



GIVAUDAN'S KERATINOSENS™ ASSAY SETS STANDARD FOR SKIN SENSITISATION TESTING

EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) publishes recommendation on the KeratinoSens™ assay

- KeratinoSens™ is the first biological assay for skin sensitisation testing validated by EURL ECVAM (The European Union Reference Laboratory for Alternatives to Animal Testing)
- The method is based upon an engineered skin cell line that emits light if contacted by an allergen
- KeratinoSens™ is the culmination of years of dedicated research by Dr Andreas Natsch, Head of in vitro Toxicology research at Givaudan Fragrances, and his team

Dübendorf, 14 March 2014 – In a statement published on 17 February 2014, EURL ECVAM confirms that Givaudan's KeratinoSens™ method is transferable and reproducible within and between laboratories. The recommendation attests that KeratinoSens™, developed by Dr Andreas Natsch, Head of in vitro Toxicology Research, and his team, can be considered as a valuable component of integrated approaches for skin sensitisation testing.

Since the 7th Amendment to the Cosmetics Directive came into force in March 2013, the use of animal testing for cosmetic ingredients is banned in Europe, underlining the urgent need for alternative test methods. KeratinoSens™ and two other methods to test for the potential to cause skin allergy were put forward for validation by EURL ECVAM.

EURL ECVAM recommends that, before embarking on animal experiments, data from the KeratinoSens™ test method should be considered in combination with complementary information in order to avoid animal testing. EURL ECVAM also indicated areas of further research to further improve usage of data from KeratinoSens™.

KeratinoSens™ is based upon a genetically engineered cell line which contains a firefly gene regulated in such a way that light is emitted if the cells are contacted by an allergen. The intensity of the light signal provides a means of measurement of the risk of skin sensitisation.

Givaudan started working on a solution in 2006, publishing a landmark scientific paper on the subject in 2008 that described a key stress pathway that is induced in the skin by allergens. Activation of this pathway is measured in KeratinoSens™.

For a replacement test to be adopted industry-wide, it must prove to be able to be consistently applied in any laboratory. To establish that results from the KeratinoSens™ test can be replicated, the method was shared with several other laboratories in the cosmetic and chemical industry as well as an independent testing lab. The different laboratories all reported highly similar test results. This study was the basis for evaluation by EURL ECVAM.

To further establish the assay as an international standard, a draft guideline has recently been proposed to the OECD by the Swiss Federal Office of Public Health in collaboration with EURL ECVAM. An OECD expert group has discussed this new guideline in a meeting held in Paris, 13-14 February 2014.

Givaudan is delighted to have helped to develop standard methods aimed at reducing the need for animal testing in the cosmetic industry. Givaudan has already helped to commercialise the method at the Institute for In Vitro Sciences in Gaithersburg Maryland (US) and is now in the process of transferring the assay to other laboratories serving the cosmetic industry.

Media release. [DOWNLOAD](#)

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To see the ECVAM statement see:

http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-publishes-recommendation-keratinosens