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(72) Inventors PIERRE JACQUET and MICHA ROUMIANTZEFF



(54) ADHESIVE PAD FOR SKIN TESTS

(71) We, INSTITUT MERIEUX, a French Body Corporate of 17, rue Bourgelat, 69002 Lyon, France, do hereby declare the invention for which we pray that a patent

5 may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

10 The present invention concerns an adhesive pad for skin tests as well as a manufacturing process for this pad.

15 Numerous adhesive pads are already known for the type of skin test known as a "patch test", comprising an absorbent patch and an adhesive backing as, for instance, adhesive plaster type material. The person making the test applies the test liquid to the absorbent part at the time of use and then the pad is applied to the skin, for instance on the arm or back of the patient.

20 The patterns known at present have numerous disadvantages. First of all, the test substances used, especially allergens such as dinitrochlorobenzene, present serious risks of sensitisation for people frequently exposed to contact with them, which is the case with regard to those applying the substance to the absorbent patch when the test pad is applied. These difficulties are enhanced by the need

25 to prepare the solutions a short time in advance or sometimes on the spot, as is especially the case with unstable allergens and those which are difficult to handle. Secondly, it is difficult or impossible to obtain in this way a homogeneous application of the substance on the skin. It frequently happens that either local overdoses are obtained, which can provoke irritations or other serious symptoms of the patient, or on the other hand an insufficient dose is given which is then reflected in a lack of reaction leading to an erroneous interpretation. Finally, the contours of the area of skin receiving the application of the substance are frequently irregular in shape and thus may either prevent the recognition of a positive reaction when this reaction is weak, or give rise to difficulties in interpreting the intensity of the reaction.

45 The present invention aims to overcome

these various disadvantages and to supply a pad for skin tests which does not require application of the active dose at the time of use, and which practically removes all risk of contact between the substances and the operator whilst preserving the properties of the substances to be applied in the test, particularly as regard volatile allergens or those in small doses.

According to one aspect of the present invention we provide an adhesive pad for skin tests, comprising an adhesive base having on its central portion: a first layer of an aluminium or similar metal foil, coated with a plastics material; a patch of an absorbent material containing a dose of the test material, the said patch being fixed at the centre of the said first layer; and a second layer of metal foil bonded to the first layer as close to the periphery of the absorbent material as possible.

70 The pads according to the invention in fact afford an excellent protection for the test materials in relation to external phenomena such as oxidation, light effects, humidity etc. It also makes it possible, at least in certain cases, to modify the procedure of the test applications by inducing spontaneous primary reactions which can be reproduced to an adequate extent, avoiding the need for the second application which at present is frequently necessary. Finally, it also permits a considerable reduction in the administered doses and thus in the risks of accident or upsets, whilst ensuring that the reactions are reproducible with the required safety factor.

85 The said second layer is preferably provided with a simple and sure means of gripping it and removing it. The plastics material coated on the first layer is preferably polyethylene, a vinyl resin, an alkyl vinyl resin, polyvinylidene chloride or a vinylic or acrylic copolymer. In general, any resin or polymer which is capable of coating aluminium foil or a similar metal may be used. The synthetic substance allows the second external layer to be bonded to the first one and also allows the absorbent material to be fixed in place.

sitised by the direct application, onto the skin of a few drops of an acetone solution introducing 1,000 to 2,000 gamma of the test material. A protective dressing is then applied to the point of application after the acetone solvent has evaporated. The patient himself removes the protective dressing after a contact time of 24 hours. Two to three weeks later, the patient returns for an inspection to see whether a possible spontaneous primary reaction has taken place. Generally, this is not the case and a fresh dose of 100 gamma, or a sequence of variable doses (100—50—20 gamma), will be applied to produce the indication of the state of sensitisation. A third visit by the patient is then necessary 24 to 48 hours later for the assessment of the reaction.

2). The test using the pad according to the invention:

On the first visit, a 100 gamma pad constructed and dosed in accordance with the invention is applied, and 24 hours later, the patient himself removes the pad.

A second visit takes place 10 to 12 days after the application of the test for an assessment of the response which may be effected immediately because of a spontaneous systematic primary reaction (referred to as "spontaneous flare" by English authors).

