A comparison between expert clinical assessment of erythema and instrumental measurements associated with cutaneous erythema

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Introduction:

The prediction of human cutaneous irritation has moved away from being primarily based on the use of experimental animals. The most widespread method applied was that based on the original procedures of Draize et al involving the rabbit, but some workers have employed other species such as mice, guinea pigs, or domestic pigs. There are however, inherent problems of extrapolating from animals to humans. There are also practical, economic and ethical reasons for attempting to devise alternatives to Draize type tests. Whilst some progress has been made in terms of alternative in vitro test systems, in vivo methods using human volunteers are more easily interpretable and are able to predict clinically relevant consumer end points, such as erythema, oedema, scaling and other undesirable consequences of exposure to an irritant. In vitro acute toxicology models, using exposures up to 48 hours to test compounds or cosmetic formulations are able to provide some data on likely irritation potential but cannot describe the range of consumer relevant end points described above that can manifest despite low toxicology irritation ranking. We have previously published work examining the optimum methodology for cutaneous irritation testing, including the influence of exposure time and occlusive chamber size in predicting irritation in even very weakly irritant cosmetic products. In this paper, we present research using experimental patch test models with surfactants and blends used in personal care products. In these studies, we sought to determine the correlation between visual scoring of erythema by trained expert assessors, with measurement of erythema using a Chromameter™ and skin temperature using an infra-red non-contact thermometer.

Materials & Methods:

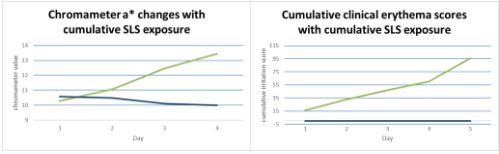
- Patch testing was according to our previously published methodology (1). All volunteers involved in these studies met the inclusion and exclusion criteria and gave written consent. The research was approved by an independent ethics committee.
- The test site for the irritancy study was the mid to lower part of the back between the waistline and the mid-point between the waist and the shoulders, avoiding the area over the vertebral column.
- Exposure to test substances was cumulative over 5 consecutive days.
- Erythema was measured with a Minolta Colorimeter CR 400.
- Temperature was measured with a Rayco infra-red thermometer. Clinical grading of erythema was by expert nurse graders using a validated 0-6 scale.
- Surfactants used were all at 0.2% dilution and were: Sodium Lauryl Sulphate SLES), Sodium Lauryl ether sulphate (SLES), Cocamidopropyl betaine (CAPB) and blends of CAPB/SLES.

References:

1.Dykes P J & Marks R (1992). An evaluation of the irritancy potential of povidone iodine solutions: Comparison of subjective and objective assessment techniques. *Clinical & Experimental Dermatology* 17, 246-249.

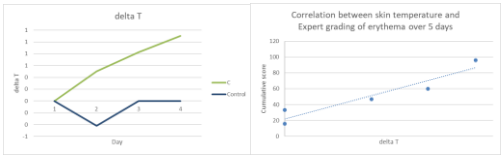
Results & Discussion:

Comparison between Expert clinical grading and Chromameter measurements using 0.2% SLS exposure: (green) or control (Black)



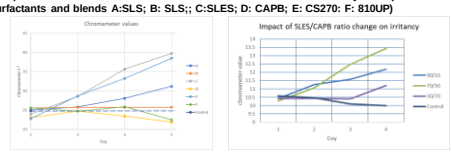
Visual grading correlated significantly with a* measurements (r=0.94)

Change in Skin temperatura using 0.2% SLS exposure: (green) or control (Black)



There was a positive cirrelation (r=0.96) between skin temperatura and clinical grading.

Comparison of Chromameter a* measurements for a series of commonly used personal care surfactants and blends A:SLS; B: SLS;; C:SLES; D: CAPB; E: CS270: F: 810UP)



Erythema severity measured by Chromameter or expert grading (not shown), both correlated highly with known mildness of surfactants and surfactant blends.

Conclusions:

Determining the irritation potential of personal care products before consumers use them is vital for consumer safety and confidence. Invitro irritation assays can be performed but do not allow for cumulative exposure to products in scenarios similar to how consumers will be exposed to products as assays are restricted to 48 hours máximum. In these experiments we have observed that expert clinical graders are able to rank the irritation potential of even very mild surfactant products and that colour and temperatura are potential valuable additional measures of irritation potential.

The primary end point discussed in this poster is erythema. However, expert graders are able to record irritation effects that do not occur when invitro models are used, such as oedema, scaling, pustules etc.

We conclude that expert grading of the irritation potential of personal care products remains the gold standard for consumer protection and safety assessments.