Title of the Invention: A micropatch for assessing chemical contact allergy
Abstract Title: Micropatch for contact allergy testing

A micropatch is used to apply allergens to the skin in existing diagnostic patch test concentrations. The micropatch of the present invention provides a reliable and effective system of elicitation necessary for the diagnostic identification of allergy cases whilst substantially reducing the chances of sensitising subjects. The application area of the micropatch may be less than 0.5cm², most preferably less than 0.1cm², and is applied to the upper arm rather than the back. The micropatch may be provided by a small chamber or stamp.
A micropatch for assessing chemical contact allergy

The invention relates to a micropatch for use in chemical contact allergy testing to identify individuals exhibiting contact allergy to one or more allergens.

Current screening methods for chemical contact allergy typically consists of applying allergens in petrolatum using an 8 mm diameter (0.5 cm²) aluminium chamber, an 8mm x 8 mm square plastic chamber, or a 10mm x 10mm impregnated stamp. The allergens are part of a collection of common allergens (e.g., the European Baseline Series) which are usually applied to the upper back for 2 days.

When the allergens are removed the skin is read for any reaction at this time and again a further 1-5 days later using standardised criteria (e.g., ICDRG criteria) (Fregert S. Manual of Contact Dermatitis, 2nd Edition Copenhagen, Munksgaard 1981).

A positive reaction indicates contact allergy to the allergen(s) in question.

The standard method for screening for hair dye allergy is with the allergen aromatic amine para-phenylenediamine (PPD). In European clinics typically between 2% and 5% of patients screened are positive for PPD allergy (Thyssen JP, White JM. Epidemiological data on consumer allergy to p-phenylenediamine. Contact Dermatitis 2008; 59: 327-3).

However, active sensitisation caused by the PPD diagnostic patch test itself (i.e. the patient becomes sensitised as a result of the actual diagnostic process) is a significant problem. The frequency with which this occurs is disputed, some reports rate the incidence as high as 1.5%
(Devos SA, van der Valk PG. The risk of active sensitisation to p-phenylenediamine. Contact Dermatitis 2001; 44: 273-275) whilst others report the rate of sensitisation caused by the test to be less than 0.2% (Dawe SA, White IR, Rycroft RJG et al. Active sensitisation to para-phenylenediamine and its relevance: a 10-year review. Contact Dermatitis 2004; 51: 96-97).

Nevertheless, of all the allergens used in standard chemical contact allergy screening, PPD is generally regarded as the allergen most likely to cause active sensitisation.

In an attempt to reduce the frequency with which sensitisation occurs, testing at a reduced concentration has been attempted. However, this more than halves the rate of detection of allergic individuals, rendering the test useless as a screen for detecting hair dye allergy.

A need exists for an accurate and reliable means of identifying allergic individuals which does not expose subjects to the risk of becoming sensitised by the test itself.

In a first aspect the invention relates to a micropatch for chemical contact allergy testing to identify individuals exhibiting contact allergy to one or more allergen having an application area of less than 0.5 cm².

In another aspect the invention relates to a micropatch wherein the micropatch is provided by a small chamber.

In another aspect the invention relates to a micropatch wherein the micropatch is provided by a stamp.
Detailed Description:

The present invention is based on the realisation that the key to separating, and so reducing, the risk of the induction of skin sensitisation from the need to elicit a skin reaction for the purposes of diagnosis is for the latter to employ a skin area below that required for effective induction, but which remains effective for elicitation.


It does not matter whether the exposed area is 1 cm² or 10 cm², if the dose per unit area is the same then the chances of becoming sensitised are the same (Friedman PS The relationship between exposure dose and response in induction and elicitation of contact hypersensitivity in humans. Br J Dermatol 2007; 81: 507-59).

However, this relationship breaks down at very low areas of application (Recs JL, Friedmann PS, Matthews JN. The influence of area of application on sensitization by dinitrochlorobenzene. British Journal Dermatology 1990; 122 (6): 29-31). Report that 96% of subjects were sensitised when exposed to the strong allergen 2,4-dinitrochlorobenzene (approximately equivalent in strength to PPD) when applied to 0.8 cm² of skin, but only 26%
of subjects were sensitised when the same dose/unit area was applied to an area of skin of 0.08 cm².

The micropatch of the present invention provides a reliable and effective system of elicitation necessary for the accurate identification of allergy cases whilst substantially reducing the chances of sensitising subjects.

The present invention provides a variety of micropatches of different types being chambers or impregnated stamps each having an application area of less than 0.5 cm². Preferably the micropatch is provided by a small chamber or ‘stamp’ as is well known in the art.

Optionally the micropatch has an application area of less than 0.45 cm².

Optionally the micropatch has an application area of less than 0.4 cm².

Optionally the micropatch has an application area of less than 0.35 cm².

Optionally the micropatch has an application area of less than 0.3 cm².

Optionally the micropatch has an application area of less than 0.25 cm².

Optionally the micropatch has an application area of less than 0.2 cm².

Optionally the micropatch has an application area of less than 0.15 cm².

Optionally the micropatch has an application area of less than 0.1 cm².

Optionally the micropatch has an application area of less than 0.05 cm².

Optionally the micropatch has an application area of less than 0.04 cm².

Optionally the micropatch has an application area of less than 0.03 cm².

Optionally the micropatch has an application area of less than 0.02 cm².

Optionally the micropatch has an application area of less than 0.01 cm².

Optionally the micropatch has an application area of less than 0.005 cm².
Preferably the micropatch is used to apply allergens in the existing diagnostic patch test concentrations. Optionally the concentration and/or the vehicle employed can be varied as necessary.

The micropatch may be applied to any suitable site on the body, more preferably the micropatch may be applied to the upper arm; thus avoiding any potential, theoretical enhancement of sensitisation risk caused by lymphatic drainage of other allergens, as may occur when multiple patches are applied to the back.
Claims:

1. A micropatch for chemical contact allergy testing to identify individuals exhibiting contact allergy to one or more allergen having an application area of less than 0.5 cm².

2. A micropatch as claimed in claim 1 wherein the micropatch is provided by a small chamber.

3. A micropatch as claimed in claim 1 wherein the micropatch is provided by a stamp.

4. A micropatch as claimed in any preceding claim having an application area of less than 0.4 cm².

5. A micropatch as claimed in any preceding claim having an application area of less than 0.3 cm².

6. A micropatch as claimed in any preceding claim having an application area of less than 0.2 cm².

7. A micropatch as claimed in any preceding claim having an application area of less than 0.1 cm².
Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

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<td>EP 2119469 A1 (HISAMITSU PHARMACEUTICAL CO., INC.) See paragraphs 14-24 and the figures at least</td>
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A Document indicating technological background and/or state of the art.
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E Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:
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A61B

The following online and other databases have been used in the preparation of this search report

EPDOC, WPI, BIOSIS, MEDLINE

**International Classification:**

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