



Scientific Committee on Consumer Safety (SCCS)

9th PLENARY

Venue: Luxembourg

Meeting date: 25 March 2015

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants.

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 28/01/2015 through written procedure and published on the website.

4. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair requested members to declare any conflict of interest regarding matters on the agenda. One member declared that from 1st April 2015 his Institute will be owned by a commercial partner entity which is not dealing with cosmetics. The Commission is assessing this declaration (see also minutes of the nano WG meeting held on 13 March for further details).

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

- The Commission provided information about the new basic Decision/next call for membership, which is planned during the summer.
- The Commission reported about its visit to ECHA to foster cooperation and the exchange of relevant REACH data.
- The resignation of SCCS Vice-Chair *Suresh Rastogi* will take effect on 1st July 2015, due to personal reason.
- Additional SCCS external experts have been selected after an open call for expression of interest, by the Secretariat and the Chair and Vice Chairs. They have been invited to participate in working groups meetings on cosmetic ingredients and hair dyes. Their CV and declarations of commitment, interest and confidentiality will be posted on the website. The SCCS welcomed this support in order to cope with the increased workload and to continue to deliver opinions of high quality.

- *Pieter –Jan Coenraads* informed about the SCCS participation in the 2nd annual IDEA workshop in Luxembourg on 17 December 2014 and its follow-up. The members also agreed he will represent the SCCS at the next workshop in June.
- SCCS Chair *Thomas Platzek* informed that the UEAPME Conference foreseen on 20 January 2015 in Brussels was postponed.
- *Ulrike Bernauer* informed about the SCCS participation in Joint Symposium on Nanotechnology – 5-6 March 2015, in Berlin.
- SCCS Chair *Thomas Platzek* reported on the outcome of the ICCG meeting held on 24 March.
- The Commission informed that the Secretariat of the scientific committees will be visiting EFSA/JRC in June.
- *Christophe Rousselle* informed he'll participate as SCCS observer in the first "BMD approach meeting" organised by EFSA on 15 April.
- *Gisela Degen* has been invited to participate and give a lecture on Endocrine Disruptors in a Cosmetics Europe event mid-June. The SCCS agreed on her representation.
- SCCS Chair *Thomas Platzek* informed that the ICCG members agreed to invite representatives of other SCs to participate in respective plenary meetings, as well as in SCCS Methodology WG meetings to facilitate exchange of information and harmonised procedures and methodologies.
- An ECHA topical scientific workshop is planned in April 2016 on soil risk assessment.

6. NEW MANDATES

Mandates were adopted; rapporteurs appointed for:

Cosmetic ingredients

- 3 separated mandates for alpha, beta and deoxy arbutins -> respective CAS n° 84380-01-8, 497-76-7 and 53936-56-4

Hair Dyes

- HC Yellow 16 (Colipa No B123) (T44P2) CAS No. 1184721-10-5. Submission I
- 2,6-Dihydroxyethylaminotoluene (Colipa No A138) CAS No. 149330-25-6 Submission III

7. OPINIONS ADOPTED ON:

Cosmetic Ingredients

- **CETYLPIRIDINIUM CHLORIDE -P97**
The opinion is adopted.

Except for potential skin, eye and oral mucosal irritation, the SCCS considers that the use of cetylpyridinium chloride in the single cosmetic products for oral and for dermal application is safe for the consumer. Aggregate exposure (based on worst case default assumptions for dermal and oral absorption) to cetylpyridinium chloride via cosmetic products for the oral applications, as well as for the oral and dermal applications together is of concern for consumers, when used as a preservative in cosmetic products in the following specified concentrations:

- mouthwashes cosmetic products up to a concentration of 0.1 %
- all other oral hygiene cosmetic products up to a concentration of 0.5 %
- skin lotions and creams up to a concentration of 0.2 %
- anti-perspirant deodorants up to a concentration of 2.0 %

Oral exposure to cetylpyridinium chloride can also occur due to use of cetylpyridinium chloride containing solutions for the removal of microbial surface contamination of raw poultry products, as described in the EFSA Opinion (Ref.: 24). Aggregate exposure (based on worst case default assumptions for dermal and oral absorption) to cetylpyridinium chloride via cosmetic products and via treated poultry is of concern for consumers.

