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Inter-laboratory study of the skin distribution of 4-n-butyl resorcinol in *ex vivo* pig and human skin

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ABSTRACT

4-n-butyl resorcinol (4-nBR) is a highly effective tyrosinase inhibitor, and can be used in cosmetic product for depigmentation purpose. Its efficacy correlates with 4-nBR that absorbed by skin. In this study, skin distribution of 4-nBR within either human or pig skin *ex vivo* was studied and compared by three independent laboratories. Good agreement was observed in each compartment considering usual inter-lab variability. This study supports the use of pig skin as an alternative source of skin when the availability of human skin is a limiting factor.

Key words

Skin distribution; Method validation; Mass spectrometry; Stratum corneum; Tape stripping; Robustness

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Declaration of interest

The authors have no conflict of interest to declare.

1. Background

The purpose of *ex vivo* skin distribution studies of cosmetic ingredients are to obtain quantitative data on the compound amounts in the different skin layers, as well as providing important information about the safety of a product in real-world use. This information is an increasingly important aspect of regulatory studies, product support claims and formulation screening [1]. Several guidelines have been developed, including the OECD test guidelines 428 (OECD, 2004) [2] and the SCCS guidelines (SCCS, 2010) [3]. The intention is to provide practical guidance to facilitate harmonized interpretation of experimental data from specific dermal absorption studies, and also to provide advice on alternative ways to estimate dermal absorption when there are no data or few specific data available. According to the guidelines, human skin is the best choice but is not always readily available. Alternatively, pig skin may be used because it shares essential permeation characteristics with human skin [4].

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