



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Health systems and products  
**Risk assessment**

Scientific Committee on Consumer Safety  
12<sup>th</sup> plenary Meeting

Held on 20 September 2011 in Brussels

MINUTES

**1. WELCOME AND APOLOGIES**

The chairman of the SCCS welcomed all the participants. Apologies were received from Prof. J. Angerer.

**2. DECLARATIONS OF INTEREST**

Dr. E. Nielsen declared a possible interest in relation to point 10 of the agenda as background documents to the Danish ban of parabens from children products were prepared at her institute. Although not personally involved in this work, Dr. Nielsen preferred not to take part in the discussion.

**3. APPROVAL OF THE DRAFT AGENDA**

The agenda was approved.

**4. ADOPTION OF THE DRAFT MINUTES OF THE 11<sup>TH</sup> PLENARY MEETING**

The minutes of the 11<sup>th</sup> plenary meeting of 21 June 2011 were approved.

**5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION**

*Information from the Commission*

The Commission informed that a call for experts will be published in October 2011. The call for the expressions of interest concerns the replacement of the current members of the three Scientific Committees appointed by Commission Decision 2009/146/EC whose term will expire in spring 2012.

The current members were invited, if they so wished, to submit their applications for the new term of office of the scientific committees.

*Commission follow-up to earlier opinions*

No points were raised.

**6. NEW REQUESTS**

The SCCS received the following mandate:

- Request for a guidance document: Guidance on Safety Assessment of Nanomaterials in Cosmetics

## **7. REPORTS FROM THE WORKING GROUPS**

### **7.1. Cosmetic Ingredients**

The Chairperson of the WG reported on the ongoing work. Two meetings had taken place since the previous plenary meeting of 21 June 2011. An addendum to opinion SCCP/1202/08 on camphor benzalkonium methosulfate (S57) was prepared and tabled for adoption.

### **7.2. Hair Dyes**

The Chairperson of the WG reported on the ongoing work. Two meetings had taken place since the previous plenary meeting. Draft opinions on 2,6-dihydroxyethylaminotoluene (A138), HC Red n° 70 + HC Red n° 71 (B71), 2,6-diamino-3-((pyridine-3-yl)azo)pyridine (B11), Basic Violet 2 (B115), Basic Red 51 (B116), Basic Blue 99 (C59) and Tetrabromophenol Blue (C183) were prepared and tabled for adoption.

### **7.3. Methodologies**

No WG meeting had taken place since the previous plenary meeting. A meeting is planned to discuss further updates of the Notes of Guidance.

### **7.4. Nano-materials in Cosmetics**

The Chairperson of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting. A draft opinion on ETH-50 was prepared and tabled for adoption.

### **7.5. TTC**

No WG meeting had taken place since the previous plenary meeting. A meeting is planned on 20 October 2011 to discuss the future work on the joint opinion of the SANCO Scientific Committees, in the light of updated information on the development of EFSA's opinion after the public consultation.

### **7.6. Nitrosamines**

The Chairperson informed that one WG meeting had taken place since the previous plenary meeting.

The WG is still working on an opinion on nitrosamines and secondary amines in cosmetics and on an opinion on NDELA in cosmetics and nitrosamines in balloons.

### **7.7. Sensitisation & Fragrances**

The Chairperson said that two WG meetings had taken place since the previous plenary meeting. The Working Group continues the update of the opinion on fragrance allergens.

## **7.8. Participation of Members in activities of other Scientific Committees and joint opinions**

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

- SCHER opinion on Chemical mixtures
- SCHER opinion on Improvement of risk assessment
- SCENIHR opinion on New Challenges in Risk Assessment

## **8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION**

### **8.1. 1,3,5-Triazine, 2,4,6-tris[1,1'-biphenyl]-4-yl- (ETH-50)**

*The SCCS was asked to answer the following questions:*

1. *Does SCCS consider that the use of ETH50 as an UV-filter in cosmetic products in a concentration up to maximum 10.0% is safe for the consumers taken into account the scientific data provided?*
2. *Does SCCS have any other scientific concerns for the safe use of the new UV-filter ETH50 in finished cosmetic products?*

The SCCS conclusion:

Dermal exposure to formulations containing the UV-filter ETH50 with a mean particle size of 81 nm, as described in the dossier, results in low absorption of ETH50. Also after oral exposure, absorption of ETH50 is low. No systemic effects are observed after oral or dermal exposure up to 500 mg/kg bw/day. Due to the low bioavailability of ETH50, a risk assessment based on a NOAEL from oral studies and applying route-to-route extrapolation was not considered appropriate. Based on comparison of the internal dose in man and rat (resulting in a MoE of 357) and comparison of the NOAEL in the 13 week dermal study in the rat and the human systemic exposure dose it was concluded that the use of 10% ETH50 can be considered safe for dermal application.

