

BIOSERVICE

SCIENTIFIC
LABORATORIES
GmbH

**Test for Sensitisation
(Local Lymph Node Assay - LLNA)**

with

**PA 2200 Reused powder (50% virgin + 50% recycled powder from
EOSINT P System)**

Report

Version: Final

Date: 22 January 2010

BSL BIOSERVICE Study No.: 094864

Sponsor:

EOS GmbH Electro Optical Systems

Robert-Stirling-Ring 1

82152 Krailling

Germany

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-The test results relate only to the items tested.-

BSL BIOSERVICE Scientific Laboratories GmbH

Behringstrasse 6/8 · 82152 Planegg, Germany

Telefon +49(0)89-899 65 00 · Fax +49(0)89-899 65 011

e-mail: info@bioservice.com · www.bioservice.com

Geschäftsführer: Dr. Wolfram Riedel

Amtsgericht München, HRB 109 770

Erfüllung und Gerichtsstand München

NORD/LB Norddeutsche Girozentrale, BLZ 250 500 00, Kto. 151 328 523, Swift-BIC: NOLADE2HXXX, IBAN: DE76 2505 0000 0151 3285 23

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1. Copy of the GLP Certificate



**BAYERISCHES LANDESAMT
FÜR GESUNDHEIT UND LEBENSMITTELSICHERHEIT,
LANDESINSTITUT FÜR ARBEITSSCHUTZ UND PRODUKTSICHERHEIT**
Pfarrstraße 3 · 80538 München · Telefon (089) 21 84-0

GLP-Bescheinigung/Statement of GLP Compliance
(gemäß/according to § 19b Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung
der Einhaltung der GLP-Grundsätze
gemäß Chemikaliengesetz bzw. Richt-
linie 2004/9/EG wurde durchgeführt in:

Assessment of conformity with GLP
according to Chemikaliengesetz and
Directive 2004/9/EC at:

☒ Prüfeinrichtung/Test facility ☐ Prüfstandort/Test site

BSL Bioservice Scientific Laboratories GmbH
Behringstrasse 6 - 8
82152 Planegg

(Unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien/Areas of Expertise
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

2 Prüfungen auf toxikologische Eigenschaften

3 Prüfungen auf mutagene Eigenschaften

9 Sonstige Prüfungen:

a) Mikrobiologische Sicherheitsprüfungen

b) Wirksamkeitsprüfungen an Zellkulturen

Datum der Inspektion/Date of Inspection

(Tag/Monat/Jahr/day/month/year)

16./17.09.2008

Die/Der genannte Prüfeinrichtung/Prüfstandort
befindet sich im nationalen GLP-Überwachungs-
verfahren und wird regelmäßig auf Einhaltung der
GLP-Grundsätze überwacht.

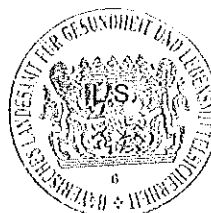
The above mentioned test facility/test site is
included in the national GLP Compliance
Programme and is inspected on a regular basis.

Auf der Grundlage des Inspektionsberichtes wird
hiermit bestätigt, dass in dieser Prüfeinrichtung/
diesem Prüfstandort die oben genannten Prüf-
ungen unter Einhaltung der GLP-Grundsätze
durchgeführt werden können.

Based on the inspection report it can be confirmed,
that this test facility/test site is able to conduct the
aforementioned studies in compliance with the
Principles of GLP.

München, 06.04.2009

Ritter
Leitender Gewerbedirektor



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4. Preface

4.1. Abbreviations

AOO	acetone / olive oil
Art.	Artikel (Article)
BGBL	Bundesgesetzblatt (Federal Law Gazette)
CPM	counts per minute
DIN	Deutsches Institut für Normung (German Institute for Standardisation)
Dipl.-Biol.	Diplom Biologe (Biology Diploma)
DPM	disintegration per minute
EC	European Commission
EC3	estimated concentration of the test item required to produce a 3-fold stimulation of draining lymph node cell proliferation compared with concurrent controls
EN	Europäische Norm
EWG	Europäische Wirtschaftsgemeinschaft (European Economic Community, EEC)
GLP	Good Laboratory Practice
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
IVC	individually ventilated cages
LLNA	Local Lymph Node Assay
MV	mean value
NaCl	sodium chloride
nsf	no specific findings
OECD	Organisation of Economic Cooperation and Development
PBS	phosphate buffered saline
QA	Quality Assurance
QAU	Quality Assurance Unit
SD	standard deviation
SOP	Standard Operating Procedures
SPF	specific-pathogen free

