



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
19TH PLENARY MEETING

Held on 21 January 2009 in Brussels
MINUTES

0. IN MEMORIAM: PROF. JEAN-PAUL MARTY

With sadness, the European Commission and the Scientific Committee on Consumer Products were informed of the passing away of Prof. Jean-Paul Marty.

Jean-Paul Marty was Professor of Dermatopharmacology and Pharmacology, Faculty of Pharmacy, University of Paris. He was the President of the Société Française de Cosmétologie. He was author and co-author of more than 200 papers and abstracts relevant to pharmaceuticals, biopharmacy and dermatopharmacology.

In the name of the SCCP, a letter of condolences was sent to his wife and his family.

The Chairman invited the meeting to stand up for a minute of silence.

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Dr. B. Jazwicz-Kanyion, Prof. C. Lidén, Prof. J. Krutmann, Prof. V. Rogiers and Prof. G. Speit.

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 18TH PLENARY MEETING

The minutes of the 18th plenary meeting of 16 December 2008 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Discussion on:

Use of the Threshold of Toxicological Concern (TTC), doc n° SCCP/1171/08
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Prof. T. Sanner illustrated the 'Background' and 'Terms of References' of the opinion. He said that the three Scientific Committees, namely the SCCP, SCHER and SCENIHR approved on 19 November 2008 a preliminary report which was put on the web for public consultation. The document tabled represented the version that takes into account all the comments received.

As a result of the discussion, it was decided to organise an additional meeting of the TTC-Working Group to finalise the document.

6. INFORMATION ON FOLLOW-UP ON OPINIONS

No items were raised.

7. NEW REQUEST / MANDATES AND OTHER EMERGING ISSUES

No issues were raised.

8. 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

8.1. ALTERNATIVES

Report of the Co-ordinator

Position statement on genotoxicity / mutagenicity testing of cosmetic ingredients without animal experiments, doc. n° SCCP/1212/09
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In the absence of Prof. V. Rogiers, Dr White presented and highlighted the main issue: the testing ban on animals of ingredients or combination of ingredients of cosmetics as of 11 March 2009.

With reference to its “Memorandum on Actual Status of Alternative Methods on the Use of Experimental Animals in the Safety Assessment of Cosmetic Ingredients in the European Union” of 19 June 2007 (doc. n° SCCP/1111/07), the SCCP concluded that, with the currently available *in vitro* assays performed in accordance with the actual international guidelines, it will not be possible to appropriately evaluate a mutagenic potential in many cases.

New *in vitro* genotoxicity tests (e.g., 3D skin models) are being developed but the process of method development and validation will take some years and the methodology will not be available by March 2009.

The statement was adopted.

8.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof; Platzek reported on the work done during the WG-meetings that had taken place since the last plenary of 16 December 2008.

Draft opinions were prepared on:

B60, 2-Nitro-5-glyceryl methylaniline, doc. n° SCCP/1162/08

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 2-nitro-5-glyceryl methylaniline safe for use as a non-oxidative hair dye with an on-head concentration of maximum 1.0 % taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of 2-nitro-5-glyceryl methylaniline in any hair dye formulations?*

The SCCP concluded that the safety of 2-nitro-5-glyceryl methylaniline could not be assessed based on the data submitted. Before any further consideration, an appropriate *in vivo* test to study the induction of gene mutations has to be submitted.

2-Nitro-5-glyceryl methylaniline is a secondary amine, and thus, prone to nitrosation. It should not be used in combination with nitrosating agents. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

Note

In December 2008, the applicant informed the European Commission that the use of this dye in oxidative formulations would also be supported and that the supporting data would be available in March 2009. Consequently, he requested to postpone the adoption of the opinion.

The SCCP, however, decided to proceed with the adoption in order to inform the applicant about the committee's request on mutagenicity.

Intermediates and reaction products of oxidative hair dye ingredients, doc. n° SCCP/1198/08

The SCCP was asked to answer the following questions:

With the current submission from Industry, does the SCCP consider that further testing with regard to potential mutagenicity and carcinogenicity of intermediates and reaction products of oxidative hair dye products formed during the hair dyeing process, is needed?

The SCCP concluded that it was not in the position to finally assess the risk of reactions products of oxidative hair dyes due to the incomplete dossier.

General conclusions regarding exposure to hair dye reaction products will be drawn after submission and evaluation of the complete results of the additional on-going/planned *in vitro* dermal absorption studies.

Based on robust data on exposure, a final decision can be made if the exposure to these substances is considered relevant from a toxicological point of view. If a relevant exposure to reaction products from hair dyeing cannot be excluded, further testing on genotoxicity will be required to exclude a genotoxicity/mutagenicity potential of the reaction products of oxidative hair dye.

