

In Vitro Skin Corrosion Test: Long Term Reproducibility and Reliability Of a Regulatory Accepted Method

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ABSTRACT/ INTRODUCTION

The potential for chemicals to cause skin effects such as corrosion is a concern of industrial toxicologists in their assessments of possible worker and consumer safety issues. Moreover, the U.S. Department of Transportation (DOT), the new regulation on the Registration, Evaluation and Authorization of Chemicals (REACH), and other international and national regulatory agencies require that substances should be labeled with regard to skin corrosivity potential for tissue destruction.

In the past, skin corrosion assessments were based on tests involving topical application of test substances to the skin of rabbits. However, based on two ECVAM Validation studies performed during 1996-2000 with two reconstructed human skin models (EpiDerm and EPISKIN), the OECD approved use of these skin models as regulatory accepted methods (OECD TG 431) replacing the in vivo test (1).

In the present study, the EpiDerm skin corrosion test was repeated with the commercially available test substances previously used in both ECVAM validation studies (2, 3). The aim was to demonstrate the long term reproducibility and reliability of the EpiDerm model and the method, as required by regulators (4). The data obtained show very good correlation over a period of 7 years. A secondary aim of this study was to evaluate the assay prediction model for materials that interfere with the MTT endpoint used in the method. This presentation summarizes data obtained with the EpiDerm skin corrosion assay and demonstrate recent improvements which allow testing materials interfering with the MTT endpoint.

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