

TEST REPORT no. E-006-PK-05K

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Testing Laboratory accredited by DAP German Accreditation System for Testing Ltd. against DIN EN ISO/IEC 17025:2000. The accreditation is valid for the testing procedures listed in the certificate (in the test report signed with *).



DAP-PL-2603.00

Member of **eurolab**-Deutschland
Verein deutscher Prüflaboratorien e.V.

Customer:

SeaCell GmbH

Breitscheidstr. 154

07407 Rudolstadt

Order details:

Order date: 20.01.2005

Samples received: 25.01.2005

Testing date: 27.01.-04.03.05

Your reference: Bestellung 2005
100029

Task:

Skin compatibility test with human keratinocytes.

Received Sample(s):

Client's Sample name	Sample specification
Faser 1	SeaCell Fasern
Faser 2	SeaCell Activ Fasern

Test Procedure and Results

1 Applied test methods and used test standards

	Accredited*
DITF-Method KV 01, 2002: Testing textiles for skin compatibility	×
DITF-Method TOX 05, 2002: Determination of inflammation mediators (IL1, IL6, IL8, CSF) with human, normal keratinocytes (Epidermal skin)	×

* if applicable, marked with cross

2 Sampling and tests carried out

The customer made the selection of the samples.

Testing specimens of any sample (size 5.5 x 10.5 cm) were prepared by punching. Incubation of the specimens for 16 h at 37 °C in a transfer system simulated the prolonged skin contact under wearing conditions. The extract of the transfer was γ -sterilized and incubated 24 h with a confluent cell culture of human keratinocytes with an end concentration of 10%. The supernatant of the cell culture was examined for inflammation mediators (IL1, IL6, IL8, CSF) by ELISA tests.

3 Test results

The test results are shown in the appendixes as tables and graphs.

Positive test results - that means with a detectable irritative effect - are all results, with at least one mediator showing a 50% higher value than the control (transfer without textile, sample number 3539).

No positive test results were detected with the samples tested.

4 Discussion of the test results and conclusions

The samples tested showed no irritative effect within the DITF- test system on skin compatibility with human keratinocytes.

Denkendorf, 2005-03-22

Bernd Janisch (Vice-head of laboratory)

Annex

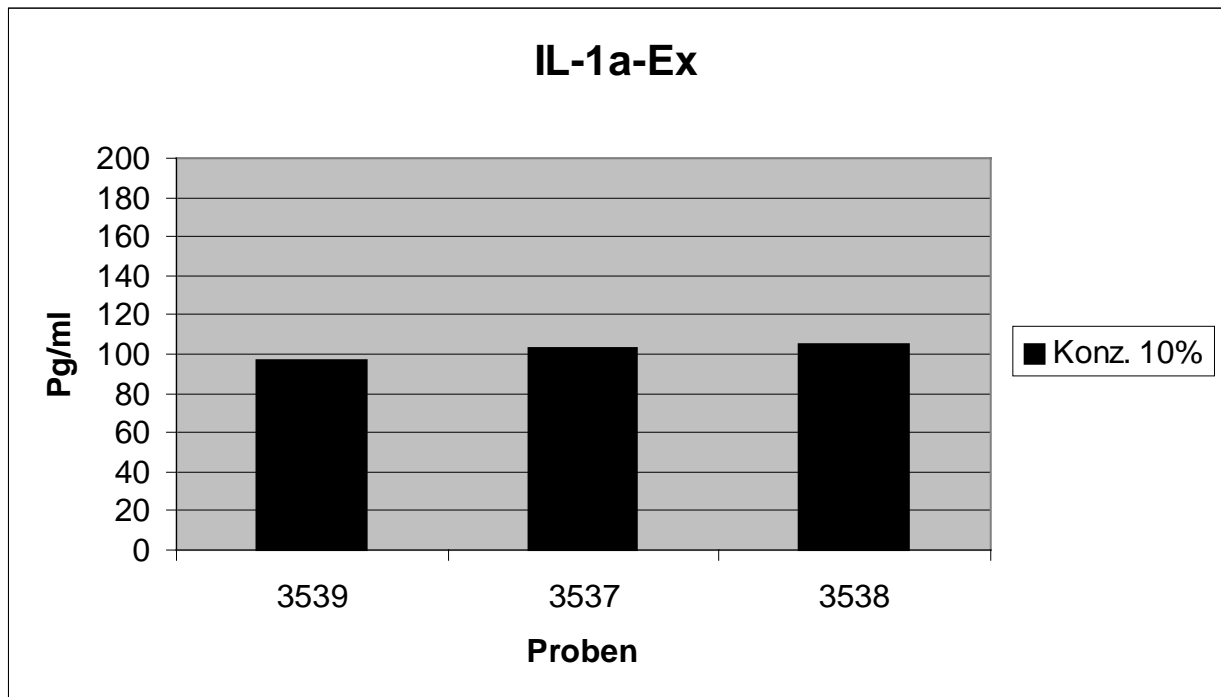
Notes:

