



In Vitro Skin Irritation Test: Increasing the Sensitivity of the EpiDerm Skin Irritation Protocol Evaluated in the ECVAM Skin Irritation Validation study

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ABSTRACT/ INTRODUCTION

During 2001-2004, refined EPISKIN and EpiDerm in vitro skin irritation protocols were developed (1, 2), showing good correlation between in vivo and in vitro data. Both methods were based on the idea of a common protocol, comprised of 15 min application and 42 h post-exposure period. In 2004, these protocols proceeded into the ECVAM validation study with the aim of replacing the rabbit *in vivo* test (OECD TG 404). Based on results published by Faller and Bracher (2002) (3) and comparing the outcomes of the EpiDerm and EPISKIN optimization studies, there is evidence that the more robust barrier of the EpiDerm model caused false negative outcomes in the common protocol design. Therefore, a modification of the common protocol was introduced by extending the exposure time from 15 min to 60 min for the EpiDerm model. With this change, we obtained a significant increase in sensitivity without decreasing the specificity of the method. This presentation summarizes results obtained with the original (15 min/ 42 h) (2) and modified protocol (60 min/ 42 h). Results are compared to *in vivo* rabbit data as well as results from a recently performed human patch study (4).

To be presented at EUROTOX 2007, October 7-10, 2007, in Amsterdam, The Netherlands