



Scientific Committee on Consumer Safety (SCCS)

4th PLENARY

Venue: Luxembourg

Meeting date: 12 December 2013

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed the participants and took note of two apologies. Two external experts were also participating as rapporteur to present the relevant opinion for adoption.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 19 SEPTEMBER 2013

These minutes were adopted on 24/10 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 reported on his presentation made at EPAA for the 9th annual Conference (13/11/2013). See [annexed presentation](#).
- A member reported on his participation in the workshop organized by IPCS on uncertainties in hazard assessment. See [annexed presentation](#).
- 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 The SCCS has been consulted on a draft guidance document through the Working Group on Methodology and SCCS comments/proposed changes have been sent to the relevant Commission service.
- DG SANCO, together with the International Fragrance Association, IFRA, is organising a workshop to report on the progress of the IDEA project about risk assessment methodologies, processes and criteria to identify fragrance allergens of concern. Further details on that project can be found at: <http://www.ideaproject.info/>. All SCCS members have been invited by the Commission, together with Academia, Fragrance Industry, Commission

departments and Agencies, and civil society representatives. Potential dates for the 2014 workshops have been forwarded to the members for their information and/or potential participation.

6. NEW MANDATES

Cosmetic Ingredients

- **BORON COMPOUND, TPO** - Trimethylbenzoyldiphenylphosphine oxide, & **KOH**: a Rapporteur was appointed for each of the dossiers during the last WG meeting on Cosmetic Ingredients.
- **NOTE:** *FRAGRANCE VETIVERYL ACETATE*: AND *FRAGRANCE 2-(4-TERT-BUTYLBENZYL)PROPIONALDEHYDE (BMHCA)*: the dossiers have been switched into the WG dealing with Hair Dyes due to the overload of the WG on Cosmetic ingredients.

Hair Dyes

- **A161- HYDROXYETHOXYAMINOPYRAZOLOPYRIDINEHCL, & BASIC BROWN 17 (B007)**: the members took note of the Rapporteur appointed for each of the dossiers during the last WG meeting on Hair Dyes.
- **FRAGRANCE TAGETES– SUBMISSION IV (PHOTOTOX ONLY)**: the members nominated a Rapporteur. This new dossier on fragrance will be added in those already dealt with in the WG meeting on Hair Dyes.

Nano

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 Chair of the WG on nanomaterials in cosmetic products informed the members about the ongoing gap analysis for each part of the dossier of the above mandate on Silica, in order to get back to the applicant as foreseen by the new Regulation. A launch of a call for information may be prepared as well, should this be required for the risk assessment. This dossier will be further discussed at the next WG meeting on nanomaterials in cosmetic products on 13/01/2013.

7. DRAFT OPINIONS ON

Cosmetic Ingredients

- **TGA- THIOGLYCOLIC ACID AND ITS SALTS** **SCCS/1520/13**
The opinion was adopted by written procedure on 11 November 2013 and published under a commenting period until 6 January 2014: see http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/
- **METHYLISOTHIAZOLINONE II – P94** **SCCS/1521/13**

The SCCS was asked to answer the following questions:

1. *On the basis of the new evidence in relation to sensitizing potential, does the SCCS consider Methylisothiazolinone (MI) still safe for consumers, when used as a preservative in cosmetic products up to concentration limit of 100 ppm? If no, it is asked to SCCS to revise this concentration limit on the basis of information provided.*

Current clinical data indicate that 100 ppm MI in cosmetic products is not safe for the consumer.

For leave-on cosmetic products (including ‘wet wipes’) no safe concentrations of MI for induction of contact allergy or elicitation have been adequately demonstrated.

For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the view of induction of contact allergy. However no information is available on elicitation.

2. *Does the SCCS have any further scientific concerns with regard to the use of Methylisothiazolinone (MI) in cosmetic products?*

MI should not be used as an addition to a cosmetic product already containing MCI/MI. More frequent review of data (than suggested in SCCS/1482/12) to monitor sensitisation frequencies of MI and related isothiazolinone preservatives is recommended. This permits trends in consumers’ sensitisation to be observed and timely intervention to be taken.

Information on the actual concentration of MI present in individual cosmetic products will allow future evaluation of safe concentrations.

Labelling is only helpful to a consumer who has a known (established by diagnostic patch test investigations) allergy. It is unknown what proportion of the general population is now sensitized to MI and has not been confirmed as sensitized.

Since MI is widely used in other consumer products (eg. detergents, paints), also exposures from such sources should be assessed.