The opinion was adopted

8.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that the following opinion had been prepared:

Citric acid and silver citrate, doc. n° SCCP/1196/08
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The SCCP was asked to answer the following questions:

1. *Does SCCP consider Citric acid (and) Silver Citrate safe for consumers when used in cosmetic products as a preservative in a concentration up to 0.2%, taken into account the scientific data provided?*
2. *And/or does the SCCP recommend any further restrictions with regard to the use of Citric acid (and) Silver Citrate in cosmetic products?*

The SCCP concluded that, on the basis of the data submitted, the safety of citric acid (and) silver citrate cannot be assessed. Before a final conclusion can be reached, an *in vitro* mammalian gene mutation assay to exclude gene mutation potential is required.

The critical aspect in the safety evaluation of silver containing compounds, like citric acid (and) silver citrate, is possible long-term effects of the silver released, in particular in relation to argyria.

The available toxicity data in relation to silver, on which various regulatory limits (RfD by US-EPA, lifetime NOAEL by WHO and group restriction limit for food contact material by EFSA)

are based, are very limited and old. Using these data and conservative dermal absorption assumptions derived from the dermal absorption study provided, the SCCP considered that consumer exposure to silver from citric acid (and) silver citrate at the proposed concentration in cosmetics amounts to only a fraction of the reference dose for silver. It came to the judgment-based conclusion that the potential risk for the development of argyria due to this exposure is low. On that basis, the SCCP considers that an additional dermal absorption study is not necessary. However, new data specifically addressing the end point of argyria is necessary to strengthen this judgement based conclusion.

The SCCP is aware that additional silver toxicity information has been generated to address other regulatory needs and would, therefore, welcome the opportunity to obtain and review these data.

This opinion is limited to the evaluation of the potential exposure and risks associated with the use of citric acid (and) silver citrate in cosmetic products at the proposed use concentration. It does not concern uses of other silver containing cosmetic ingredients or exposure to silver from other non-cosmetic sources. Evidence in the public domain suggests an increase in the exposure of consumers to silver from sources other than cosmetics (e.g. textiles, cleaning products, medical products). Therefore, the SCCP strongly recommends the consideration of an aggregate exposure and risk assessment.

The opinion was adopted

P32, Triclosan, 1192/08

The SCCP was asked to answer the following questions:

1. *Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe for the consumer at the current concentration limit of maximum 0.3% taking into account the provided toxicological data?*
2. *Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe taking into account the new provided documentation of resistance development by certain micro-organisms and cross-resistance?*

The SCCP concluded that, taking into account the provided toxicological data, the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.

However, its use at a maximum concentration of 0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks ("common-use products" as defined by the applicant) is considered safe. Any additional use of triclosan in face powders and blemish concealers at this concentration is also considered safe but the use of Triclosan in other leave-on products (e.g. body lotions) and in mouthwashes is not considered safe for the consumer due to the resulting high exposures.

Importantly, before a final conclusion on the safety of triclosan in cosmetic products can be reached, the potential development of resistance to triclosan and cross-resistance by certain

micro-organisms must be assessed. This aspect is not covered in this document and will be discussed in a separate opinion.

Inhalation exposure to triclosan from spray products (e.g. deodorants) was not assessed.

The opinion was adopted.

P64, Climbazole, doc. n° SCCP/1204/08

The SCCP was asked to answer the following questions:

- 1) *Does the SCCP consider with the scientific data provided that Climbazole is safe for the consumers, when used as a preservative in cosmetic products up to a maximum concentration of 0.5%?*
- 2) *Does the SCCP consider with the scientific data provided that Climbazole is safe for the consumers, when used for non-preservative purposes as an anti-dandruff active ingredient in hair care formulations up to a maximum concentration of 2.0% in rinse-off products?*
- 3) *Does the SCCP consider with the new scientific data provided that Climbazole is safe for the consumers, when used for non-preservative purposes as an anti-aging ingredient in leave-on products up to a maximum concentration of 0.5%, even though this application might already be covered by (1)?*

Question 1: *Does the SCCP consider with the scientific data provided that Climbazole is safe for the consumers, when used as a preservative in cosmetic products up to a maximum concentration of 0.5%?*

The SCCP concluded that the use of Climbazole as a preservative at a maximum concentration of 0.5% in all cosmetic products cannot be considered safe. However, when used as a preservative in hair cosmetics and face cosmetics at 0.5%, climbazole does not pose a risk to the health of the consumer.

Question 2: *Does the SCCP consider with the scientific data provided that Climbazole is safe for the consumers, when used for non-preservative purposes as an anti-dandruff active ingredient in hair care formulations up to a maximum concentration of 2.0% in rinse-off products?*

The SCCP concluded that the use of Climbazole in rinse-off hair cosmetics up to a maximum concentration of 2.0% does not pose a risk to the health of the consumer.

Question 3: *Does the SCCP consider with the new scientific data provided that Climbazole is safe for the consumers, when used for non-preservative purposes as an anti-aging ingredient in leave-on products up to a maximum concentration of 0.5%, even though this application might already be covered by Question 1?*

The SCCP concluded that the non-preservative use of Climbazole in hair cosmetics and face cosmetics at 0.5% does not pose a risk to the health of the consumer. The use of Climbazole at 0.5% in leave-on products other than those mentioned above, however, is not considered safe.