This Opinion covers only the use of cetylpyridinium chloride in non-spray cosmetic products.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_171.pdf

- **CYCLOPENTASILOXANE (D5)**

The opinion is adopted.

The SCCS considers that the use of Cyclopentasiloxane (D5) in cosmetic products is safe except for use in body lotion and hair styling formulations, in those product forms that can give rise to lung exposure of the consumer through inhalation, e.g. aerosols, pressurised sprays, powders, etc. This is because Margin of Safety based on the Point of Departure is less than 100 for the oral and inhalation routes, using the maximum concentrations reported by the applicant of 92% and 85% of D5 respectively in the finished product for application in body lotion and hair styling formulations in inhalable delivery forms. Aggregate exposure to Cyclopentasiloxane (D5) via cosmetic products is not safe as driven by the use of body lotion and hair styling aerosol with high concentrations of Cyclopentasiloxane (D5). Cyclopentasiloxane (D5) may contain traces of Cyclotetrasiloxane (D4) which is classified in the EU as toxic to reproduction. Therefore, the level of impurity of Cyclotetrasiloxane (D4) as an impurity of Cyclopentasiloxane (D5) should be as low as possible. The SCCS recommends that the level of purity of Cyclopentasiloxane (D5) in the cosmetic products put on the market should be > 99%. SCCS is aware that a restriction dossier on D4 and D5 in personal care product has been announced by UK due to environmental issue¹. This opinion did not address the effects of D5 on the environment.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_174.pdf

- **BETA – ARBUTIN**

¹ <http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance-rev/1524/term?searchname=Decamethylcyclopentasiloxane+%28D5%29&searchecnumber=208-764-9>

The opinion is adopted.

The SCCS considers the use of β -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% in face creams provided that the contamination of hydroquinone in the cosmetic formulations remain below 1 ppm. A potential combined use of β -arbutin and other hydroquinone releasing substances in cosmetic products has not been evaluated in this Opinion.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_169.pdf

- **DICHLOROMETHANE**

The opinion is adopted.

No new data on the neurobehavioural effects and the exposure-related observations in humans of dichloromethane have been provided in Submission IV. The conclusion remains therefore as in the previous Opinion on dichloromethane (SCCS/1408/11): *“The evidence does not suggest that dichloromethane shows cardiotoxicity or reproductive toxicity in man except at high levels. Although it is carcinogenic by inhalation in the mouse, factors have been identified which explain the higher susceptibility of mice compared to humans. Quantification of the risk to humans by modelling and comparison of the toxicokinetics indicates that the cancer risk that dichloromethane may pose would be negligible. Due to the inadequate data on exposure by hair spraying and limited data on neurobehavioral and neurodevelopmental effects of dichloromethane after short-term exposure, dichloromethane in a concentration of up to 35% in hair sprays is not considered safe for the consumer.”*

No information concerning other uses in cosmetic products is available to the SCCS.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_170.pdf

Hair Dyes/Fragrances

- **FRAGRANCE TAGETES (PHOTOXICITY)**

(Rapporteur: P.J. Coenraads)

The opinion is adopted.

The SCCS considers a maximum level of 0.01% Tagetes minuta and T. patula extracts and essential oils in leave-on products (except sunscreen cosmetic products) as safe, provided that the alpha terthienyl (terthiophene) content of the Tagetes extracts and oils does not exceed 0.35%. The Tagetes extracts and oils should not be used as ingredients of sunscreen products.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_172.pdf

- **ADDENDUM TO THE SCIENTIFIC OPINION ON THE SAFETY OF OXIDATIVE HAIR DYE SUBSTANCES AND HYDROGEN PEROXIDE IN PRODUCTS TO COLOUR EYELASHES**

The opinion is adopted.