The risk assessment of nanomaterials is evolving. It should be noted that the testing of the substance and the present assessment are based on methodologies initially developed for toxicity testing of substances in non-nano form and current knowledge. From this perspective, the SCCS concluded that the use of 10% ETH50 can be considered safe for dermal application. This assessment, however, is not intended to provide a blue-print for future assessments, where depending on the developments in methodology and risk assessment approaches and probable development of nano-specific testing requirements, additional/different data could be required and/or requested on a case-by-case basis.

At this moment there is too much uncertainty to conclude about safe use of 10% ETH50 in spray applications, because of concerns over possible inhalation exposure. Therefore, the SCCS concluded that spray products containing ETH-50 cannot be recommended until additional information on safety after repeated inhalation is provided.

The opinion was adopted.

### **8.2. Addendum to opinion SCCP/1202/08 on camphor benzalkonium methosulfate, S57**

Based on comments received from Switzerland and France, the SCCS is of the opinion that the conclusion in SCCP/1202/08, assessing the safety of the UV filter camphor benzalkonium methosulfate, needs to be adapted. This addendum provides the scientific rationale for the changed conclusion with regard to this substance.

The SCCS concluded that, with the described indications for limited oral bioavailability and in the absence of quantitative information that would allow for correction of the NOAEL, an assessment relying on route-to-route extrapolation from the results of oral repeated dose toxicity studies cannot be performed.

The addendum was adopted.

### **8.3. 2,6-Dihydroxyethylaminotoluene, A138**

*The SCCS was asked to answer the following questions:*

*Does the Scientific Committee on Consumer Safety (SCCS) consider 2,6-dihydroxyethylaminotoluene and its salts safe for the consumers, when used as a precursor in oxidative hair dye formulations with a concentration on-head of maximum 1.0% (calculated for the free base) taking into account the scientific data provided?*

The SCCS conclusion:

The positive results found in the *in vitro* gene mutation assay in bacteria were not confirmed nor ruled out in an appropriate *in vivo* test on the same genetic endpoint. Consequently, a final conclusion on the genotoxic potential of 2,6-dihydroxyethylaminotoluene cannot be drawn.

The safety assessment of 2,6-dihydroxyethylaminotoluene relates to the free base only. No information on any salt of 2,6-dihydroxyethylaminotoluene was available for safety evaluation.

The opinion was adopted.

### **8.4. HC Red n° 70 + HC Red n° 71, B71**

*The SCCS was asked to answer the following questions:*

- 1. Does SCCS 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 SCCS consider HC Red n° 10 + HC Red n° 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. And/or does the SCCS have any further concerns with regard to the use of HC Red n° 10 + HC Red n° 11 in any hair dye formulations?*

The SCCS conclusion:

The evaluation relates to a mixture of HC Red n° 10 (53 – 57%) and HC Red n° 11 (32 – 40%).

The SCCS concluded that the use of HC Red n° 10 + HC Red n° 11 with a maximum on-head concentration of 1.0% in oxidative and 2.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

A sensitising potential of HC Red n° 10 + HC Red n° 11 cannot be excluded.

HC Red n° 10 and HC Red n° 11 are secondary amines and therefore prone to nitrosation. In addition, 5 of the impurities also contain secondary and tertiary amino-groups. The nitrosamine content in the hair dye HC Red n° 10 and HC Red n° 11 is not reported. These substances should not be used in combination with nitrosating agents. The nitrosamine content should be less than 50 ppb.

The opinion was adopted.

### **8.5. 2,6-Diamino-3-((pyridine-3-yl)azo)pyridine, B111**

*The SCCS was asked to answer the following questions:*

- 1. Does the Scientific Committee on Consumer Safety (SCCS) consider 2,6-Diamino-3-((pyridine-3-yl)azo)pyridine safe for use as a non-oxidative hair dye with an on-head concentration of maximum 0.25 % taken into account the scientific data provided?*
- 2. Does the SCCS consider 2,6-Diamino-3-((pyridine-3-yl)azo)pyridine safe for use as an oxidative hair dye with an on-head concentration of maximum 0.25 % taken into account the scientific data provided.*
- 3. Does the SCCS recommend any further restrictions with regard to the use of 2,6-Diamino-3-((pyridine-3-yl)azo)pyridine in any non-oxidative or oxidative hair dye formulations?*

The SCCS conclusion;

The use of 2,6-diamino-3-((pyridine-3-yl)azo)pyridine with a maximum on-head concentration of 0.25% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

For a final assessment of the use of 2,6-diamino-3-((pyridine-3-yl)azo)pyridine with a maximum on-head concentration of 0.25% in oxidative hair dye formulations, data on the stability in an oxidative environment should be provided.

