ECVAM Validation of the EpiDerm Skin Irritation Test. H. KANDAORVA, P.J. Hayden, M. Klausner. MatTek Corporation, Ashland, MA. hkandarova@mattek.com, phayden@mattek.com

Abstract #1566990:

In April 2007, ECVAM endorsed 2 alternative methods (EPISKIN and EpiDerm Skin Irritation Tests (SIT)) as replacements of the in vivo rabbit skin irritation test. While EPISKIN assay was recognized as a stand alone method, EpiDerm SIT was endorsed for use in a tiered testing strategy (OECD TG 404), where irritating results are accepted and non-irritating results may require further testing by another method. Based on results published by Faller and Bracher (2002), and analysis of results of the ECVAM validation study, there was evidence that differences in the barrier properties between the 2 models were responsible for the lower sensitivity of EpiDerm SIT when using an identical protocol as used for EPISKIN. Therefore, modifications of the exposure conditions were introduced to the EpiDerm protocol: a) exposure time was increased from 15 min to 60 min; b) the temperature during the exposure was increased to 37°C. With these modifications, when testing chemicals from the pre-validation and validation studies, a significant increase in sensitivity (84%) was obtained, while maintaining an acceptable specificity of the method. In autumn 2007, an international validation study between 4 laboratories was performed to evaluate reproducibility and confirm the predictive ability of the modified EpiDerm SIT. Results of the study are presented here. Overall, sensitivity and specificity of 80% were obtained, which is comparable to results for the EPISKIN SIT for the same set of chemicals (sensitivity of 70%, specificity 80%). The inter-laboratory reproducibility of the modified EpiDerm SIT and its concordance with the in vivo rabbit data was also very good. The method was formally accepted by ECVAM as a validated method in November 2008. These results together with 14 years of consistent Quality control data for the EpiDerm tissue model make it the ideal choice for skin irritation testing without the use of animals.

To be presented at the Society for In Vitro Biology (SIVB) Annual Meeting, June 6-10, 2009 in Charleston, SC (USA)