Consumers cannot find information on the presence of MI in products except in cosmetics and household detergents because, as yet, there is no harmonised classification of MI as a skin sensitizer. The risk for skin sensitization by MI is at least equivalent to that of other substances which have received a harmonised classification according to the CLP Regulation.

- **BORON COMPOUND**

SCCS/1523/13

The SCCS was asked to answer the following questions:

1. *Based on the current knowledge on the chemistry of borates, tetraborates and octaborates, does the SCCS consider that these compounds break in the product, due to contact with water, into boric acid?*

The SCCS is of the opinion that all the substances mentioned above (borates, tetraborates and octaborates) as well as other boric acid salts/esters reported in CosIng database such as MEA-borate, MIPA-borate, potassium borate, trioctyldodecyl borate, zinc borate break in the product due to contact with water into boric acid.

2. *If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to boric acid should apply to the whole group of borates?*

SCCS considers that these compounds have chemical, biological and toxicological properties similar to boric acid. Therefore the general restrictions applicable to boric acid should apply to the whole group of borates.

Hair Dyes

- **BISMUTH CITRATE**

SCCS/1499/12

The SCCS was asked to answer the following questions:

1. *Does SCCS consider that the use of bismuth citrate as an hair dye substance in cosmetic products is safe for the consumers when used in a concentration up to maximum 2.0 % taken into account the provided scientific data?*
2. *Does SCCS have any other scientific concerns for the safe use of bismuth citrate in finished cosmetic products?*

From the data provided by the applicant, SCCS cannot assess the safety of bismuth citrate. Following information is required to evaluate the safety of bismuth citrate.

A complete and adequate physico-chemical characterisation of Bismuth citrate is needed.

Skin and eye irritation studies are required at the concentration of 2% as applied for by the applicant.

A local lymph node assay (LLNA) in mice was claimed to be negative when using 10 to 50% bismuth citrate dissolved in DMSO. Clarification regarding conflicting information on the solubility of Bismuth citrate in DMSO is required before the test can be accepted as valid.

The mutagenicity of bismuth citrate can presently not be assessed given the studies provided. A complete set of *in vitro* studies according to the current Notes of Guidance is required.

- **DISPERSE RED 17 (B005) - SUBMISSION IV**

SCCS/1522/1

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider Disperse Red 17 safe for use as an ingredient in non-oxidative hair dye formulations with a concentration on the scalp of maximum 0,2% taken into account the scientific data provided?*
2. *Does the SCCS consider Disperse Red 17 safe for consumers, when used as an ingredient in oxidative hair dye formulations with a concentration on the scalp of maximum 2.0% taken into account the scientific data provided?*
3. *And/or does the SCCS recommend any restrictions with regard to the use of Disperse Red 17 in oxidative and non-oxidative hair dye formulations (e.g. max conc. in the finished cosmetic product, dilution ratio with hydrogen peroxide, warning)?*

The SCCS considers that Disperse Red 17 as an ingredient at 0.2% in non-oxidative hair dye formulations and at 2% in oxidative hair dye formulations is safe for the use by consumers.

The nitrosamine content in Disperse Red 17 should be < 50 ppb, and it should not be used in the presence of nitrosating agents.

A sensitising potential of Disperse Red 17 cannot be excluded.

This safety assessment of Disperse Red 17 is based on the specification for use as a hair dye ingredient as described in Section 3.1.4.

Nanomaterial in cosmetic ingredients

- **CARBON BLACK**

SCCS/1515/13

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider Carbon Black, CI 77266 in its nano form safe for use as a colorant with a concentration up to 10 % in cosmetic products taking into account the scientific data provided?*

On the basis of the available evidence, the SCCS has concluded that the use of carbon black CI 77266 in its nano-structured form with a size of 20 nm or larger at a concentration up to 10% as a colorant in cosmetic products, is considered to not pose any risk of adverse effects in humans after application on healthy, intact skin. However, on the basis of the evidence provided, an eye irritation potential of carbon black cannot be completely excluded.

This opinion does not apply to applications that might lead to inhalation exposure to carbon black nanoparticles, where the preparation might lead to inhalable particles.

2. *Does the SCCS have any further scientific concern with regard to the use of Carbon Black, CI 77266 in its nano form as a colorant in cosmetic products?*

The purity of carbon black nanomaterials used in cosmetic products should be >97%. The impurity profile of carbon black should be comparable with those nanomaterials tested for toxicity in this submission and should also comply with FDA specifications with respect to carbon black produced by furnace method¹.

In the evidence provided in the submission, imaging was considered the only practical method by the applicant for investigating skin penetration. The use of this method is considered by the SCCS as only semi-quantitative. Other methods need to be explored.

