



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
15TH PLENARY MEETING

Held on 15 April 2008 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. G. Degen, Prof. R. Dubakiene, Prof. J. Krutmann, Prof. C. Lidén, Prof. J-P. Marty, Prof T. Platzek 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 14TH PLENARY MEETING

The Minutes of the 14th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White said that, during the 20th meeting of the Inter-Committee Coordination Group (ICCG) of 7 February 2008, Mr. Karapiperis described the role of STOA (Science and Technology Options Assessment) in the European Parliament and presented its activities. It was considered very important to establish formal contacts and to ensure discussion of issues of mutual interest.

6. EMERGING ISSUES

No issues were raised.

7. 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

7.1. ALTERNATIVES

Report of the Co-ordinator

Prof. V. Rogiers said that no Working Group meetings have taken place since the plenary meeting of 18 December 2007. However, a meeting is planned on 3 June 2008 to discuss, amongst others, the issue of dermal absorption.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

There was a report on the work done during the meetings of the WG that had taken place since the last plenary of 18 December 2007.

Draft opinions were prepared on:

A11, Resorcinol, doc. n° SCCP/1117/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider resorcinol safe for use as an oxidative hair dye with a concentration on the head of maximum 1.25% taken into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of resorcinol in oxidative hair dye formulations?*

The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out.

Before any further consideration, an *in vivo* Comet assay on stomach, liver and bladder cells should be performed as the mutagenic potential of resorcinol *in vitro* was not excluded in an *in vivo* study.

Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A17, 1-Naphthol, doc. n° SCCP/1123/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 1-naphthol safe for use as an oxidative hair dye with a concentration on-head of maximum 2.0% taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of 1-naphthol in oxidative hair dye formulations?*

The SCCP concluded that, apart from the risks associated with the use of a strong sensitiser, the use of 1-naphthol itself in oxidative hair dye formulations at a maximum concentration of 2.0% on the head, does not pose any other risk to the health of the consumer.

1-Naphthol itself has no mutagenic potential. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A130, 6-Methoxy-2-methylamino-3-aminopyridine HCl, doc. n° SCCP/1121/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 6-methoxy-2-methyl-2,3-pyridinediamine and its salts safe for use as an ingredient in any hair dye formulation at a concentration on-head of maximum 1.0% taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use of 6-methoxy-2-methyl-2,3-pyridinediamine and its salts in hair dye formulations?*

This risk assessment relates only to 6-methoxy-2-methylamino-3-aminopyridine HCl. No data was submitted on other salts.

The SCCP concluded that, apart from the risks associated with the use of a moderate sensitiser, the use of 6-methoxy-2-methylamino-3-aminopyridine (free base or dihydrochloride) as an ingredient in any hair dye formulation, oxidative and non-oxidative, does not pose a risk to the health of the consumer at a maximum concentration on the head of 0.68% as free base (1.0% as dihydrochloride).

6-Methoxy-2-methylamino-3-aminopyridine HCl is a secondary amine, and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The characterised batches of 6-methoxy-2-methylamino-3-aminopyridine HCl contained many unknown impurities in concentrations up to 2.8% (HPLC peak area), which should be identified.

6-Methoxy-2-methylamino-3-aminopyridine HCl itself has no mutagenic potential. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

A132, 2-Amino-3-hydroxypyridine, doc. n° SCCP/1126/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider the use of 2-Amino-3-hydroxypyridine safe for consumers, when used as a precursor in any hair dye formulations with a concentration on the scalp 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-Amino-3-hydroxypyridine in hair dye formulations?*

Since no data on dermal absorption under non-oxidative conditions were provided, this opinion relates to the use of 2-amino-3-hydroxypyridine in oxidative hair dye formulations only.

The SCCP concluded that the use of 2-amino-3-hydroxypyridine in oxidative hair dye formulations at a maximum concentration of 1.0% on the head does not pose a risk to the health of the consumer.