Szinti	scintillation fluid
TCA	trichloroacetic acid
v/v	volume per volume

4.2. General

Sponsor:	EOS GmbH Electro Optical Systems Robert-Stirling-Ring 1 82152 Krailling Germany
Study Monitor:	Ms. Monika Gessler Substitute Mr. Peter Keller
Test Facility:	BSL BIOSERVICE Scientific Laboratories GmbH Behringstraße 6/8 82152 Planegg Germany
BSL BIOSERVICE Study No.:	094864
Test Item:	PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)
Title:	Test for Sensitisation (Local Lymph Node Assay - LLNA) with PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)

4.3. Project Staff

Study Director:	Dr. Daniela Stelter
Deputy Study Director:	Dr. Varun Ahuja
Management:	Dr. Wolfram Riedel Dr. Angela Lutterbach
Head of Quality Assurance Unit:	Dipl.-Biol. Uwe Hamann

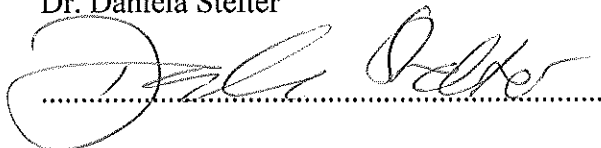
4.4. Schedule

Arrival of the Test Item:	25 November 2009
Date of Final Study Plan:	10 December 2009
Start of Experiment:	03 January 2010
End of Experiment:	15 January 2010
Date of Final Report:	22 January 2010

5. Project Staff Signatures

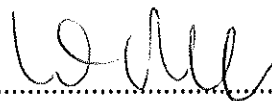
Study Director

Dr. Daniela Stelter



Date: 22 Jan 2010

Management



Print Name: Dr. Wolfram Riedel

Date: 22 Jan 2010

6. Quality Assurance

6.1. GLP Compliance

This study was conducted to comply with:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended and promulgated on June 20, 2002 (BGBl. I Nr. 40 S. 2090), revised October 31, 2006 (BGBl. I Nr. 50 S. 2407).

OECD Principles of Good Laboratory Practice (as revised in 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring - Number 1. Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998.

This study was assessed for compliance with the study plan and the Standard Operating Procedures of BSL BIOSERVICE. The study and/or the test facility were periodically inspected by the Quality Assurance unit according to the corresponding SOPs. These inspections and audits were carried out by the Quality Assurance unit, personnel independent of staff involved in the study. A signed Quality Assurance Statement, listing all performed audits, is included in the report.

The test method is part of the BSL BIOSERVICE accreditation scope according to guideline 90/385/EWG, 93/42/EWG and DIN EN ISO/IEC 17025 for testing of medical devices.

6.2. Guidelines

This study followed the procedures indicated by internal BSL BIOSERVICE SOPs and the following internationally accepted guidelines and recommendations:

OECD Guidelines for Testing of Chemicals, number 429 "Skin Sensitisation: Local Lymph Node Assay" (adopted: 24th April 2002)

Commission Regulation (EC) No. 440/2008, L 142, Annex Part B, May 30, 2008

ISO 10993-1: 2009 "Evaluation and testing within a risk management process"

DIN EN ISO 10993-10: 2007 (ISO 10993-10: 2002 + Amendment 1: 2006) "Tests for irritation and delayed-type hypersensitivity"

ISO 10993-12: 2007 "Sample preparation and reference materials"

6.3. Archiving

The following records will be stored in the scientific archives of BSL BIOSERVICE Scientific Laboratories GmbH according to the GLP Regulations:

A copy of the final report, the study plan and a documentation of all raw data generated during the conduct of the study (documentation forms as well as any other notes of raw data, printouts of instruments and computers) and the correspondence with the Sponsor concerning the study.

If test item is left, a sample will be stored according to the period fixed by the GLP Regulations. Samples that are unstable may be disposed of before that time. No raw data or material relating to the study will be discarded without the Sponsor's prior consent. Unless otherwise agreed upon, the remaining test item will be discarded three months after the release of the report.