The test results relate to the above-specified samples, and may not be used as a basis for a lawsuit or advertisement without any written permission by the testing laboratory. The test report shall not be duplicated in parts without written permission of the testing laboratory.

Annex 1:

Test:	IL-1 a - Extrazellulär	Operator:	Ott	Datum (Beginn):	07.02.05
Zellen:	Keratinozyten	Zellzahl:	200.000	Medium:	KBM-2 +Sup. (konditioniert)
Kulturgefäß:	24er Well	Vorinkubation:	48 h	Inkubation m. Proben:	24 h
Geprüftes Material:	3537 - 3538				
Bemerkung	Konzentration der Proben : 10%				

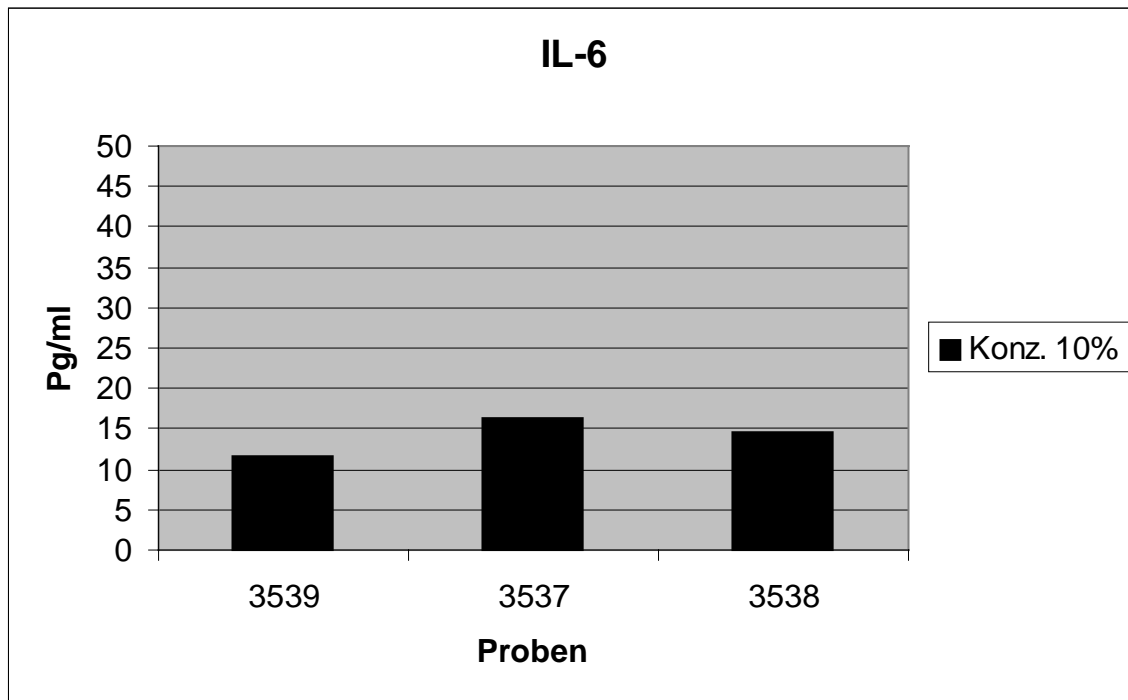
Proben	Mittelwert [Pg/ml]	St.abw.	% der Kontrolle
3539	96,717	14,820	100,00%
3537	103,504	12,108	107,02%
3538	104,635	34,080	108,19%