¹Ash content < 0.15%, total sulphur < 0.65%, total PAH < 500 ppb and benzo(a)pyrene <5 ppb, dibenz(a,h)anthracene < 5 ppb, As < 3 ppm, Pb < 10 ppm, and Hg < 1 ppm).

This opinion is based on the currently available scientific evidence, which shows an overall lack of dermal absorption of carbon black nanoparticles. If any new evidence emerges in the future to show that the carbon black nanoparticles used in cosmetic products can penetrate skin (healthy, compromised, sunburnt or damaged skin) to reach viable cells, then the SCCS may consider revising this assessment.

Since the skin absorbance studies have only been performed with carbon black nanoparticles ≥ 20 nm, the current opinion applies to nano-structured form of carbon black with a particle size of 20 nm or larger. Additional information will be required on the use of carbon black with particles smaller than 20 nm size intended for use in cosmetic products.

- **MEMORANDUM ON SUBMISSION OF DATA AND QUALITY OF DATA SCCS/1524/13**

Conclusion:

The relevance, adequacy and quality of the data presented in a dossier are of utmost importance in relation to the smooth and transparent evaluation of safety of nanomaterials used in cosmetic products. In this regard, the key message in this Memorandum is that the data provided in a dossier in support of nanomaterial safety must be relevant to the types of nanomaterials under evaluation, sufficiently complete, and of appropriate standards to allow adequate risk assessment. Further details on the aspects to be considered in relation to safety assessment of nanomaterials in cosmetic products are provided in the SCCS Nano-Guidance (SCCS/1484/12).

Methodology

The Chair of that Working Group reported briefly on the content of the meeting held on 14/11 that focused on low bioavailability. Minutes have been published already. The follow-up of this meeting is foreseen on 28/03/2014 together with a discussion on BMD approach (if time allows); in addition, on 17/02/2014 will be held a general Methodology WG meeting to discuss genotoxicity again, sensitisation issue, and the possible revision of the SCCS Notes of Guidance.

8. COMMENTS ON OPINIONS FROM PLENARY IN 2013

- **P95, Ethyl Lauroyl ArginateHCl (SCCS/1519/13)**
Additional information provided by the applicant after the publication of this opinion on tradenames and section 3.1.8 are amending the (revised) opinion through an Annex II. It will be published.
- **B15, Acid Black 1 (SCCS/1492/12)**
The draft replies to the different questions that are also amending the opinion have been adopted. Senders will be informed accordingly and the revised opinion will be published.
- **S-75, TiO₂ (nano-form) (SCCS/1516/13)**
The draft replies to the different questions took more time than foreseen due to their lengthiness. Some are amending the opinion as well. Both the replies and the revised opinion have been adopted provided that a last clarification will be received from the applicant. Senders will be informed accordingly. The revised opinion will be published.

- **S76, Addendum to Opinion on Zinc oxide (nano-form) (SCCS/1489/12)**
The draft replies to the different questions have been adopted and are not amending the opinion. The institutions/companies/persons that sent comments on the addendum will be informed accordingly.

9. DISTRIBUTION OF TASKS

Tasks were distributed among SCSS members.

10. ANY OTHER BUSINESS

The SCCS Secretariat reminded the SCCS members that the annual declaration of potential risk of conflict of interests will be done prior to the next Plenary meeting (23/03/14) and stressed the importance of the completeness and accuracy of this exercise.

- Next Working group meetings

13 January 2014:	WG on nanomaterials in cosmetic products
14 January 2014:	WG on cosmetic ingredients
21 January 2014:	WG on hair dyes
31 January 2014:	WG on nanomaterials in cosmetic products
17 February 2014:	WG on methodology (notes of guidance, genotox, sensitisation)
18 February 2014:	WG on cosmetic ingredients
13 March 2014:	WG on nanomaterials in cosmetic products
14 March 2014:	WG on cosmetic ingredients
28 March 2014:	WG on methodology (low bioavailability and notes of guidance)
07 April 2014:	WG on nanomaterials in cosmetic products

- Next Plenary meetings

27 March 2014
18 June 2014
23 September 2014
16 December 2014

11. ANNEX: LIST OF PARTICIPANTS

Annex

List of Participants

Members of the SCCS

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

Apology

Prof. Nancy Monteiro- Rivière and Dr Jan van Benthem

SCCS Secretariat (DG SANCO C2)

Ms Natacha Grenier and Ms Diana Herold

DG SANCO B2

Ms Federica de Gaetano