

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

CONCERNING

HYDROXYPROPYL BIS (N-HYDROXYETHYL-P-PHENYLENEDIAMINE), HCl

Colipa A121

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

Executive Summary

1. General data

- 1.1 Identity of the ingredient : Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine), HCl
1.2 CAS n° : 128729-28-2 (free base: 128729-30-6)
1.3 Use : oxidative hair dye; max. use concentration 3.0%, 1.5% in combination with hydrogen peroxide (1:1)

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.

2.2 The SCCNFP is requested to answer the following questions :

- * Is Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine), HCl safe for use in cosmetic products?
- * Does the SCCNFP propose any restrictions or conditions for its use in cosmetic products?

3. Safety Assessment & Classification

The assessment followed the Notes of Guidance under scientifically based premises of consumer safety and leads to a classification 1 for the intended use.

Evaluation of acute toxicity (oral), skin and mucous membrane irritation, sensitisation, sub-chronic toxicity (oral), reproductive toxicity (oral), genotoxicity, percutaneous absorption have shown that the compound can be safely used under the conditions stated in the Opinion.

4. Opinion

The SCCNFP is of the opinion that Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine), HCl can be used safely in oxidation hair dye formulations to a maximum concentration of 3.0 %. However, as oxidation hair dyes are mixed with hydrogen peroxide before application, the maximum in-use concentration should not exceed 1.5 %.

Since Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine), HCl is a sensitisier, cosmetic products containing this substance must carry a label warning of a risk of sensitisation.

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 extend 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.