



Scientific Committee on Consumer Safety
17th plenary Meeting

Held on 11 December 2012 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Prof. J. Angerer, Dr. C. Chambers, Dr. Q. Chaudhry, Prof. G. Degen and Dr. J. van Benthem.

2. APPROVAL OF THE DRAFT AGENDA

The agenda was approved.

3. DECLARATIONS OF INTEREST

No member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 15TH PLENARY MEETING

The minutes of the 16th plenary meeting of 18 September 2012 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

5.1. Follow-up of previous opinions

The Commission informed the Committee on some of the actions taken by Commission on the basis of the past opinions adopted. Proposals for amendments of the annex to the Cosmetic products Regulation (EC) No 1223/2009 are under preparation on the basis of recent SCCS Opinions, such as the nitrosamines and secondary amines opinion, the ZnO nano form opinion, and the methylene glycol opinion.

5.2. Other points

The Commission updated the members on the status of the renewal of the Committee.

6. NEW AND UPCOMING REQUESTS

- S61, 3-benzylidene camphor
- Carbon Black, nano-form

7. ON-GOING WORK

7.1. WG on Cosmetic Ingredients

The Chairperson of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting of 18 September 2012. Five draft opinions had been prepared which were tabled for adoption.

7.2. WG on Hair Dyes

The chairman of the WG reported on the on-going work. Two WG meetings had taken place since the previous plenary meeting of 18 September 2012. Five draft opinions had been prepared and tabled for adoption.

7.3. WG on Methodologies

The chairman of the WG reported on the on-going work. Two WG meetings had taken place since the previous plenary meeting of 18 September 2012. The 8th revision of the Notes of Guidance was tabled for adoption.

7.4. WG on Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. Three meetings had taken place since the previous plenary meeting. The draft opinion on Titanium dioxide was tabled for adoption. A preliminary opinion on S79 (2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol) was tabled for discussion.

7.5. Participation of Members in activities of other Scientific Committees

The members involved in the activities of WGs developing joint opinions, reported on the progress of the work on:

- Joint opinion on Improvement of risk assessment
- Joint opinion on New Challenges in Risk Assessment

8. DRAFT OPINIONS – FOR DISCUSSION AND POSSIBLE ADOPTION

8.1. Climbazole

The adoption of the opinion was postponed.

8.2. Dichloromethane

The SCCS was asked to answer the following questions:

1. *On the basis of the provided data the SCCS is asked to assess the risk to consumers when dichloromethane is used in cosmetic products under the current use conditions of max. 35% in cosmetic products*
2. *If this limit is considered safe, should the restriction of 35% be limited to its use as a propellant or can other uses as solvent up to 35% be accepted?*
3. *Can the SCCS assess whether the restriction on purity should be interpreted as purity criteria for the dichloromethane itself or should it be its presence as an impurity in cosmetic products that should be restricted to 0.2%?*
4. *Does the SCCP have any further scientific concern with regard to its use in cosmetic products?*

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 toxicokinetic modelling and subsequent comparison of the toxicokinetics between mice and humans indicates that the cancer risk that dichloromethane may pose would be negligible.

Based on the available 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 for other uses in cosmetic products was available to the SCCS.

The opinion was adopted.

8.3. A33, 1,2,4-Trihydroxybenzene

The SCCS was asked to answer the following questions:

- 1. Is 1,2,4-trihydroxybenzene safe for use in direct hair dye formulations at a maximum use concentration of 3% taken into account the data provided?*
- 2. And/or does the SCCS recommend any other restrictions with regard to the use of 1,2,4-trihydroxybenzene in hair dye formulations?*

The SCCS concluded that the information submitted was inadequate to assess the safe use of the substance. Before any further consideration, the following information is required:

- Proper characterisation and quantification of 1,2,4-Trihydroxybenzene as well as identification and quantification of impurities in all test batches.
- Characterisation of the oxidation reaction product(s) of 1,2,4-trihydroxybenzene to which the consumer is exposed, because of the reported instability of 1,2,4-trihydroxybenzene in aqueous systems. In the case of relevant exposure to the reaction products, further toxicity data might be required.
- *In vivo* testing would be required to explore the potential to induce gene mutations; such tests are no longer permitted.

1,2,4-Trihydroxybenzene was found to be an extreme skin sensitiser.

The opinion was adopted.

