

Patch Test Guidelines

CTPA guidelines for the supply of patch test materials for diagnostic patch testing

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Acknowledgements

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CTPA welcomes comments, questions or suggestions for improvements to this guideline. These should be addressed to Caroline Rainsford, Head of Scientific Services, at the CTPA Secretariat or sent via email to: info@ctp.org.uk.

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Section A: Overview

This guideline has been developed to facilitate a dialogue between dermatologists and companies. It is important for companies to engage with dermatologists if they are contacted seeking patch testing samples. A discussion will help determine if patch test samples of ingredients are appropriate and attainable, or if other samples may be provided. If it is appropriate for patch test materials to be provided by the company to the dermatologist, this guidance provides information to help with this process. If samples for patch testing are provided, it is essential that the results from the testing are communicated back to the company from the dermatologist for inclusion in the company's Cosmetovigilance programme.

A dermatologist may request a product and/or ingredient sample(s) from a manufacturer in order to conduct a patch test on a patient. Patch testing is a procedure to determine whether a skin condition is caused or aggravated by an allergy to substances which have come into contact with the skin. This Guideline has been developed with reference to the [European Society of Contact Dermatitis guideline for diagnostic patch testing – recommendations on best practice](#), and in collaboration with the CTPA Cosmetovigilance Working Group and the CTPA – British Society for Cutaneous Allergy (BSCA) Working Group. The guideline aims to inform cosmetic companies of the practical aspects of supplying patch test materials to dermatologists who request cosmetic ingredient samples for diagnostic patch testing.

Ideally, the dermatologist/allergologist should first examine the reproducibility of the reported skin reaction, where appropriate, by testing the finished product as it is or in a suitable dilution (recommended or mildly exaggerated use conditions).

There are two possible formats of product ingredients which may be requested by dermatologists, namely **Neat and undiluted** or **Pre-diluted and ready for patch testing**.

Raw materials used in the manufacture of the finished product should be provided on specific request since it is often extremely difficult for the dermatologist to obtain and prepare the chemicals in a ready-to-use format. While chemicals should ideally be provided in a ready-to-use format, as testing with the neat material could put the patient at risk of a severe skin reaction, dermatologists may request neat samples in order to dilute them to their own preferred concentrations.

Inorganic pH adjusters, such as sodium hydroxide and hydrochloric acid, should not be supplied, whether neat or diluted. If access to these materials is required, it must be obtained through the pharmacy. Organic pH adjusters may be supplied.

When diluting the raw material, care should be taken to ensure that the concentrations remain below the irritation threshold of the respective cosmetic ingredients.

In order to allow for the precise identification of the formula involved, the dermatologist needs to provide the exact details and/or actual product implicated in the patient's dermatitis. If the actual product is not available, other reasonable means should be used to identify the formula. These could include photographs, or other visual representations, of the product's pack or artwork. Ideally, if visual images are requested, they should include both the front of pack and the Ingredient list from the back of pack.

Any products received by a company should be returned to the requesting dermatologist. A sample of freshly-manufactured product should also be sent by the company.

Irrespective of the format requested, the samples should all be taken from factory dispensary stock or equivalent grades used in the manufacture of finished products. Laboratory analytical grade materials should not be supplied.

A copy of the pack 'INCI' list **and** a 'composite ingredient list' should also be supplied with the ingredient samples; a 'composite ingredient list' is a list which exemplifies the specific composition of each Ingredient added in to the formula at time of manufacture. This composite list should include any subsidiary substances such as antimicrobial preservatives or antioxidants which may be present in the ingredients (see Annex 1 – Example of a composite ingredient list).

The samples provided should be labelled in such a way as to allow the dermatologist to identify the individual substances or blends in each container, along with the concentration and vehicle if relevant. If the labelling system used only displays a Dispensary Code (DC), a decode list should be provided to allow the identification of the container's contents.

While companies are urged to make every effort to provide samples from factory dispensary stock or equivalent grades used in the manufacture of finished products, it must be acknowledged that this may not always be possible especially for a global company with manufacturing sites around the world. If it is not possible for such samples to be obtained, companies should contact the dermatologist to explain the situation and to discuss and agree what samples can be provided and in what form.

The dermatologist should be informed of the timescale for supplying the samples, in order that an appointment may be made for the patient at patch test clinic.

Once the patch testing has been completed, the outcome should be communicated back to the cosmetic company by the dermatologist within an agreed timescale, to allow for its inclusion in the company's Cosmetovigilance programme. An ongoing dialogue between dermatologists and the cosmetic industry is an essential part of an effective Cosmetovigilance process.

In order for dermatologists to contact the correct personnel responsible for Cosmetovigilance within companies and so help improve the dialogue between companies and the dermatologists, CTPA has collated and holds, in confidence, these company contact details to be shared with dermatologists on request.

