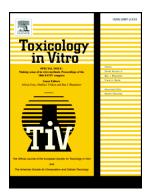
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Usefulness of the EpiSkinTM reconstructed human epidermis model within Integrated Approaches on Testing and Assessment (IATA) for skin corrosion and irritation



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ACCEPTED MANUSCRIPT

Usefulness of the EpiSkin[™] Reconstructed human Epidermis model within Integrated Approaches on Testing and Assessment (IATA) for Skin Corrosion and Irritation

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Abstract

Predictive capacity of the EpiSkin[™] model was evaluated on 87 chemicals using the Bottom-Up and the Top-Down testing approaches recommended within Integrated Approach on Testing and Assessment for the identification of both skin irritation and corrosion hazards. Classified (UN GHS Cat. 1 and Cat. 2) chemicals were identified with a very high sensitivity (≥94%) and the non-classified (UN GHS Cat. 3 and No Cat.) chemicals with an appropriate specificity (70%). Very high sensitivities were obtained for the identification of Cat. 1 chemicals (≥98%), very high specificities for non-Cat. 1 chemicals (93%), and accuracies of -95% for the identification of skin corrosives vs. non-corrosives by both approaches. Overall accuracies of 72% were found for predicting the single (sub)categories: non-classified, Cat. 2, Subcat. 1B/1C and Subcat. 1A. Results indicated the testing strategies to be more predictive than the individual assays on a conservative safety approach. Finally, no extreme misclassifications (no under-prediction of *in vivo* Subcat. 1A as non-Cat. 1, and no over-prediction of non-classified chemical as Subcat. 1A) occur. These findings, independently of the approach used, confirm the usefulness of the EpiSkin[™] *in vitro* model for a safe prediction of the skin irritant and corrosive hazards of chemicals.

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