II-6

Test:	IL-6	Operator:	Ott	Datum (Beginn):	07.02.05
Zellen:	Keratinocyte n	Zellzahl:	200.000	Medium:	KBM-2 +Sup. (konditioniert)
Kulturgefäß:	24er Well	Vorinkubation:	48 h	Inkubation m. Proben:	24 h
Geprüftes Material:	3537 - 3538				
Bemerkung	Konzentration der Proben : 10%				

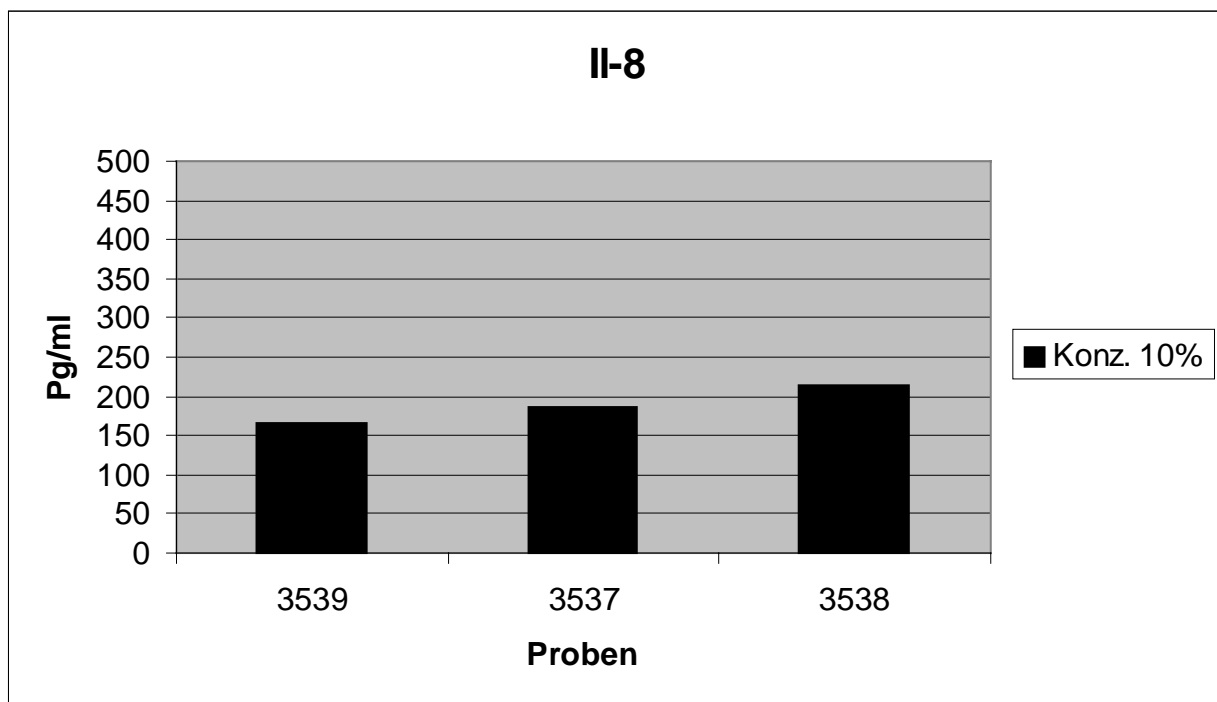
Proben	Mittelwert [Pg/ml]	St.abw.	% der Kontrolle
3539	11,672	3,495	100,00%
3537	16,328	1,434	139,89%
3538	14,647	8,201	125,49%



