

## SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

### Request for a scientific opinion: Toluene CAS 108-88-3

#### Background

Council Directive 2003/15/EEC amended Directive 76/768/EEC introducing Article 4b. It states that *“the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.”*

Toluene is classified as a CMR<sup>1</sup> category 3 substance toxic for reproduction. The substance is not regulated in any Annex to the Cosmetics Directive nor has it been evaluated before for cosmetic usage.

A dossier for the continued use of toluene as a solvent in certain nail products was submitted by COLIPA<sup>2</sup>.

The Scientific Committee on Consumers products (SCCP) adopted by its 9<sup>th</sup> plenary meeting in December 2007 an opinion (SCCP/1029/06) on toluene with the following conclusion:

*“For the present evaluation, measurements for two situations of nail product use were available:*

- Home use conditions (non-ventilated rooms): toluene air levels of 1 - 4 ppm*
- Client exposure in (ventilated) professional nail studios: 0.26 ppm*

*The duration of exposure is less than 30 min (typical application times 10-20 min). This exposure situation has been viewed in comparison to:*

- a) consumer exposure as characterized in the EU report on toluene (for two scenarios [U1 and U3A], for which there are at present no restrictions), and*
- b) occupational exposure limits (OEL) set for continuous 8 hour exposures where risks from levels of 25 to 50 ppm are considered as acceptable.*

*This comparison demonstrates that occasional consumer exposure to toluene present in nail cosmetics where the exposure may be within the range of 1 to 4 ppm can be considered as safe.*

*Although specific information related to the effects in children is limited and because of the low and occasional exposure, the SCCP is of the opinion that the presence of toluene as a solvent in nail cosmetics does not pose a risk to the health of all groups of consumers, independent of their age.*

*This conclusion is based on an exposure driven evaluation of both, acute inhalation effects and reproductive toxicity.”*

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<sup>1</sup> CMR: carcinogenic, mutagenic or toxic to reproduction

<sup>2</sup> COLIPA: European Cosmetic Toiletry and Perfumery Association

As part of the implementation of this opinion a discussion took place with stakeholders. From this discussion some questions were raised:

1. It is stated that "penetration through the nail plate is nil or minimal" (3.4.1. Cosmetic exposure p.10). However, this assumption was questioned by member states and industry was asked to provide documentation to support this statement.
2. From the consumer exposure scenarios (U1 = gluing and U3A = car maintenance (car polishing)) in the EU Risk Assessment Report on toluene, which were used to compare the actual consumer exposure, when toluene is used as a solvent in nail products the exposure was 1.89 ppm and 2.66 ppm respectively. These exposures resulted in a MOS of 21 and 15 for acute effects such as headache and dizziness, and of 40 and 28 for functional performance. For the same scenarios the MOS for reproductive toxicity by inhalation were 317 and 225, respectively. Questions were raised as to whether the MOS should be higher also for acute effects such as headache, dizziness and functional performance.
3. Whether a content of 25% really was technical needed.

The current submission from industry is a response to questions 1 and 3 above.

### **Request to the SCCP**

*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?*