



Scientific Committee on Consumer Safety

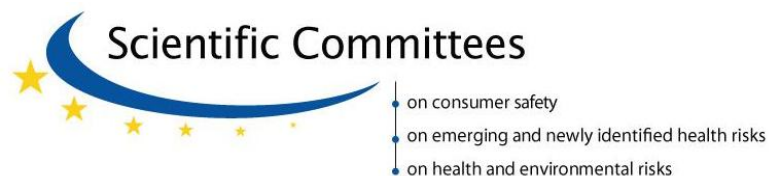
SCCS

Addendum to OPINION n° SCCP/1202/08

ON

Camphor benzalkonium methosulfate

COLIPA n° S57



The SCCS adopted this addendum at its 12th plenary of
20 September 2011

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. ADDENDUM

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.

In opinion SCCP/1202/08, a MOS of 109 was calculated for the use of Camphor benzalkonium methosulfate in sun protection and other cosmetic products, which was based on a NOAEL of 300 mg/kg bw/day for Mexoryl SO (a 30% solution of Camphor benzalkonium methosulfate) and data from an *in vitro* dermal absorption study.

The national authorities pointed out that in the case of Camphor benzalkonium methosulfate there are indications for a low oral bioavailability:

- 1) Only low levels of parent compounds could be detected in the blood following oral administration in a 90 day repeated dose toxicity study, and only at the highest dose level (1000 mg/kg bw/day Mexoryl SO).
- 2) In the dose-range finding study where Camphor benzalkonium methosulfate was administered subcutaneously, lethality (2 of 3 dosed animals) was observed at dose levels where no effects were seen in the oral study (300 mg/kg bw/day Mexoryl SO).

The information available in the submission is insufficient to quantify to the extent of oral bioavailability. A targeted request made to the applicant for this UV-filter did not produce further data suited to estimate the oral bioavailability.

The MoS calculation made in SCCP/1202/08 was based on some conservative assumptions:

- The amount dermally absorbed was based on an *in vitro* study using a formulation containing 6% Camphor benzalkonium methosulfate and the mean dermal absorption + 2 standard deviations was used for the calculation
- The NOAEL was based on local effects in the GI tract rather than systemic effects.

However, the SCCS is of the opinion that, with the above 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.