



Exclusion of a sensitizing/allergizing effect (Sensitization Test)

Objective:

In this cell culture test, the allergy potential (sensitization potential) of substances that may leach out of the sample material is determined with the help of immune cells (so-called "sentry cells"). The Sensitization Test thus permits the substances under investigation to be assessed in terms of their potential to trigger allergies. This potential is recorded as a summation parameter. The test is no analysis for single allergens.

This test is particularly suitable for:

- Medical devices made from all types of materials
- Clothing worn close to the body
- Clothing for sensitive persons such as allergy-sufferers, pregnant women, infants, patients and elderly
- Textiles forming the subject of complaints that are suspected of triggering allergies
- Cosmetic, wellness and functional textiles

Description:

The Sensitization Test makes use of the test principles described in the standard DIN EN ISO 10993-10. The technical prerequisite for the Sensitization Test is that the Skin Friendly Test / Cytotoxicity Test has been passed. An extract is prepared for the test from the sample material and this, in diluted form, is incubated for 24 hours with immune cells. By means of sensitizing substances, the cells are stimulated to form surface markers that bond to the specific fluorescently labeled antibodies. The percentage of positive cells is determined from the fluorescence intensity in the flow cytometer.

Customer benefit:

- Product optimization
- Consumer safety
- Advertising impact
- Minimization of complaints

Labels and Certificates:

On passing the test the product may be awarded the Quality Label "hypoallergenic", in order to provide customers with visible proof of quality. Prerequisite for awarding of the label is an existing Oeko-Tex® Certificate.

On passing the test the product may be awarded the certificate "Biological Safety" with the attribute "No allergy potential".

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Test sample requirements:

General:

- Technical prerequisite: Samples have to pass the Cytotoxicity Test
- Test samples can cover an entire group of articles. Please contact us for further information.
- When dyestuffs, auxiliaries or reviving agents are used in different quantities, articles which use the highest quantity must be selected (worst-case)
- Send assembled samples as total products
- In the event of complaints, provide the product under claim for testing wherever possible (please do not send retain sample)
- Test samples must be packed individually, e.g. in plastic bags, to avoid contamination during transport
- Please indicate adequate names and specific denotations of the sample (composition of material, article number, etc.)

Quantity of material:

- At least 40 g of the test sample or size of A3, respectively

Duration of the test:

- Between two and three weeks; the date will be confirmed once the test sample has been received