

OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD
PRODUCTS INTENDED FOR CONSUMERS

CONCERNING

2,4-BIS- {[4-(2-ETHYL-HEXYLOXY)-2-HYDROXY]-PHENYL} -6-(4-
METHOXYPHENYL)-(1,3,5)-TRIAZINE

Colipa n° S81

adopted by the plenary session of the SCCNFP
of 17 February 1999

Executive Summary

1. General data

- 1.1 Identity of the ingredient : 2,4-bis- {[4-(2-Ethyl-hexyloxy)-2-hydroxy]-phenyl}-6-(4-methoxyphenyl)-(1,3,5)-triazine
- 1.2 CAS n° : 187393-00-6
- 1.3 Use : sunscreen products, concentration : max. 10%

2. Terms of reference

2.1 Context of the question

The adaptation to technical progress of the Annexes to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

Request for inclusion of S81 in Annex VII, part 1 – List of UV filters which Cosmetic Products may contain – to Council Directive 76/768/EEC.

2.2 Request to the SCCNFP

The SCCNFP is requested to answer the following questions :

- * Is 2,4-bis- {[4-(2-Ethyl-hexyloxy)-2-hydroxy]-phenyl}-6-(4-methoxyphenyl)-(1,3,5)-triazine safe for use in cosmetic products?
- * Does the SCCNFP propose any restrictions or conditions for its use in cosmetic products?

3. Toxicological Evaluation & Characterisation

- 3.1 Acute toxicity (dermal, oral) : No abnormal signs of any kind were noted
- 3.2 Chronic/sub-chronic toxicity : No evidence of any dose related abnormalities
- 3.3 Reproductive toxicity : No evidence of teratogenicity
- 3.4 Percutaneous absorption : Very low absorption observed
- 3.5 Irritation and corrosivity : The active ingredient was judged to be non-irritant
- 3.6 Allergenicity and sensitisation : There was no evidence of sensitisation or photo-sensitisation
- 3.7 Genotoxicity/carcinogenicity : No evidence of mutagenicity or photo-mutagenicity

4. Opinion

The SCCNFP is of the opinion that 2,4-bis-[[4-(2-Ethyl-hexyloxy)-2-hydroxy]-phenyl]-6-(4-methoxyphenyl)-(1,3,5)-triazine is safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%.

The SCCNFP proposes no further restrictions or conditions for its use in cosmetic products.

5. Statement on the toxicological evaluation

The SCCNFP is the scientific advisory body to the European Commission in matters of consumer protection with respect to cosmetics and non-food products intended for consumers.

The Commission's general policy regarding research on animals supports the development of alternative methods to replace or to reduce animal testing when possible. In this context, the SCCNFP has a specific working group on alternatives to animal testing which, in co-operation with other Commission services such as ECVAM (European Centre for Validation of Alternative Methods), evaluates these methods.

SCCNFP opinions include evaluations of experiments using laboratory animals; such tests are conducted in accordance with all legal provisions and preferably under chemical law regulations. Only in cases where no alternative method is available will such tests be evaluated and the resulting data accepted, in order to meet the fundamental requirements of the protection of consumer health.