The inhalation exposure to Climbazole from spray products was not assessed in this opinion.

The opinion was adopted.

8.4. UV FILTERS AND AD HOC SUBSTANCES

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

S57, camphor benzalkonium methosulfate, doc. n° SCCP/1202/08
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The SCCP was asked to answer the following questions:

1. *Does the SCCP consider Camphor benzalkonium methosulphate safe for use as an UV-filter in cosmetic products in a concentration up to 3.0% taking into account the data provided?*
2. *And/or does the SCCP have any further scientific concerns with regard to the use of Camphor benzalkonium methosulphate as a UV-filter in cosmetic products?*

In response to opinion SCCP/1015/06 of 19 December 2006, the applicant preferred not to perform a new dermal absorption study as requested by the SCCP. Instead, a reduction of maximum authorised concentration from 6.0 to 3.0% as a UV filter in cosmetic products was proposed.

The SCCP concluded that, on the basis of the available data, a reduced maximum concentration of 3% as a UV filter in cosmetic products is considered safe.

Camphor benzalkonium methosulfate is irritating to the eyes at the concentration of 6%. No study of eye irritation has been conducted with a 3% concentration.

The inhalation exposure to Camphor benzalkonium methosulfate from spray products (e.g. deodorants) was not assessed.

The opinion was adopted.

9. NEW REQUESTS FOR OPINION

Not applicable

10. ANY OTHER BUSINESS

Clarification on opinions on:

The safety of fluorine compounds in oral hygiene products for children under the age of 6 years, doc n° SCCNFP/0653/03 and SCCP/0882/05

In the opinion 0882/05, the SCCP concluded that *"the maximum permitted concentration of 0.15% (1500 F ppm) fluoride does not pose a safety concern when used by children under the age of 6 years, based on the available scientific evidence."* The Cosmetics Directive regulates in Annex III, part 1 fluorine compounds and the scientific opinion given by the SCCP was based on the assessment of fluorine compounds.

The SCCP was asked to provide clarification on the following question:

Did the SCCP mean in the conclusion of its opinion the concentration of 0.15% fluorine instead of fluoride?

The SCCP approved the following clarification:

Confusion may have been generated since the terms 'fluorine' and 'fluoride' are often used interchangeably in the literature as generic terms. However, in the opinion SCCP/0882/05 the term 'fluoride' was used deliberately, as only safety data on sodium fluoride in toothpaste was made available for evaluation. In addition, SCCP opinion SCCP/0882/05, stated that 'If the sole source of fluoride exposure is toothpaste containing fluoride between 1000-1500 F- ppm, used as recommended, there is a minimal concern that children under the age of 6 will develop fluorosis since the amount absorbed would be less than half the accepted adequate intake of 0.7 mg/day fluoride intake for children between the ages of 1 and 3, that maximally reduces dental caries without causing unwanted side effects'.

In both opinion SCCNFP/0653/03 and SCCP/0882/05, it is pointed out that extrapolation to other fluorine containing compounds listed in Annex III, part 1 can only be made with respect to fluorosis.

However, for the purpose of the reference to fluorine containing compounds in Annex III, part 1, made in Directive 2007/53/EC, the SCCP considers that the terms "fluorine" and "fluoride" are equivalent and interchangeable.

Clarification on the use of zinc oxide in its non-nano form as UV-filter

The SCCP was asked to provide clarification on the following question:

In the SCCP statement 0932/05 of 20 September 2005 "on Zinc oxide used in sunscreens", regarding the SCCNFP opinion 0649/03 of 24-25 June 2003 on zinc oxide, the SCCP indicates that further data on micronised zinc oxide should be provided in order to allow its safety evaluation. Therefore, in order to take the appropriate measures regarding the use of zinc oxide as UV-filter in its non-nano form, can the SCCP confirm that it considers the use of the latter as safe in cosmetic products as a UV-filter up to 25% on the basis of the SCCNFP opinion from 2003?

The SCCP approved the following clarification:

The SCCP considers that, on basis of the dossier reviewed in 2003, the use of ZnO in its non-nano form (pigment grade, with particle sizes above 100 nm) is considered safe. The concern expressed in the SCCNFP opinion 0693/03 with regard to photo-toxicity is not relevant for this form of ZnO due to the absence of dermal penetration.

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products 19 th Plenary Meeting

Held on 21 January 2009
in Brussels

List of Participants**Members of the SCCP**

Dr. C.M. Chambers, Prof. G. Degen, Prof. V. Kapoulas, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. J. Revuz, Prof. T. Sanner (Vice chair), Dr. J. van Engelen, Dr. I.R. White (Chair)

SCCP Secretariat (DG SANCO)

Mrs. K. Kilian, Mr. A. Van Elst

DG ENTR F3

Mrs. A. Orloff