



FKT Test Method and Certification

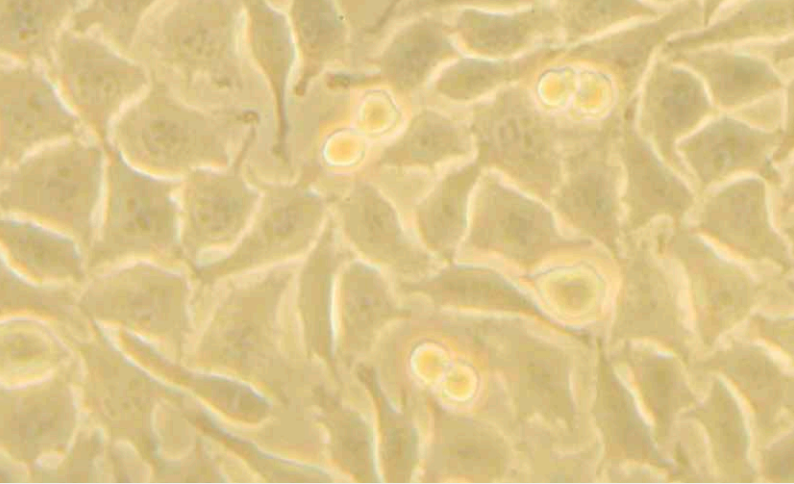
The FKT label „MEDICALLY TESTED – TESTED FOR TOXINS“ labels textiles that don't release any chemicals that may irritate the skin or damage a person's health. This unique to the market combination of tests for harmful substances and for sensitive efficiency-based body compatibility provides double tested safety. The manufacturers of high-quality textiles use this scientific certification to verify their quality standards and build up a high degree of trust with their end customers.

How safe is safe?

Responsible consumers ask for more safety when buying textiles and they expect manufacturers to have their products tested and certified beyond what is required by the law. Conventional tests for harmful substances don't provide sufficient safety because they usually only cover an extremely narrow range of predefined substances.

Their limits hardly ever consider the release rates for harmful substances while wearing a textile product or the possible effects of such substances when absorbed through the skin.

The FKT tests not only examine the content of harmful substances but also verify a textile product's body compatibility by testing the direct effects of the product on skin. An intense simulation of the wearing situation releases the substances from the textile product that are critical for its body compatibility. The basis of the high-quality testing standards we can promise are strict skin compatibility tests that are in line with the approval criteria for medical devices. This method is designed to test the final products in their retail packages. In specific cases, however, it also makes sense to probe samples from different production steps.



The FKT Test Method

Test for body compatibility

Step 1: Wearing simulation and substance transfer

- > Release of unbound substances and chemicals from the textile product under the simulation of intense wearing conditions.

Step 2: Fibroblast cytotoxicity test

- > Checks the toxic effect of extracted substances on connective tissue cells.

Step 3: Cytokine test with keratinocytes

- > Checks the inflammatory effect on skin cells.

Test for harmful substances

Works with the same limit values and criteria as the OEKO-TEX® Standard 100, product class 1.

Double tested safety

This combination of tests for harmful substances and for sensitive efficiency-based body compatibility provides double tested safety – for the manufacturers of high-quality textiles as well as for the consumers. Certified textiles bearing the FKT label „MEDICALLY TESTED – TESTED FOR TOXINS“ are proven to be compatible with the body and do not contain any substances that irritate the skin or are hazardous to health. The FKT label represents an important criterion for the decision-making of wholesale customers and consumers when buying textiles.

FKT works with the independent testing laboratories of the ITV Denkendorf Produktservice GmbH (ITVP) that are accredited by the DAkkS (Deutsche Akkreditierungsstelle) under DIN EN ISO/IEC 17025. This guarantees that the tests are conducted in accordance with the standards and meet the highest quality requirements, according to objective measures.

Test for body compatibility

A fundamental requirement for the award of the FKT label is the three-step body compatibility test:

Step 1: Wearing simulation and substance transfer

Intense wearing and use conditions are simulated in a scientific environment. Thus substances can be released from the textile product that directly may affect the skin in practice. These substances are transferred to a special gel with properties that are similar to skin, which functions as a carrier material during the tests that follow. The hundred-fold concentration of the carrier gel provides for strict test conditions.

Step 2: Fibroblast cytotoxicity test

The fibroblast cytotoxicity test assesses the effects of transferred substances on connective tissue cells (fibroblasts). It shows whether toxic and thus heavily irritating substances are released from the tested textile product. If the vitality of the fibroblasts is not changed or impaired during the test, the textile is considered to have passed the test.

Step 3: Cytokine test with keratinocytes

The cytokine test with keratinocytes is performed if the cytotoxicity test does not show any impairment of the cells' vitality. It is even more sensitive and shows even slightly irritating substances. This highly sensitive and extremely efficient test is used to measure the transferred substances' effect on live skin cells (keratinocytes). The cells' physiological reactions over a period of 24 hours define the degree of the sample's skin irritation potential. To successfully pass the test, there must be no reaction that could indicate irritation or inflammation of the skin.

Both methods are accredited by the DAkkS (Deutsche Akkreditierungsstelle) in accordance with DIN EN ISO/IEC 17025. If additional information is requested, ITVP has available comprehensive chemical tests that can precisely analyse and allocate the transferred substances. The results can be used to optimise the tested products.

Test for harmful substances

Another criterion for the award of the FKT label is a comprehensive test for harmful substances that is carried out in addition to the body compatibility test. A highly sensitive chemical analysis is used to test compliance with all statutory limits for potentially hazardous substances in Germany.

FKT's test for harmful substances works with the same limit values and criteria as the OEKO-TEX® Standard 100, product class 1. However, in addition, it covers and evaluates substances that are not illegal but must be assessed as critical with respect to their effect on the skin.



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