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Via E-mail: niceatm@niehs.nih.gov

Frankfurt, June 14 2007

Dear Madam / Sir

Re. LLNA: Request for Comments, Nominations of Scientific Experts, and Submission of Data (Federal Register 72 (95), May 17, 2007, page 27815)

The European Federation for Cosmetic Ingredients (EFFCI) appreciates a.m. request of NICEATM and the opportunity to contribute with comments and available data relevant to the term of references. EFFCI member companies have experienced over the last years more and more unexpected and unexplainable positive findings in the murine local lymph node assay. Most of these materials are in consumer use for decades without exhibiting any indication of skin sensitizing properties on the basis of guinea pig tests (M+K, Buehler), human data and/or experience. Based hereupon, EFFCI installed a LLNA working group to consider the scientific accuracy of LLNA results with cosmetic raw materials. Beside mechanistic considerations also experimental work was initiated by this working group with materials which apparently are not adequately represented in the existing validation trials of the LLNA.

In this respect EFFCI sponsored the following comparative experimental test with cosmetic raw materials and which we would like to share with NICEATM. EFFCI would appreciate if this report will be included in the ICCVAM evaluation process of the LLNA:

“Comparative Experimental Study
on the Skin Sensitising Potential of
Selected Unsaturated Chemicals as
Assessed by the Murine Local Lymph Node Assay (LLNA)
and the Guinea Pig Maximisation Test (GPMT)”
(Annex)

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In this study, eight unsaturated substances and one saturated substance - that were assumed to have low or no sensitisation potentials - were subjected to comparative testing in the LLNA and the Guinea Pig Maximisation Test (GPMT). The aim of this project was to investigate the justification or the potential limitations of the LLNA as a stand-alone method by comparing the sensitizing potential data obtained with these two different tests in strict adherence to their respective OECD guidelines.

EFfCI is also willing to actively participate in the evaluation and review process of this exercise and nominates Dr. Reinhard Kreiling, Chair of the EFfCI Toxicology Working Group as potential member of a possible peer review panel. Dr. Reinhard Kreiling is a Senior Toxicologist and Deputy Head of the Toxicology Department of Clariant GmbH, Sulzbach, Germany. A CV would be available if necessary.

We are at your disposal should you need further clarification or if you wish to discuss the results.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Peter Ungeheuer', is written over a light blue horizontal line.

Peter Ungeheuer
Secretary General

Annex