

AN IMMATURE HUMAN RECONSTRUCTED EPIDERMIS MODEL TO ASSESS INFANT PERSONAL CARE PRODUCT RANGES

<u>Catoire, Sophie</u>¹; Lopez, Fabiola²; Mora, Daniel²; Ficheux, Hervé¹; Thélu, Amélie¹; Josseaume, Adeline¹; Lambert, Elodie¹; Rodriguez, Benjamin² and Cano, Andrea².

In Vitro Toxicology, THOR Personal Care, Compiègne, France.
In Vitro Toxicology, THOR Químicos, Querétaro, México Corresponding authors: sophie.catoire@thorpc.fr, fabiola.lopez@thor.com and daniel.mora@thor.com

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Introduction. The personal care market for children is rapidly expanding and increasingly requires a specific approach. Recent publications have re-evaluated the old notion that skin is fully matured at birth and have shown that infant skin differs in structure, function and composition from that of adults (1, 2). In consequence, these qualitative and quantitative differences may facilitate the development of pathological conditions, such as topic dermatitis and irritant contact dermatitis. Therefore, the safety assessment of raw materials and finished products for baby cannot be extrapolated from human adult data but must be considered as a new approach with adapted models.

The purpose of this work is to evaluate the use of an immature human reconstructed epidermis model as a new safety assessment tool during the formulation phase of baby care products.

Material and methods. THOR VitroDerm human epidermis model is reconstructed from primary keratinocytes grown at air-liquid interface. In order to respect the morphology and properties of baby skin, especially the stratum corneum, an "immature" human reconstructed epidermis has been developed. Baby care formulations were applied for 15 and 20 hours (dilution at 2% for rinse off formulations). Adult and baby epidermis models were compared using the % of cell viability endpoint, MTT assay (3). Results of 48 hours single patch test (20 adults) were used as reference.

Results

VitroDerm vs baby VitroDerm

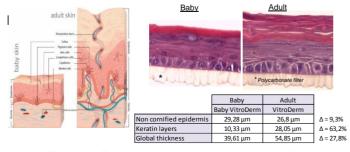


Figure 1 & Table 1. Histological vertical section of Baby VitroDerm and VitroDerm (X40, hematoxylin/eosin staining)

MTT Viability assay results are shown in Figure 2. Results of patch test (*In vivo*) / *In Vitro* comparison with commercialized rinse-off products are not shown in this resume.

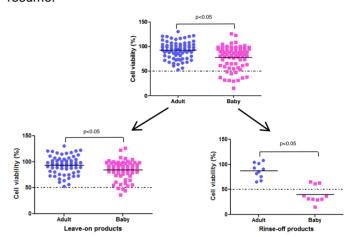


Figure 2. Paired t test data 72 personal care

Conclusions. A statistically significant difference (t test; p<0.05) was found when adult (mature) and baby (immature) models were compared as a whole. This difference became more relevant when stratified analysis was made between rinse-off and leave-on products.

Improvement in the prediction of irritation with this new model allows a better safety assessment during the development of baby products and can be used as a tool to select the most appropriate ingredients during formulation.

References

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