Based on the newly submitted in vitro studies, the SCCS considers that there is no concern for severe eye irritation in the consumer for the use of Toluene-2,5-diamine (A005), p- Aminophenol (A016), Methylresorcinol (A044), Tetraaminopyrimidine (A053), Hydroxyethylp-phenylenediamine sulphate (A080) and 2-Amino-3-hydroxypyridine (A132) in products to colour eyelashes at the tested maximum concentrations for eyelashes and their use is considered safe in eyelashes dye formulations. No information is available on the ocular irritant properties of permanent eyelash dyes formulations intended for the consumer and these formulations need to be assessed on a case-by-case basis by the supplier.

The SCCS considers that the potential risk to the consumer from the use of these products is greater from non-professional use compared with professional use of the same products as there may be increased eyelid contamination.

As no new data has been submitted with respect to skin sensitisation, the risk of allergic contact dermatitis developing in previously sensitised individuals for those hair dyes which are skin sensitisers cannot be excluded (SCCS/1475/12).

Based on SCCP/1129/07 and other information, it could be extrapolated that transient exposure to 2% hydrogen peroxide may be slightly irritant to the eye. Therefore, up to 2% hydrogen peroxide could be considered safe for the consumer when applied on eyelashes and direct eye contact is avoided (SCCS/1475/12).

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_173.pdf

Nanomaterial in cosmetic ingredients

- **SILICA (NANO)**

The opinion was adopted by written procedure on 20 March and is planned to be published soon. After detailed evaluation of the current submission, the SCCS has concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for, or, against the safety of any of the individual SAS material, or any of the SAS categories, that are intended for use in cosmetic products.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf

- **HYDROXYAPATITE**

A request for additional info/data has been adopted and will soon be sent to the additional applicant. **The deadline for replying via e-mail and through the CPNP portal is 31 July 2015.**

- **S79 - MBBT – 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)**

The opinion is adopted.

The calculation for margin of safety in this Opinion is based on a 39-week dermal toxicity study in the mini-pig, as no repeated dose toxicity study with the nano-sized material is available in rats. Also, dermal penetration data are not available for mini-pig skin. The SCCS has based this Opinion on the overall weight of evidence that suggests a very low absorption of MBBT in human skin, and the lack of adverse effects in mini-pigs up to the highest dose tested (1000mg a.i./kg bw/day) over 39 weeks. These together indicate that dermal application of nano-sized MBBT with regard to systemic effects is not likely to be a safety concern. The SCCS has therefore concluded that the use of MBBT [2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)] in nano-structured form with the following characteristics as a UV-filter at a concentration up to 10% in dermally applied cosmetic products is considered to not pose a risk of adverse effects in humans after application on healthy, intact skin:

- The material has a purity of $\geq 98.5\%$ with the isomer fraction not exceeding 1.5%, and the impurity profile not significantly different from that indicated in section 3.1.5.
- The material has a median particle size (d0.5) of 120 nm or larger in terms of mass distribution, and/or 60 nm or larger in terms of number size distribution.

- The material complies with other physicochemical specifications of the evaluated material as listed under section 3.1 of this opinion in terms of chemical identity, physical form, chemical composition, solubility, zeta potential, etc.

