

Review of Analytical Methodologies for the Study of Interactions between Cosmetics and Personal Care Products and Skin

Dr Ben Cliff,

Intertek NWTC, Quarry Road East, Bebington, Wirral, CH63 3JW, ben.cliff@intertek.com

The Challenge

When developing new products for the cosmetics and personal care markets a vital consideration is how the product will interact with the skin. This may be from a regulatory point of view to ensure that the product does no harm to the user or from a product development or claim support angle. We present here an overview of analytical methodology in this field together with relevant examples.

Tape Stripping for Adhesive Assessment

Tape stripping is simply a process to remove the top layer of skin cells from a test subject in order to determine the concentration of a specific chemical species in this layer. It can be utilised to monitor delivery of actives to the skin from applied products (e.g. aluminium in deodorants). In this case it was used to quantify the difference in "skin removal" between two different adhesives in a wound care product application.

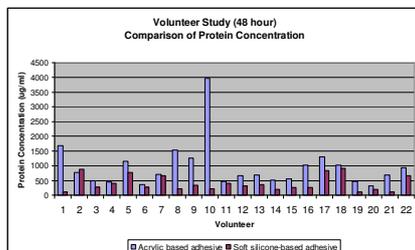
The effect on skin when a wound care product is removed is important to consider during product development. It is clear that the dressing needs to remain in place for the intended duration however the dressing must not cause further damage to the skin upon removal. This is particularly pertinent with patients with thin or fragile skin such as the elderly.

Methodology

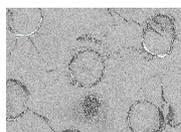
Examples of acrylic and silicone based adhesives were tested on 22 volunteers. Examples of the dressings were applied to healthy skin and the adhesives were left in contact for 48 hours and carefully removed. After removal, the volunteers were asked to quantify the level of discomfort to establish if the pain could be correlated with the skin removal. The removed dressings were extracted using an SDS solution and the level of protein (and hence skin) removed in each case was quantified using a standard BCA protein assay. In some cases electron microscopy was also used on the adhesive surface to visualise the difference in the skin attachment.

Results

The graph below shows the level of protein on each dressing (blue: acrylic adhesive, red: silicone adhesive). There is clearly significant variability in the results but the trend shows that silicone adhesive causes less skin to adhere to the dressing upon removal.



The SEM images also show a clear difference in the level of skin cells attached to the dressing after removal.



SEM images of acrylic adhesive (top) and silicone (lower)

Conclusions

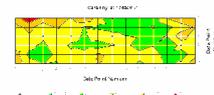
The results show that the silicone adhesive is significantly "kinder" to the volunteer's skin after removal. This observation was also backed up by the discomfort questionnaire which also showed that the silicone adhesive was preferred by most test subjects.

FTIR Analysis of Skin – Organic Deposition

Fourier Transform Infra Red (FTIR) spectroscopy is a well established technique for the analysis of organic molecules. At Intertek we can apply this powerful technique to the analysis of skin samples. We use an attenuated total reflectance (ATR) accessory which is used to obtain spectra from the surface of solid materials, usually with a penetration depth of around a few microns. There are two main methods for skin analysis using FTIR:

- (i) The technique can examine the subject's skin surface directly. In this instance the subject's applies the cream/lotion to their forearm using a protocol method. The forearm is placed into contact with the crystal surface and the Fourier Transform infrared (FTIR) spectrum acquired to detect/monitor the deposited ingredient.
- (ii) Alternatively an adhesive test strip can be applied to the treated skin area. This is subsequently analysed and will give information from slightly deeper into the skin.

It is also possible to perform imaging of the concentration of an active on the skin surface using the ATR imaging accessory. Example shown right.



Point contour map

In Vitro Skin Testing – Animal Free

With the 7th amendment of the cosmetics directive banning animal testing of these products together with the REACH regulations alternative testing methods have been developed, coordinated by the European Centre for Validation of Approved Methods (ECVAM).

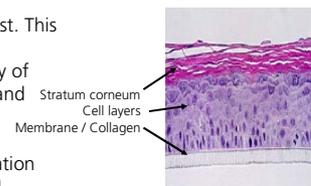
Alternative methods (AMs) are essentially carefully designed "biological predictor systems" which allow the adverse (hazardous) effects of chemicals and products to be determined by extrapolating from local cellular effects in the dish to an intact organism.

There are a several types of synthetic models which may be utilised: Episkin® and Skinethic® human reconstructed epidermis.

- Corneal
- Oral / Oesophageal / Gingival / Mucosal / Vaginal
- Coloured and non-coloured skin.

Skin irritancy assay can be performed using a (ECVAM) method as an alternative to the Rabbit Draize test. This predicts the cytotoxic effect of a chemical based on the cell viability of the test substrate after exposure and incubation

Histology of the Episkin model



Methods also exist for ocular irritation currently pre-validated by ECVAM

Summary

There is a wide range of chemical testing methods available for the study of the interactions of products with skin (either synthetic or real). Intertek has a wide ranging experience of carrying out such testing for clients in a variety of industrial sectors.

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