



EpiDerm's Skin Irritation Test Fully Validated in European Union

Significant milestone met in development and validation of non-animal alternative test methods

December 17, 2008 / MatTek Corp., Ashland, MA (USA) announced that the ECVAM Scientific Advisory Committee (ESAC) endorsed the scientific validity of the Modified EpiDerm™ Skin Irritation Test (SIT) at its November meeting. ESAC concluded that the Modified EpiDerm SIT has sufficient accuracy and reliability for the prediction of skin irritating and non-irritating test substances.

The Updated EpiDerm SIT is a modification of the previously validated EpiDerm skin irritation method (ESAC Statement, April 2007). The major modification is an extended chemical exposure time from 15 to 60 minutes that reflects the robust barrier function of the EpiDerm model. The new exposure time provides an improved sensitivity of the *in vitro* EpiDerm SIT and better correlation with *in vivo* Draize rabbit skin irritation results.

The Modified EpiDerm SIT eliminates the need for animal testing when used to determine skin irritation potential of chemicals, including raw cosmetic materials. This development allows companies world-wide to comply with new European Union (EU) REACH legislation as well as the EU directive on the protection and welfare of animals used for experimental and other scientific purposes. This directive (EU 86/609) prohibits the use of animals in experiments if a validated alternative is available.

The Modified EpiDerm SIT will also be of great benefit to the Cosmetic Industry because testing of cosmetic raw materials in animals will be prohibited in the EU beginning March 2009 (7th Amendment of EU Cosmetic Directive).

John Sheasgreen, MatTek's President, added, "The validation of the Modified EpiDerm SIT involved multiple successful transatlantic tissue shipments from MatTek's US production facility to EU testing laboratories. The ability to ship EpiDerm tissues in this manner is yet another reason why MatTek has become the supplier of choice for both European and US organizations testing safety and efficacy of finished products and ingredients."

The Modified EpiDerm SIT validation study on which ECVAM based its new statement was performed under the auspices of ZEBET (BfR) in 4 independent EU and US laboratories during 2007. The testing fully complied with all validation rules outlined by OECD and ICCVAM (e.g. independent study management, coded reference chemicals, inclusion of naive laboratory, etc.).

About MatTek - MatTek Corp., founded in 1985, is the world's largest independent producer of *in vitro* human epithelial tissue equivalents. MatTek maintains a database that currently contains over 400 technical references and over 10 years of publicly available QC data supporting its claim of "Unsurpassed Tissue Reproducibility." MatTek human tissue equivalents are used in product development, claims substantiation (over 100 company patents cite the use of MatTek tissues), safety assessment, and drug discovery/development in many industries including Cosmetics, Personal Care, Household Products, Chemicals, Pharmaceuticals and Biotech.

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