



Medical Evidence on Dermatological Tolerance

Micro Fibre Tissues

performed at the

**University Clinic for Dermatology and Venerology (Univ. Klinik für
Dermatologie und Venerologie)
Anichstrasse 35, 6020 Innsbruck**

Board Chairman: Univ. Prof. Dr. P. Fritsch.

1. Objectives:

At the request of the companies REZI® and INTERTREND Handels GmbH & Co KG for Micro Fibre Products the outpatient clinic for allergology of the University Clinic for Dermatology and Venerology Innsbruck conducted a study on the dermatological tolerance of these Micro Fibre Tissues from 26 March to 13 June 2003.

For an assessment of potential skin sensitisation, examinations were performed through skin tests of the final product. In addition, application tests were performed on selected test subjects.

2. Method of Testing (Epicutan Test):

In order to assess the risk of potential allergic or irritative reactions to this Micro Fibre Tissues, a skin test was performed on a test group of volunteers.

The test was conducted according to the provisions of the Team Contact Allergies of the German Society for Dermatology (Deutsche Gesellschaft für Dermatologie) via an epicutan test. So-called Finn Chambers – which are commonly used for such purposes – were filled with pieces of micro fibre that had been moistened with distilled water.

In order to rule out toxic reactions, some volunteers underwent an open 30 minute application of the coated Finn Chambers on the volar side of the forearm as well as a closed 24 hour epicutan testing.

The epicutan test proper was conducted via coated Finn Chambers that were attached to the back and were left in place occlusively for 48 hours. The assessment of a potential toxic and/or allergic reaction of the test spot took place after 48 and 72 hours.

3. Method of Testing:

The application test was performed on 5 test subjects. Requirements for test participation included a negative anamnesis concerning contact allergies and atypical dermatitis. Additional requirements included appropriate topical findings prior to the commencement of the application, willingness to apply the preparation properly once a day over the period of a week, as well as undergoing a final examination. For test preparations, the facial cleansing tissues and make-up removal pads, made available by the ordering company, were used.

The test subjects were explicitly instructed to follow their normal daily routine. After one week of daily application, local findings were examined by the same physician as before commencement of the application; in addition, a questionnaire was used in order to document subjective and objective parameters of irritative and/or allergenic effects of the product.

The assessment comprised the following criteria on the basis of a school grading system (1=no reaction, 5=massive reaction):

Objective criteria: dryness of skin
 redness of skin
 formation of rhagadae
 scaling of skin

Subjective parameters: itching
 burning
 feeling of dryness

4. Application Test Results:

The application test was properly conducted by all of the 5 test subjects. Local dermatological findings prior to the application of the test products were inconspicuous in 4 out of 5 cases, in 1 case a "slight" (grade 2) dryness of skin as well as a "slight" (grade 2) facial redness occurred.

- None of the test subjects displayed an objective deterioration of local dermatological findings after 1 week. The skin irritations observed prior to the application of the product on one test subject remained unchanged.
- All test subjects perceived the product as non-irritative to the skin.

5. Results of the Epicutan Test:

No toxic-irritative or allergic reactions to the test product could be detected on any of the 35 test subjects after either the first examination after 48 hours or the second examination after 72 hours.

In summary, we were unable to find evidence for an irritative or allergenic potential of these micro fibre cloth, both in a user and a standard patch test in a total of 35 test subjects. Although it is obviously impossible to rule out rare intolerance reactions under circumstances of mass use, no objection can be made from the data presented against using these products for cleaning of the human skin.