8.4. A94, 5-Amino-6-chloro-o-cresol

The SCCS was asked to answer the following questions:

- 1. Does SCCS consider 5-amino-6-chloro-o-cresol (A094) safe for use as oxidative and non-oxidative hair dye with a concentration on-head of maximum 1.0% taking into account the scientific data provided?*
- 2. And/or does the SCCS recommend any further restrictions with regard to the use of 5-amino-6-chloro-o-cresol (A094) in oxidative and non -oxidative hair dye formulations?*

The SCCS concluded that the use of 5-amino-6-chloro-o-cresol as oxidative hair dye with a concentration on head of maximum 1.0% and as non-oxidative hair dye with a

concentration on head of maximum 0.5% does not pose a risk to the health of the consumer.

The opinion was adopted.

8.5. A155, 2,2'-Methylenebis 4-aminophenol HCl

The SCCS was asked to answer the following questions:

1. *Does SCCS consider 2,2'-methylenebis 4-aminophenol dihydrochloride safe for use in oxidative hair and non-oxidative hair dye formulations with a concentration on-head of maximum 1.0% taken into account the scientific data provided?*
2. *And/or does the SCCS have any scientific concern with regard to the use of 2,2'-methylenebis-4-aminophenol dihydrochloride in oxidative hair dye formulations?*

The SCCS concluded that the use of 2,2'-methylenebis 4-aminophenol HCl at a maximum on-head concentration of 1.0% in oxidative and in non-oxidative hair dye formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

8.6. B87, 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider 4-amino-2-nitrodiphenylamine-2'-carboxylic acid 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 SCCS consider 4-amino-2-nitrodiphenylamine-2'-carboxylic acid safe for use in oxidative hair dye formulations with an on-head concentration of maximum 2.0% taken into account the scientific data provided?*
3. *Does the SCCS recommend any restrictions with regard to the use of 4-amino-2-nitrodiphenylamine-2'-carboxylic acid in any non-oxidative or oxidative hair dye formulations?*

The SCCS concluded that a conclusion on the gene mutation potential of 4-amino-2-nitrodiphenylamine-2'-carboxylic acid cannot be drawn without further *in vivo* testing.

All batches of 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid as well as raw material contain about 2% impurity(ies), which has not been chemically characterised. This impurity(ies) must be characterised, especially to rule out the presence of 2-nitro-p-phenylenediamine (CAS No. 5307-14-2), which is banned for the use in cosmetic products (Cosmetic Directive, Annex II/1319).

A sensitising potential of 4-amino-2-nitrodiphenylamine-2'-carboxylic acid cannot be excluded.

The opinion was adopted.

8.7. C9, Basic Brown 16

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Basic Brown 16 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 SCCS recommend any restrictions with regard to the use of Basic Brown 16 in non-oxidative hair dye formulations?*

The SCCS concluded that a conclusion on the mutagenic potential of Basic Brown 16 cannot be drawn at the moment.

Characterisation of impurities in Basic Brown 16 and data on its stability in test solutions are required.

Basic Brown 16 is a moderate skin sensitiser.

The opinion was adopted.

8.8. Notes of Guidance, 8th revision

The 8th revision of the Notes of Guidance was adopted.

8.9. S79, 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl) phenol)

The document was tabled for discussion only.

8.10. Titanium dioxide, nano form

The document was tabled for discussion only.

9. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 18 September 2012 have been received. All comments were reviewed and discussed by the experts at the WG and opinions were modified as appropriate.

The following draft opinions were discussed:

- Acetaldehyde
- S76, Zinc oxide – nano form
- B50, HC Red n° 3
- B119, HC Blue 16
- C181, Pigment Red 57
- Hair dye substances and hydrogen peroxide used in products to colour eye lashes

10. ANY OTHER BUSINESS

The next plenary meeting will take place on 26 February 2013

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

Dr. U. Bernauer, Dr. W. Lilienblum (associate scientific advisor), Dr. E. Nielsen, Prof. T. Platzek, Dr. S.C. Rastogi, Dr. C. Rousselle, Prof. V. Rogiers (vice-Chair), Prof. T. Sanner (vice-Chair), Dr. J. van Engelen, Prof. M.P. Vinardell, Prof. R. Waring Dr. I.R. White (Chair),

Apologies

Prof. J. Angerer, Dr. C. Chambers, Dr. Q. Chaudhry, Prof. G. Degen, Dr. J. van Benthem

SCCS Secretariat (DG SANCO)

Ms. C. Arranz Aceves, Mr. T. Daskaleros, Mr. T. Piha, Mr. A. Van Elst

DG SANCO B2

Mrs. F. de Gaetano