2-Amino-3-hydroxypyridine itself has no mutagenic potential. However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

B71, HC Red n° 10 + HC Red n° 11, doc. n° SCCP/1134/07

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider HC Red n° 10 + HC Red n° 11 safe for use as a non-oxidative hair dye with an on-head concentration of maximum 2.0 % taken into account the scientific data provided?*
2. *Does the SCCP consider HC Red No. 10 + HC Red No. 11 safe for use in oxidative hair dye formulations with an on-head concentration of maximum 1.0 % taken into account the scientific data provided?*
3. *Does the SCCP recommend any further restrictions with regard to the use of HC Red n° 10 + HC Red n° 11 in any non-oxidative or oxidative hair dye formulations?*

The mixture of HC Red n° 10 + HC Red n° 11 (COLIPA B71) is highly variable with the two compounds having different physico-chemical properties which possibly also affect toxicological properties.

The SCCP concluded that it was not in a position to perform a risk assessment of HC Red n° 10 + HC Red n° 11 because of the absence of a proper chemical characterisation of the test substance.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that the following opinions had been prepared by the Working Party since the plenary meeting of 18 December 2007.

P95, Ethyl lauroyl arginate HCl, doc. n° SCCP/1106/07

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider, with the data provided in the attached submission that Ethyl lauroyl arginate HCl is safe for the consumers, when used as a preservative up to a maximum authorised concentration of 0.4 % in cosmetic products?*
2. *Does the SCCP consider, with the data provided in the attached submission that Ethyl lauroyl arginate HCl is safe for the consumers, when used for specific use up to a maximum authorised concentration of 0.8 % in the following cosmetic products: soap, anti-dandruff shampoos, deodorants and oral hygiene products?*
3. *Does the SCCP recommend any limitations and requirements or conditions of use for Ethyl lauroyl arginate HCl in cosmetic products based on the toxicological profile and risk assessment presented in the attached submission?*

The SCCP concluded that, with the additional data provided, Ethyl Lauroyl Arginate HCl is safe for the consumers, when used:

- up to a maximum authorised concentration of 0.4 % as a preservative in cosmetic products, but excluding products for the lips, oral hygiene products and spray products
- up to a maximum authorised concentration of 0.8 % in soap, anti-dandruff shampoos, and non-spray deodorants.

The conclusion was based on the use of ethyl lauroyl arginate HCl in the specified cosmetic products only. It takes no account of other possible and probable sources of exposure by the consumer of this substance.

The opinion was adopted.

Oak moss / Tree moss, doc. n° SCCP/1131/07
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The SCCP was asked to answer the following questions:

1. *Does the SCCP consider oakmoss/treemoss extracts safe for consumers when used in cosmetic products in a total concentration up to 0.1% as currently recommended by IFRA, taken into account the scientific data provided?*
2. *Does the SCCP recommend any further restrictions with regard to the use of oakmoss/treemoss extract in cosmetic products?*

In response to question 1, the SCCP concluded that:

Oakmoss/treemoss contain atranol and chloroatranol. In the opinion of the SCCP of 7 December 2004 (SCCP/0847/04) it was stated that these allergens should not be present in cosmetic products. Therefore, untreated oakmoss/treemoss is not safe for the consumer. In treated preparations of oakmoss, it is possible to reduce the levels of atranol and chloroatranol to less than 2 ppm. Although it might be anticipated that reduction of these allergens could reduce elicitation on the skin of previously sensitised individuals. This will need to be demonstrated by appropriate clinical studies. Until such studies are available, it is not possible to estimate if oakmoss, containing atranol and chloroatranol to 2 ppm each, when present up to 0.1% in finished cosmetic products is safe for the consumer.

Little data is available for treemoss and cedar moss. However, if they are treated to reduce the levels of atranol and chloroatranol to less than 2 ppm as is possible for oakmoss, then, if present at 0.1% in finished cosmetic products, the comments above for oakmoss apply. Similar, appropriate clinical studies as above are required.

The primary prevention of the induction of contact allergy can be achieved by eliminating consumer exposure or reducing exposure to a level at which induction is improbable.

