



Scientific Committee on Consumer Safety

SCCS

**OPINION ON
Dichloromethane
Submission IV**

The SCCS adopted this opinion at its 9th plenary meeting
on 25 March 2015

Opinion on Dichloromethane

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

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1. BACKGROUND

Dichloromethane (CAS No 75-09-2) is currently listed in Annex III (Entry 7) of the Cosmetics Regulation (EC) 1223/2009 to be used as solvent in cosmetic products with concentration limits up to 35% and furthermore, when the substance is mixed with 1,1,1-trichloroethane, the total concentration must not exceed 35%. In addition, under column (h) "Other" entry III/7 states "0.2% as maximum impurity content". The safety of these use conditions were confirmed by two scientific assessments in 1987 and 1989.

Dichloromethane has been classified as CMR 2 substance by the CLP Regulation (EC) 1272/2008. Regarding CMR 2 substances, Article 15.1 of the Cosmetic Regulation states that:

"The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products."

The latest opinion of the Scientific Committee on Consumer Safety (SCCS) of 11 December 2012 on the safety assessment of Dichloromethane with concentration up to 35% in cosmetic products concluded that:

"...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" (SCCS/1408/11)¹

Following these conclusions, in August 2014 EFfCI² has provided new data on the neurobehavioural effects and the exposure-related observations in humans of Dichloromethane.

2. TERMS OF REFERENCE

(1) In light of the new data provided, does the SCCS consider Dichloromethane (CAS No 75-09-2) safe when used in cosmetic products under the current use conditions up to maximum of 35%?

(2) Can the SCCS assess whether the restriction on purity present in column (h) is related to purity criteria for the dichloromethane itself or is related to its presence as an impurity in cosmetic products that should be restricted to 0.2%?

(3) Does the SCCS have any further scientific concern regard the use of Dichloromethane in cosmetic products?

¹ http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_118.pdf

² The European Federation for Cosmetic Ingredients

3. OPINION

No comprehensive safety dossier was submitted for the previous assessment of dichloromethane (SCCS/1408/11), which consequently was based primarily on publicly available data and recent risk assessments performed by other bodies.

The introduction to section 3.3 (Toxicological Evaluation – Animal data) in the previous Opinion (SCCS/1408/11) reads as follows: *"As the abundant human data are much more relevant in order to assess the risk to consumers for the use of dichloromethane in cosmetic products, toxicity data from animal studies are only briefly summarised in this opinion and are based on the evaluations performed by the Scientific Committee on Occupational Exposure Limits (SCOEL) in 2009 (82) and the IPCS/WHO in 1996 (47) as well as by IARC in 1999 (45)."*

Submission IV consists of original study reports describing various toxicological investigations in experimental animals performed in 1972-2000 (Ref.: 1-12), publicly available data and risk assessments performed by other bodies, as well as of two recent documents from the European Chlorinated Solvent Association (ECSA).

The submitted original study reports have all been included in the evaluations performed by the Scientific Committee on Occupational Exposure Limits (SCOEL) in 2009 (Ref.: 14), the IPCS/WHO in 1996 (Ref.: 15) and/or by IARC in 1999 (Ref.: 16) and thus, already included in the previous Opinion (SCCS/1408/11).

The publicly available data and risk assessments performed by other bodies were also available for the previous Opinion (SCCS/1408/11), although they were not specifically referenced in that Opinion.

One of the documents from ECSA is an extract of the REACH Chemical Safety Report (version March 2014), chapter 5 'Human health hazard assessment' of the joint submission REACH dossier. The other document from ECSA is their 'Comment to the Scientific Committee on Consumer Safety (SCCS) on the use of dichloromethane (DCM; CAS 75-09-2, EC 200-838-9) in hairspray' of July 2013; this document is a summary of the information from the joint REACH submission and from the OECD HPV dossier. The SCCS notes that no new information on the neurobehavioural effects and the exposure-related observations in humans of dichloromethane has been included in these two documents.

In conclusion, no new data on the neurobehavioural effects and the exposure-related observations in humans of dichloromethane have been included in Submission IV.

4. CONCLUSION

1. *In light of the new data provided, does the SCCS consider Dichloromethane (CAS No 75-09-2) safe when used in cosmetic products under the current use conditions up to maximum of 35%?*

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

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neurobehavioral and neurodevelopmental effects of dichloromethane after short-term exposure, the SCCS is of the opinion that dichloromethane in a concentration of up to 35% in hair sprays is not considered safe for the consumer."

2. *Can the SCCS assess whether the restriction on purity present in column (h) is related to purity criteria for the dichloromethane itself or is related to its presence as an impurity in cosmetic products that should be restricted to 0.2%?*

Not applicable.

3. *Does the SCCS have any further scientific concern regard the use of Dichloromethane in cosmetic products?*

No information concerning other uses in cosmetic products is available to the SCCS. However, based on the data provided, use of dichloromethane in spray formulations in general is not considered safe for the consumer.

5. MINORITY OPINION

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