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

UPDATED BASIC REQUIREMENTS FOR TOXICOLOGICAL DOSSIERS TO BE EVALUATED BY THE SCCNFP

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adopted by the SCCNFP during the 22nd plenary meeting
of 17 December 2002

On the basis of its experience, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) has defined a set of actions to be considered by the cosmetic industry when preparing and submitting a dossier for an ingredient to be evaluated by the SCCNFP for its possible inclusion in one of the Annexes III, IV, VI and VII of Council Directive 76/768/EEC.

SCCNFP BASIC REQUIREMENTS

1. For Cosmetic Industries when preparing and submitting a dossier for an ingredient to be evaluated by SCCNFP for its possible inclusion in one of the Annexes III, IV, VI and VII of Council Directive 76/768/EEC, the basic and minimal specifications for any ingredient should be:

- chemical identity
- physical form
- Molecular weight
- purity of the chemical
- characterisation of the impurities or accompanying contaminants
- solubility
- partition coefficient (Log P_{ow}).

This information must be included in each of the toxicological studies in the form of a certificate of analysis, for a definite characterisation of the sample employed in the study.

2. As stated in the "Notes of Guidance for Testing of Cosmetic Ingredients for Their Safety Evaluation" (SCCNFP/0119/99 Final[1]) toxicity studies should be performed according to the Guidelines laid down by the European Commission (Commission Directives 87/032/EEC and 92/69/EEC) or by the OECD, as well as in "accordance with the principles of Good Laboratory Practice (Council Directive 87/032/EEC)" as requested by the Sixth Amendment (Council Directive 93/35/EEC). All possible deviations from this set of rules must be explained and scientifically justified.

3. All new cosmetic ingredients, whose dossiers are submitted to SCCNFP's approval for their inclusion in the Annexes of Council Directive 76/768/EEC must contain studies for their *in vitro* assessment of percutaneous absorption, following the basic criteria indicated by the SCCNFP in Annex 10 of the Notes of Guidance for Testing of Cosmetic Ingredients for Their Safety Evaluation (doc. n° SCCNFP/0321/00).

4. In the case of a UV-light absorbing cosmetic ingredient the UV-light absorption spectrum must be included in the dossier; moreover, all the studies relating to the photo-toxic potential of the ingredient must be performed by applying the corresponding UV-light wavelength.

5. All UV-light absorbing new cosmetic ingredients whose dossiers are submitted to SCCNFP's approval for their inclusion in Annex VII of Council Directive 76/768/EEC must include, besides toxicological information required by Annex I, the reports of the *in vitro* studies on photo-genotoxicity/mutagenicity, and on photo-toxicity, by following the recommendations

[1] The document is updated at intervals. http://europa.eu.int/comm/food/fs/sc/sccp/outcome_en.html, 17.12.2002

provided by the SCCNFP. The *in vitro* photo-toxicity studies must be performed by applying the 3T3 NRU PT Test, according to the guidelines adopted by OECD (Draft New Guideline n° 432, March 2002 / B.41, Directive 2000/33/EC, JO L136, 8.2.2000, p. 90).

6. *In vitro* methods for the assessment of potentially cutaneous irritants, sensitising cosmetic ingredients or mixtures of ingredients have currently not been validated yet. Animal studies to predict the above said effects are reliable and well documented in scientific literature.

7. The use of human volunteers in the confirmatory testing of potentially cutaneous irritant cosmetic ingredients or mixtures of ingredients are subjected to ethical concern. The use of human volunteers in the predictive testing of potentially cutaneous sensitising cosmetic ingredients or mixtures of ingredients, as a contribution to human safety is questionable in comparison with animal testing. Moreover, in these studies a risk for human volunteers cannot be excluded and there is still a lack of information on the severity and frequency of adverse effects.

8. In the case of a hair dye ingredient, the dossier must conform to :

- the comments in the Memorandum on Scientific Evaluations and Opinion, doc. n° SCCNFP/0461/01

- the Assessment Strategies for Hair Dyes, doc. n° SCCNFP/0553/02, and to

- the Strategy for Testing Hair Dye Cosmetic Ingredients for their potential Genotoxicity/Mutagenicity, doc. n° SCCNFP/0566/02.