This important initiative has been approved by the CTPA Cosmetovigilance Working Group and Scientific Committee.

Please contact patchtesting@ctpa.org.uk for details.

Section B: Detailed Guidance

1. Ingredients requested in the neat and undiluted state

- 1.1 If a dermatologist wishes to prepare patch test allergens using their own preferred concentration(s) and vehicles, they will request that companies supply the product's ingredients in the 'neat and undiluted state'.
- 1.2 The sample size should be in the range of 5g to 10g, contained in virgin glass bottles of an appropriate size, sealed with polypropylene screw caps. For ingredients of high commercial value, peptides for example, the sample size can be reduced to 500mg.
- 1.3 Ideally, the samples should be labelled with the relevant INCI name(s) of the component substances, in the composite format described earlier, where relevant. If another method is used to identify the samples, the advice given earlier should be followed. The samples should also be marked with the:
 - date of packing;
 - lot or batch number;
 - expiry date.
- 1.4 A copy of the contemporary Safety Data Sheet (SDS) in the EU Format (in English) should always be supplied for each ingredient sample. Ideally, a copy of technical data sheet for each ingredient should also be supplied to allow the presence or absence of subsidiary materials (antimicrobial preservatives for example) to be corroborated.
- 1.5 Once prepared, the samples should be stored and transported under appropriate, documented conditions. It is recommended to contact the recipient regarding any specific condition requirements.
- 1.6 The stability of the materials when transported should be taken into consideration.

2. Ingredients requested in the prediluted format, ready for patch testing

- 2.1 In some cases, individual dermatologists may not have a hospital pharmacy available to manufacture patch test materials for them. If such a request is received, cosmetic companies should arrange for the materials to be manufactured, either in their own laboratories or using the services of a contract manufacturing pharmacy company. If manufacturing in their own laboratories for a non-UK country, companies must ensure they are in compliance with the national law regarding the regulatory status of the patch test material.
- 2.2 Substances to be supplied in the prediluted format should be manufactured using the concentration(s) and vehicles described by de Groot [1] (including updates since publication in 2008) and NOT at the concentration used in the product. CTPA has a copy of de Groot should companies need to ask for dilution advice. Alternatively, reference can be made to the catalogues published by third party companies which supply patch test allergens. Please contact CTPA for further information if required.

In the event that the concentrations differ between the commercial catalogues and de Groot, the de Groot dilution should be used [1].

In addition, the dermatologist may request a particular concentration. If this differs from de Groot [1], then the manufacturer should query this with the dermatologist. In rare instances, a dermatologist may request a "novel" material at different test concentrations.

- 2.3 Substances supplied in the prediluted state should be labelled in such a way as to allow the dermatologist to identify the constituent substance(s), together with the:
- concentration;
 - vehicle;
 - batch or lot number;
 - date of manufacture;
 - expiry date.
- 2.4 Composite ingredients should be diluted so that the concentration of the principal constituent complies with the concentration conditions described by de Groot (1) or other selected data source.
- 2.5 In those circumstances where there are no published standard conditions, the concentration selected should be the highest non-irritant concentration reported in either the on-line toxicology or dermatology literature, or the substance's SDS. The vehicle should be chosen with reference to the standard conditions specified for similar materials, or according to the solubility of the substance if the former information is not available. If insoluble, the material should be suspended homogeneously in white soft paraffin.
- 2.6 A sample of the vehicle used to prepare the allergens should accompany the manufactured samples on dispatch to the requesting dermatologist.
- 2.7 Occasionally, de Groot [1] may stipulate the testing of substances in their neat and undiluted state. In these cases, the principles described earlier for this format should be followed.
- 2.8 Occasionally a dermatologist may stipulate the conditions which should be used for the manufacture of the allergens.
- 2.9 The sample size should be in the range of 5g to 10g, contained in virgin glass bottles of an appropriate size, sealed with polypropylene screw caps.
- 3.0 Once prepared, the samples should be stored and transported under appropriate, documented conditions. It is recommended to contact the recipient regarding any specific condition requirements they might have.
- 3.1 The stability of the materials when transported should be taken into consideration.

References

[1] Anton C. De Groot. Patch Testing. Test Concentrations and Vehicles for 5200 Chemicals, 5th Edition; Wapserveen, the Netherlands: acdegroot publishing, 2022.

Annex I – Example of a composite ingredients list

Dispensary Code (DC)	Aqua
DC	Aqua + Sodium laureth sulfate + Phenoxyethanol + Methyparaben
DC	Aqua + Cocamidopropylbetane
DC	Aqua + Methylisothiazolinone
DC	Parfum + dipropylene glycol + benzyl alcohol + benzyl benzoate + linalool