II-8

Test:	IL-8	Operator:	Ott	Datum (Beginn):	07.02.05
Zellen:	Keratinozyten	Zellzahl:	200.000	Medium:	KBM-2 +Sup. (konditioniert)
Kulturgefäß:	24er Well	Vorinkubation:	48 h	Inkubation m. Proben:	24 h
Geprüftes Material:	3537 - 3538				
Bemerkung	Konzentration der Proben : 10%				

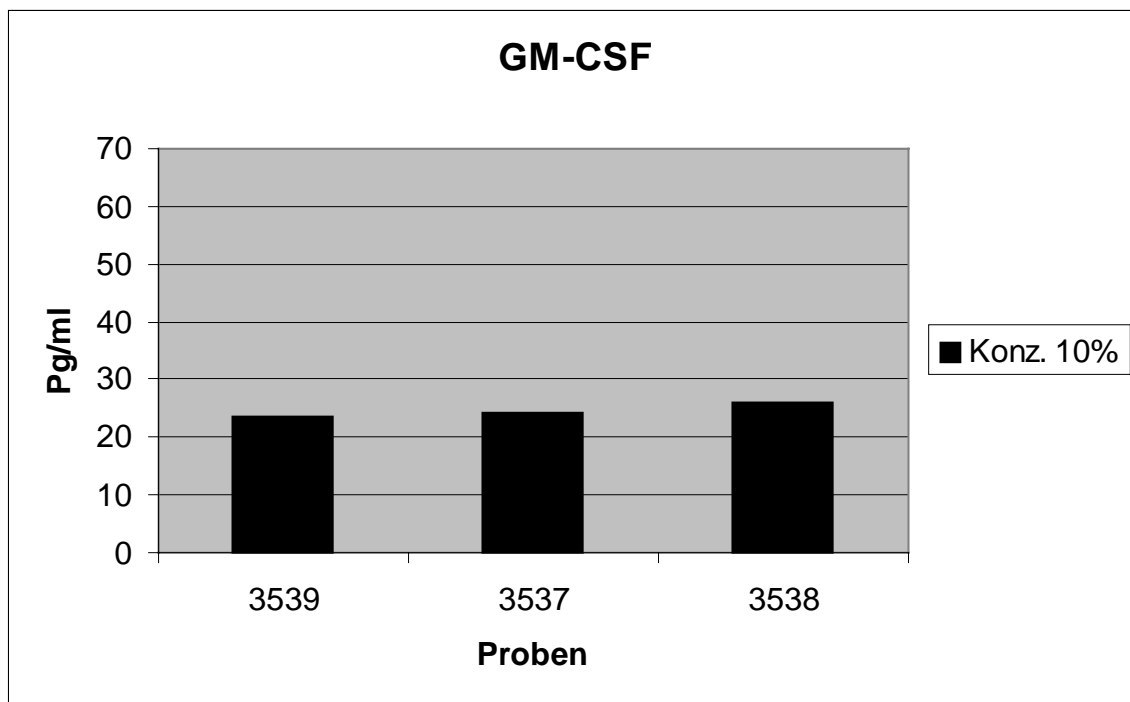
Proben	Mittelwert [Pg/ml]	St.abw.	% der Kontrolle
3539	165,898	7,425	100,00%
3537	185,625	27,199	111,89%
3538	213,725	43,956	128,83%



GM-CSF

Test:	GM-CSF	Operator:	Ott	Datum (Beginn):	07.02.05
Zellen:	Keratinozyten	Zellzahl:	200.000	Medium:	KBM-2 +Sup. (konditioniert)
Kulturgefäß:	24er Well	Vorinkubation:	48 h	Inkubation m. Proben:	24 h
Geprüftes Material:	3537 - 3538				
Bemerkung	Konzentration der Proben : 10%				

Proben	Mittelwert [Pg/ml]	St.abw.	% der Kontrolle
3539	23,591	2,884	100,00%
3537	24,251	4,819	102,80%
3538	25,927	4,858	109,90%



Annex 2: List of sample numbers (internal / external)

ITVP Sample number	Client's sample name	Sample specification
3539	Control	Control
3537	Faser 1	SeaCell Fasern
3538	Faser 2	SeaCell Activ Fasern