



Scientific Committee on Consumer Products

SCCP

Position statement

on

genotoxicity / mutagenicity testing of cosmetic ingredients without animal experiments



The SCCP adopted this opinion at its 19th plenary on 21 January 2009

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 Products (SCCP), 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 Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCP

Questions concerning the safety of consumer products (non-food products intended for the consumer).

In particular, the Committee addresses questions related to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.

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1. POSITION STATEMENT

The Seventh Amendment to the EU Cosmetics Directive 76/768/EEC bans the testing on animals of ingredients or combination of ingredients of cosmetics as of 11 March 2009. Thus, *in vivo* genotoxicity / mutagenicity tests will no longer be available for this important group of chemicals. At present, *in vivo* mutagenicity testing plays a crucial role in the evaluation of the mutagenic potential of cosmetic ingredients. According to the current "SCCP Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation" (SCCP/1005/06), *in vivo* tests are required in cases of positive *in vitro* mutagenicity test results. *In vivo* tests are not necessary when comprehensive *in vitro* testing has led to clearly negative results. However, current *in vitro* test protocols, as defined by international guidelines (e.g., OECD), are designed to identify hazards and to avoid false negative results.

Consequently, negative *in vitro* test results are highly reliable. In contrast, positive results may be due to experimental conditions that have no relevance for the *in vivo* situation and thus do not reflect a mutagenic risk of the test compound *per se*. In order to determine whether a positive *in vitro* result has any relevance *in vivo*, follow-up testing in animals is inevitable.

The practical importance of *in vivo* tests can be illustrated by recent SCCP evaluations of hair dyes (opinions adopted between March 2007 and June 2008). Among the 26 hair dyes evaluated, only two were assessed on the basis of negative *in vitro* tests only. *In vivo* tests were performed for 24 out of the 26 hair dyes. These hair dyes showed positive responses in different types of *in vitro* tests but all led to negative *in vivo* test results. The following conclusion can be drawn from these data:

- (1) *In vivo* testing has a decisive role in current mutagenicity testing since it is not possible to predict the results *in vivo* based on the outcome of positive *in vitro* tests alone.
- (2) The use of an *in vitro*-only test battery with the currently established *in vitro* tests for mutagenicity testing might lead to a scientifically unjustified high attrition rate of substances which would have been considered safe after *in vivo* testing.

In 2007, the SCCP stated in its "Memorandum on Actual Status of Alternative Methods on the Use of Experimental Animals in the Safety Assessment of Cosmetic Ingredients in the European Union" (SCCP/1111/07) that "with the currently available *in vitro* assays performed in accordance with the actual international guidelines it will not be possible to appropriately evaluate a mutagenic potential in many cases. New *in vitro* methods and test strategies are needed." There are several ongoing efforts by international expert groups to define better *in vitro* test conditions to avoid "irrelevant positives" and to improve existing tests. New *in vitro* genotoxicity tests (e.g., 3D skin models) are being developed but the process of method development and validation will take some years and the methodology will not be available by March 2009. It is impossible to predict whether these tests can completely substitute *in vivo* mutagenicity testing. Furthermore it should be noted that *in vitro* tests do require tissue from treated animals (liver S9-mix).

In summary, the current *in vitro* tests are very sensitive. In cases where clearly negative results are seen in an appropriate *in vitro* test battery, a mutagenic potential is excluded. At present no validated replacement methods are available that allow the follow-up of positive

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results from standard *in vitro* assays without further animal experiments. Consequently, after 11 March 2009, in many cases, it will not be possible to evaluate the mutagenic potential of cosmetic ingredients on a sound scientific basis. Because the potential mutagenicity of these ingredients is of major concern, an important part of the toxicological evaluation of cosmetic ingredients cannot be accomplished.