If required, one can, of course, complete the immunological investigation by applying an indication test with a dose of 1—10 gamma.

WHAT WE CLAIM IS:—

1. An adhesive pad for skin tests, comprising an adhesive base having on its central portion, a first layer of an aluminium or similar metal foil, coated with a plastics material; a patch of an absorbent material containing a dose of the test material, the said patch being fixed at the centre of the said first layer; and a second layer of metal foil bonded to the first layer as close to the periphery of the absorbent material as possible.

2. A pad according to claim 1, wherein the test material is mixed with an excipient.

3. A pad according to claim 2, wherein the excipient comprises at least one of glycerides of fatty acids, isopropyl myristates or palmitates, glycerides of fatty acids in a C_{12} chain, fatty acid esters or ethers, fatty alcohols or glycols, and short chain alcohols.

4. A pad according to claim 3, wherein said glycerides of fatty acids are palmitostearic glycerides.

5. A pad according to any one of claims 2 to 4, wherein the excipient is a semi-synthetic glyceride having a melting point of 33 to 45°C.

6. A pad according to any one of claims 1 to 5, wherein the excipient comprises at least one of propylene glycol, glycerol, polyoxyethylene glycols and alcohols.

7. A pad according to any one of claims 1 to 6, wherein the test material is an allergen.

8. A pad according to claim 7, wherein the allergen is constituted by dinitrochlorobenzene or dinitrofluorobenzene.

9. A pad according to claim 7 or 8, wherein the quantity of the allergen is at least equal to 60 gamma and the pad is a sensitisation pad.

10. A pad according to claim 9, wherein the quantity of the allergen is less than 150 gamma.

11. A pad according to claim 7 or 8, wherein the quantity of allergen is between 1 and 10 gamma and the pad is an indication pad.

12. A pad according to any one of claims 1 to 11, wherein said first layer is coated by polyethylene or polycarbonate.

13. A pad according to any one of claims 1 to 12, wherein the absorbent material is made of filter paper or blotting paper.

14. A pad according to any one of claims 1 to 13, wherein the surface of the absorbent material has an area of from 2 to 7 cm².

15. A pad according to any one of claims 1 to 14, wherein the second layer has a gripping tab.

16. A process for manufacturing an adhesive pad according to any one of claims 1 to 15, comprising advancing a strip of metal foil coated with a plastics material, intended to form the first layer, past a station where discs or patches of absorbent material are affixed to the said strip at regular intervals; spreading on each patch a given quantity of the test material diluted in a solvent; evaporating the solvent from said patch; bringing a second strip, forming the second layer, adjacent the strip; bonding the two layers to each other as closely to the periphery of the said patches as possible; and then effecting the various operations of cutting and of attachment to a strip of the adhesive base at regular intervals, and of cutting the adhesive base to form the finished pads.

17. A process according to claim 16, wherein a given quantity of the test material and of an excipient in a solvent common to the test material and the excipient is distributed on each patch.

18. A process according to claim 16 or 17, wherein the solvent is trifluorotrichloroethane or an acetone chloroform mixture.

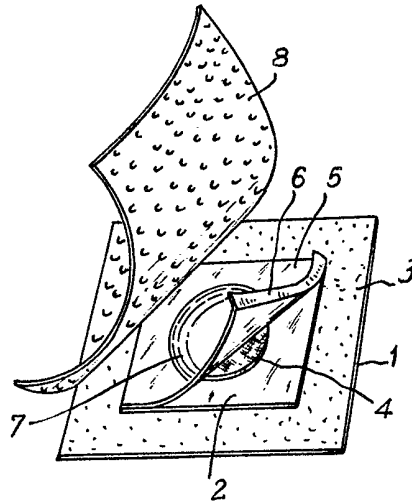
19. A process according to claim 17 or 18, wherein the excipient is a semi-synthetic glyceride having a melting point of 33 to 45°C.

20. An adhesive pad substantially as hereinbefore described with reference to, and illustrated in, the accompanying drawings.

21. A process for manufacturing an adhesive pad, substantially as hereinbefore described with reference to the accompanying drawings.

J. A. KEMP & CO.,
Chartered Patent Agents,
14, South Square,
Gray's Inn,
London, WC1R 5EU.

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Fig.1*Fig.2*