The opinion was adopted.

### **8.6. Basic Violet 2, B115**

*The SCCS was asked to answer the following questions:*

- 1. Does SCCS consider Basic Violet 2 safe for use as an oxidative hair dye with a maximum concentration up to 1.0% on the scalp taken into account the scientific data provided?*
- 2. Does SCCS consider Basic Violet 2 safe for use as a non-oxidative hair dye with a maximum concentration of 0.5% in the finished cosmetic product taken into account the scientific data provided?*

3. *And/or does the SCCS have any further scientific concerns with regard to the use of Basic Violet 2 in hair dye formulations?*

The SCCS conclusion:

the use of Basic Violet 2 with a maximum on-head concentration of 1.0% in oxidative hair dye formulations does not pose a risk to the health of the consumer.

The safety under non-oxidative conditions cannot be assessed due to an inadequate dermal absorption study.

A sensitisation potential of Basic Violet 2 cannot be excluded.

The opinion was adopted.

### **8.7. Basic Red 51, B116**

*The SCCS was asked to answer the following questions:*

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Basic Red 51 to be safe for use in non-oxidative hair dye formulations at a maximum on-head concentration up to 1% and in oxidative hair dye formulations at a maximum on-head concentration of 0.5% taken into account the data scientific provided?*
2. *Does the SCCS recommend any restrictions with regard to the use of Basic Red 51 in non-oxidative and oxidative hair dye formulations?*

The SCCS conclusion:

The use of Basic Red 51 with a maximum on-head concentration of 0.5% in oxidative and 1.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

The opinion was adopted.

### **8.8. Basic Blue 99, C59**

*The SCCS was asked to answer the following questions:*

*Does the Scientific Committee on Consumer Safety (SCCS) consider the use of Basic Blue 99 safe for consumers, when used as a direct hair dye substance in hair dye formulations with a concentration on-head of maximum 1.0% taking into account the scientific data provided?*

The SCCS conclusion:

Basic Blue 99 is a mixture of 23-32 substances of varying concentrations as demonstrated by the HPLC analysis of two batches RS2798801 and 74/75. (Figures 1-3)

Due to the highly variable composition of Basic Blue 99 in these batches, the safety of Basic Blue 99 cannot be evaluated.

The opinion was adopted.

### **8.9. Tetrabromophenol Blue, C183**

The SCCS considered that further discussion on the opinion was needed. The adoption of the opinion was postponed and the opinion will be further discussed at the WG.

## **9. ONGOING OPINIONS FOR DISCUSSION**

### **9.1. Updated scientific opinion on the labelling of 26 fragrance substances**

A draft opinion was presented for discussion. The chairman, Dr. I. White illustrated the Terms of Reference and the approach the WG has taken to answer the questions.

## **10. REQUEST FOR CLARIFICATION ON OPINION SCCS/1348/10 IN THE LIGHT OF THE DANISH CLAUSE OF SAFEGUARD BANNING THE USE OF PARABENS IN COSMETIC PRODUCTS INTENDED FOR CHILDREN UNDER THREE**

A revised draft opinion was presented for discussion. The SCCS reached agreement on the principle elements of the document. Due to the time restraints of this task, the SCCS decided that the opinion will be adopted by written procedure after having been revised according to the discussion.

## **11. COMMENTS ON OPINIONS FROM PREVIOUS PLENARY MEETINGS**

Comments on opinions adopted in the SCCS plenary meeting of 21 June 2011 have been received. All comments were reviewed and discussed by the experts at the WG and opinions were modified as appropriate.

The following opinions have been considered:

- C172, HC Blue n° 14
- P95, Ethyl lauroyl arginate HCl

## **12. ANY OTHER BUSINESS**

The next plenary meeting will take place on 13-14 December 2011

Annex 1: List of Participants

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## **Annex 1**

### **List of Participants**

#### **Members of the SCCS**

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

#### **Apologies**

Prof. J. Angerer

#### **SCCS Secretariat (DG SANCO)**

Ms. C. Arranz Aceves, Mrs K. Kilian, Mr. A. Van Elst

#### **DG SANCO B2**

Mrs G. Ciarlo, Mrs. F. de Gaetano