In view of the limited available information on inhalation toxicity, which indicates severe inflammatory effects of microfine MBBT in the respiratory tract, caution is warranted against the use of the material in applications that could lead to exposure of the consumer's lungs by inhalation. This Opinion therefore does not apply to such applications that might lead to exposure of the consumer's lungs to MBBT nanoparticles by inhalation. It should also be noted that this Opinion is based on the currently available scientific evidence, which shows an overall very low dermal absorption of MBBT in nano- or larger particle forms. If any new evidence emerges in the future to show that the nano-form of MBBT used in cosmetic products can penetrate skin (healthy, compromised, sunburnt or damaged skin) in any significant amounts to reach viable cells, the SCCS may consider revising this assessment. The in vitro genotoxicity assessment of MBBT was negative in two different test systems. These tests were appropriately applied and demonstrate that there was no evidence for chromosomal damage or mutagenicity when mammalian cells were exposed to both non-micronised and nano-forms of MBBT. Although these test data are accepted by the SCCS, no experimental data on uptake/internalisation of the particle by cells has been provided.

In addition, the SCCS has the following concerns:

- In the study in rats, clinical effects (pain and vocalisation) after dermal application were noted at concentrations of 20% (500mg a.i. /kg bw/d and higher). In the carcinogenicity study, scabs were seen at a dose level of 100 mg a.i./kg/bw/day and higher. It is worthwhile to monitor possible irritation effects via the cosmetovigilance programs. SCCS/1546/15 Opinion on 2,2'-methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (nano form)

- Given the physicochemical properties (high lipophilicity) of the substance, potential bioaccumulation in selected tissues is of concern, especially over long-term use.

The SCCS has also noted that due to the poor biodegradation potential, and the very high octanol-water partition coefficient, long term effects or bioaccumulation of MBBT in the environment cannot be excluded. MBBT is currently classified as Aquatic Chronic 4 H413 ("may cause long lasting harmful effects to aquatic life" according to Annex VI of Regulation (EC) No 1272/2008 (CLP regulation). The use of MBBT as an ingredient in sunscreen products might lead to environmental exposure. Potential environmental effects of MBBT have not been addressed in this Opinion.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_168.pdf

Methodology

The Chair of that Working Group reported briefly on the content of the meetings held on 18-19 February 2015. The **revision of the SCCS Notes of Guidance (NoG)** text is not completed yet but finalised chapters (3-1->3-4.9) were adopted. The whole document is planned to be finalised at the next Working Group meeting (3 June) and adopted at the next plenary meeting (25 June).

8. SCCS RESPONSES ON COMMENTS ON OPINIONS ADOPTED FOR:

Cosmetic Ingredients

- **PHMB** – poly(hexamethylene) biguanide hydrochloride– SCCS/1535/14. The SCCS response to the comments of the applicant was adopted and will be sent out. The opinion was not revised except for the CAS numbers (cf. Corrigendum).
http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- **HAA299** (2-(4-(2-(4-Diethylamino-2-hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)- (4-diethylamino-2-hydroxyphenyl)-methanone) - SCCS/1533/14. The SCCS response to the comments of the applicant was adopted and the opinion has been revised accordingly.
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_159.pdf
- **ADDENDUM TO OPINION ON PRESERVATIVE ETHYL LAUROYL ARGINATE HCl (P95) – SCCS/1543/14:** this opinion was revised by adding the annex II of the previous opinion.
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_166.pdf

9. ANY OTHER BUSINESS

Next working group meetings

23/04, 27/05 and 02/07/2015:

WG on cosmetic ingredients

22/04, 28/05 and 02/07/2015:

WG on hair dyes

03/06 and 01/07/2015 (*and 04/11 to be confirmed*)

WG on methodology

04/06/2015 (*and 28/09 to be confirmed*):

WG on nano in cosmetics

Next plenary meetings

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, Qasim Chaudhry (Vice-Chair), Pieter-Jan Coenraads, Gisela Degen, Maria Dusinska, Werner Lilienblum, Elsa Nielsen, Thomas Platzek (Chair), Suresh Chandra Rastogi (Vice-Chair), Christophe Rousselle and Jan van Benthem.

Apologies

None.

SCCS Secretariat (DG SANCO C2)

Donata Meroni, Natacha Grenier and Diana Herold

DG SANCO B2

Federica de Gaetano, Gaetano Castaldo