

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

CONCERNING

REFINED COAL TAR BY BI-DISTILLATION

adopted by the SCCNFP during the 13th Plenary meeting of
of 28 June 2000

Executive Summary

1. General data

- 1.1 Identity of the ingredient : Refined Coal Tar by Bi-distillation. Maximum benzo(a)pyrene content: 0.1 ppm, total of the following polyaromatic derivatives: benz(a)anthracene, chrysene, benzo(k)fluoranthene, benzo(j)fluoranthene, dibenz(a,h)anthracene, indeno(1,2,3-cd)pyrene and benzo(b)fluoranthene must not exceed 1 ppm
- 1.2 CAS n° : not available
- 1.3 Use (applied for) : cosmetic ingredient at the level of maximum 5% in hair care rinse-off products

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 to change Annex II, to Council Directive 76/768/EEC. Modify n° 420: Crude and refined tars with the exception of Refined Coal Tar by Bi-distillation listed in the annex III, part 1, n° .

2.2 Request to the SCCNFP

The SCCNFP is requested to answer the following questions:

- * Can refined coal tar by bi-distillation be removed from Annex II listing?
- * Can refined coal tar by bi-distillation with the following specification of the raw materials:
 - maximum benzo(a)pyrene content: 0.1 ppm
 - total of the following polyaromatic derivatives: benz(a)anthracene, chrysene, benzo(k)fluoranthene, benzo(j)fluoranthene, dibenz(a,h)anthracene, indeno(1,2,3-cd)pyrene and benzo(b)fluoranthene must not exceed 1 ppm

be present at a maximum concentration of 5% in rinse-off products only, not applied to the mucus membrane, be used safely?

3. Safety Assessment & Classification

The assessment followed the Notes of Guidance under scientifically based premises of consumer safety and leads to a classification 2A for the intended use.

Evaluation of genotoxicity, (*in vitro/ in vivo*) and carcinogenicity have shown that the compound cannot be safely used under the conditions stated in the Opinion.

4. Opinion

Refined coal tar by bi-distillation should not be removed from the Annex II listing. Refined coal tar by bi-distillation present at a maximum concentration of 5% in rinse-off products cannot be used safely as it contains polycyclic aromatic hydrocarbons which are genotoxic carcinogens and it may represent an unacceptable high risk of skin cancer.

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.

The extent to which these validated methods are applicable to cosmetic products and its ingredients is a matter of the SCCNFP.

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.