragrance ingredient in cosmetic leave-on and rinse-off type products?

Based on the available data, there is evidence that vetiveryl acetate has skin and eye irritation potential and is a moderate skin sensitiser. Concern was raised in the previous opinion (SCCP/0984/06) that vetiveryl acetate may also have a phototoxic potential; however, based on the submitted data, the photosensitising / photoirritation and phototoxic potential of the test substances cannot be evaluated.

Genotoxicity data are inadequate to exclude the genotoxic/mutagenic effects of vetiveryl acetate which were observed in an Ames test. There was no justification for the use of alpha-tocopherol. New data on genotoxicity of vetiveryl acetate without inclusion of alpha-tocopherol need to be provided.

On the basis of the inadequate data provided, a reliable safety assessment cannot be performed whether vetiveryl acetate on the market is safe for use in cosmetics at the concentration limits proposed by the IFRA. However, due to the major concern of genotoxicity the SCCS considers vetiveryl acetate as not being safe as a cosmetic ingredient.

- **BASIC BLUE 124:** this opinion was adopted. The SCCS was asked to answer the following questions:

1. In light of the data provided, does the SCCS consider Basic Blue 124 safe when used as a direct hair dye in semi-permanent hair dye formulations at on-head concentration up to a maximum of 0.5% (w/v)?

The safety of Basic Blue 124 cannot be assessed since no final conclusion on mutagenicity can be drawn without further studies to exclude gene mutation potential.

2. Does the SCCS have any further scientific concerns with regard to the use of Basic Blue 124 in cosmetic products?

The SCCS considers Basic Blue 124 a strong skin sensitiser. Basic Blue 124 is a tertiary amine. It should not be used together with nitrosating agents. Total nitrosamine content should be < 50 ppb.

Methodology

The Chair of that Working Group reported briefly on the content of the meetings held on 8 October, 4-5 November and 10 December. The revision of the SCCS Notes of Guidance (NoG) text is not complete yet and is planned to be finalised during the next WG meeting (18-19/02/15).

8. COMMENTS ON OPINIONS

Cosmetic Ingredients

- **PHMB** – poly(hexamethylene) biguanide hydrochloride– SCCS/1535/14
The SCCS updated the content of the opinion in accordance to the results of the new dermal absorption study, and conclusion accordingly. Replies to comments will be sent out. The updated version of the opinion will be replacing the previous one and will be published. A new commenting period will be allocated until the end of January.
- **FORMALDEHYDE IN NAIL HARDENERS** – SCCS/1538/14
The SCCS updated the content of the opinion in accordance to comments received, mainly editorial. Replies to comments will be sent out. The updated version of the opinion will be replacing the previous one and will be published.
- **HYDROLYSED WHEAT PROTEIN** - SCCS/1534/14
The revised version of the opinion was adopted on 22/10/2014 by written process and published already, replacing the previous version.

Nanomaterial in cosmetic ingredients

- **CLARIFICATION REQUEST** *from Member States on the meaning of the term “sprayable applications/products” for the nano forms of carbon Black, TiO₂ and ZnO* – SCCS/1539/14
The SCCS adopted its responses that will be sent out, as well as the revised opinion that will replace the previous version and will be published.

9. ANY OTHER BUSINESS

Next working group meetings

20/01, 04/03/2015: WG on cosmetic ingredients
18-19/02/2015: WG on methodology
21/01, 05/03/2015: WG on hair dyes
16/01, 23/02, 13/03/2015: WG on nano in cosmetics

Next plenary meetings

25 March 2015, 25 June 2015, 29 September 2015, 15 December 2015.

List of Participants: see Annex I

Annex I: List of Participants

Members of the SCCS

Ulrike Bernauer, Pieter-Jan Coenraads, Gisela Degen, Maria Dusinska, Werner Lilienblum, Andreas Luch, Elsa Nielsen, Thomas Platzek (Chair), Suresh Chandra Rastogi (Vice-Chair), Christophe Rousselle and Jan van Benthem

Apologies

Qasim Chaudhry (Vice-Chair)

SCCS Secretariat (DG SANCO C2)

Stefan Schreck, Natacha Grenier and Diana Herold

DG SANCO B2

Federica de Gaetano and Gaetano Castaldo