In response to question 2, the SCCP concluded that:

It appears that it is possible to reduce, on a commercial scale, the levels of the main allergens (chloroatranol and atranol) in oakmoss to < 2 ppm each in the 'neat' product. The levels of these allergens, which would then be present in cosmetic products where oakmoss is used at 0.1%, would be such that the risks of induction and elicitation of allergic reactions to them would be low. However, appropriate clinical studies on individuals with characterised contact allergy to oakmoss are required to demonstrate the dose response characteristics of allergic elicitation reactions with the modified preparations.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

Arbutin, doc. n° SCCP/1158/08

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider the use of β -arbutin to be safe for consumers in cosmetic products in a concentration up to 7% with the provided scientific data?*
2. *Does the SCCP recommend any restrictions with regard to the use of β -arbutin in cosmetic products?*

The SCCP concluded that, although the general toxicological assessment of beta-arbutin suggests that the substance may be safe, the bioavailability of hydroquinone under conditions of intended use of the substance is of concern. Whereas hydroquinone was initially permitted at a concentration of 2%, a 1998 opinion of the SCCNFP recommended that the substance should not be used any more as a depigmentating agent in cosmetic products due to observed clinical side effects, among which exogenous ochronosis.

Consequently, the SCCP considers the currently requested use of beta-arbutin in cosmetic products unsafe.

In addition, the SCCP concluded that the same concern can be expressed for other products that result in the release and/or formation of hydroquinone before or upon application on the skin.

The opinion was adopted.

Choline chloride, doc. n° SCCP/1159/08
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The SCCP was asked to answer the following questions:

Does SCCP consider the use of Choline chloride as a humectant in cosmetic rinse-off products safe for the consumers when used in a maximum concentration of 5%, taking into accounts the new provided data on skin and mucous membrane irritation?

The SCCP concluded that the study included in the present submission is not sufficient to answer the concerns about mucous membrane irritation.

Before any further consideration, a study on mucous membrane irritation at the intended use concentration of 5%, in accordance with the SCCP Notes of Guidance.

The opinion was adopted.

S83, Diethylamino hydroxybenzoyl hexyl benzoate, doc. n° SCCP/1166/08

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider that the use of the Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester is safe for the consumer in a concentration up to 10 % when used in cosmetic products including sunscreen products?*
2. *Does the SCCP propose any further restrictions or conditions for its use in other cosmetic products?*

The SCCP concluded that, based on the information provided, the use of diethylamino hydroxybenzoyl hexyl benzoate at a maximum concentration of 10% w/w in cosmetic products, including sunscreen products does not pose a risk to the health of the consumer.

Only the dermal application of diethylamino hydroxybenzoyl hexyl benzoate was considered. Due to lack of data with regard to inhalation exposure and toxicity, the safety of applications which would result in consumer exposure via the inhalation route could not be assessed.

The opinion was adopted.

Toluene (use as a solvent in nail cosmetics), doc. n° SCCP/1170/08

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider that the penetration through the nail plate is practically nil taking into account the data provided or does the SCCP have any other information that can document this assumption?*
2. *Considering that toluene is a CMR 3 substance and assuming also a MOS of 100 or above for the acute effects like headache, dizziness and functional performance, is it possible for the SCCP to calculate a concentration for the specific use in cosmetic products?*

The SCCP concluded that inclusion of toluene up to 25% is safe from the general toxicological view in nail cosmetics used as intended in adults and children. However, the SCCP would like to point out that there is a foreseeable risk of increased inhalation by children as part of the normal playing behaviour from cosmetics promoted as children's toys. Therefore, the use of toluene in such products is not considered appropriate.

The opinion was adopted.

8. NEXT PLENARY MEETING

The 16th plenary meeting of the SCCP will take place on 24 June 2008.

9. ANY OTHER BUSINESS**- Dates of WG meetings:**

29 April	Hair Dyes
13 May	ad hoc substances + Fragrances & Preservatives
22 May	TTC (Threshold of Toxicological Concern)
27 May	Hair Dyes
3 June	Alternatives to Animal Testing
11 June	TTC (Threshold of Toxicological Concern)
17 June	ad hoc substances + Fragrances & Preservatives

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products 15 th Plenary Meeting

Held on 15 April 2008
in Brussels

List of Participants**Members of the SCCP**

Dr. C.M. CHAMBERS, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Dr. S.C. RASTOGI, Prof. J. REVUZ, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Dr. J. VAN ENGELEN, Dr. I.R. WHITE (Chair)

SCCP Secretariat (DG SANCO)

Mrs. I. COPPOLA, Mr. T. Daskaleros, Mrs. K. KILIAN, Mr. A. VAN ELST

DG ENTR F3

Mrs. B. MENTRE, Mrs. A. ORLOFF