

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: Picramic acid (CAS 831-52-7) submission III (B028)

1. Background

Submission I for Picramic acid with the chemical name 2-Amino-4,6-dinitrophenol has been submitted in January 1988 by COLIPA^{1,2}.

Submission II for Picramic acid has been submitted in May 1993 by COLIPA².

The Scientific Committee on Cosmetology (SCC) adopted at its 51th plenary meeting on 7 October 1992 an opinion (SPC/319/91) with the final conclusion that:

*“Picramic acid has moderate acute toxicity by the oral route, however, studies suggest that dermal penetration from hair dye formulation is low. There was no evidence of skin irritation with a 2.5 % solution. Mild transient conjunctival irritation was seen with a 2.5 % solution instilled into the eye and rinsed out after 10 seconds; although no data are available from animals not subjected to very rapid washout. The compound was a mild sensitiser in a maximisation test in guinea pigs. In a 90 day oral study a minimal effect level of 20 mg/kg was reported. The compound clearly has mutagenic potential. Positive results were consistently obtained in assays for gene mutation in Salmonella. It is essential to ascertain whether this potential can be expressed **in vivo**. Studies in the whole animal have been limited to the bone marrow. Negative results were obtained from a micronucleus test but only one harvest time was used. Negative results were also reported in an assay for SCE induction in bone marrow. No conclusions can be drawn regarding the carcinogenicity of picramic acid. No adverse effects were reported in an oral teratogenicity study in rats at up to 15 mg/kg. **In vivo** data are needed from a well conducted micronucleus test, to a current protocol, and also from an **in vivo** liver UDS assay.”*

Submission III has been submitted in July 2005 by COLIPA and concerns the sodium picramate (CAS 831-52-7). According to this submission Sodium picramate and Picramic acid are used in hair colouring formulations. As the pKa of Picramic acid is around 4, it is always the Picramate which is available in typical hair dye formulation (pH 6.5 – pH 10). Therefore the submission discussed mainly the sodium picramate.

Sodium picramate, a non-reactive dye, is used as a direct hair colouring agent up to on-head concentration of 0.6% in non-oxidative as well as in oxidative hair dye formulation. For non-oxidative hair dye formulations it is common practice to apply 35 – 50 mL of the undiluted formulation while for oxidative ones 100 mL are applied after mixing with H₂O₂. The application time for both formulation types covers a period of 30 minutes followed by washing off with water and shampoo. It is assumed that application may be repeated weekly.

Submission III presents updated scientific data on the above mentioned substance in line with the second step of the strategy for the evaluation of hair dyes

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

² According to records of COLIPA.

(<http://europa.eu.int/comm/enterprise/cosmetics/doc/hairdyestrategyinternet.pdf>) within the framework of the Cosmetics Directive 76/768/EEC.

2. Terms of reference

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Sodium picramate and Picramic acid safe for use as a non-oxidative hair dye with an on-head concentration of maximum 0.6 % taken into account the scientific data provided?*
2. *Does the SCCP consider Sodium picramate and Picramic acid safe for use in oxidative hair dye formulations with an on-head concentration of maximum 0.6 % taken into account the scientific data provided?*
3. *Does the SCCP recommend any further restrictions with regard to the use of Sodium picramate and Picramic in any non-oxidative or oxidative hair dye formulations?*

3. Deadline

December 2006.