7. Statement of Compliance

BSL BIOSERVICE-
Study No.: 094864
Test Item: PA 2200 Reused powder (50% virgin + 50%
recycled powder from EOSINT P System)
Title: Test for Sensitisation (Local Lymph Node
Assay - LLNA) with PA 2200 Reused powder
(50% virgin + 50% recycled powder from
EOSINT P System)
Study Director: Dr. Daniela Stelter

This study performed in the test facility BSL BIOSERVICE Scientific Laboratories GmbH was conducted in compliance with Good Laboratory Practice Regulations:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended and promulgated on June 20, 2002 (BGBl. Nr. 40 S. 2090), revised October 31, 2006 (BGBl. I Nr. 50 S. 2407).

"OECD Principles of Good Laboratory Practice (as revised in 1997)", Paris 1998.

There were no circumstances that may have affected the quality or integrity of the study.

Study Director: Dr. Daniela Stelter



Date: 01 Feb 2010

This statement does not include the positive-control test.

8. Statement of the Quality Assurance Unit


BSL BIOSERVICE-
Study No.: 094864
Test Item: PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)
Title: Test for Sensitisation (Local Lymph Node Assay - LLNA) with PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)
Study Director: Dr. Daniela Stelter

This report was audited by the Quality Assurance unit and the conduct of this study was inspected on the following dates:

<i>Phases of QAU Inspections</i>	<i>Dates of QAU Inspections</i>	<i>Dates of Reports to the Study Director and Management</i>
Audit Final Study Plan:	14 December 2010	14 December 2010
Audit Experimental Phase (Method Audit):	01 September 2009	01 September 2009
Audit Final Report:	25 January 2010	25 January 2010

This report reflects the raw data.

Member of the
Quality Assurance Unit:

..........

Print name:

Dipl.oec.troph (FH)
Anne Krabiell

Date:01 Feb 2010.....

This statement does not include the positive-control test.

9. Summary

With regard to the data reported it can be stated that the test item produced no reactions identified as sensitisation.

Species/strain:	CBA/CaOlaHsd mice
Number of animals:	5 per test group 5 treated with the negative control

The extract of the test item was assessed at three concentrations: 25%, 50% and 100%, diluted with AOO 3+1 (v/v). The 100% extract concentration corresponds to an extraction ratio of 60 cm² / 20 mL.

Extraction vehicle / negative control: AOO (3+1 (v/v) acetone/ olive oil).

The stimulation index at an extract concentration of	25%	was	1.1
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The stimulation index at an extract concentration of	50%	was	1.3
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The stimulation index at an extract concentration of	100%	was	1.2
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The EC3 value (derived by linear interpolation) could not be stated, as all measure points were below the stimulation index of 3.

9.1. Conclusions

Under the conditions of the present study it can be stated that the test item PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System) causes no reactions identified as sensitisation, as the stimulation index was below 3.0 for each concentration tested.

10. Aim of the Study

10.1. Justification for Selection of the Test System

The LLNA has been developed as an alternative method for the identification of skin sensitising test items and measures the proliferation of lymphocytes isolated from lymph nodes (auricular lymph nodes) draining the site of exposure (dorsal aspect of the ears) in mice.

Lymphocyte proliferation is measured by determining the incorporation of 3H-methyl thymidine.

10.2. Justification for Selection of the Test Method

No validated *in vitro* method is available for assessing sensitisation potential.

11. Materials and Methods

11.1. Characterisation of the Test Item

The test item and the information concerning the test item were provided by the Sponsor. All data related to the test item are the responsibility of the Sponsor and have not been verified by the test facility.

Name:	PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)
Batch no.:	919389
Specifications:	Recycled powder was taken from part cake of an EOSINT P system after build
Sterility:	unsterile
Storage:	at room temperature
Expiry date:	not applicable
Nature of material:	synthetic polymer: Polyamide 12
Safety precautions:	Routine hygienic procedures were sufficient to assure personnel health and safety.

11.2. Extraction of the Test Item

The extraction of the test item was performed according to ISO 10993-12.

In total a ratio of 60 cm² of sample to 20 mL of extraction medium was used.

The test item was extracted under agitation at 37 ± 1 °C for 72 ± 2 h.

The extraction vehicle was AOO (3+1 (v/v) acetone/olive oil)

(Acetone, Prolabo, lot no. 20066.296, expiry date: 07/2014; olive oil highly refined, Sigma, lot no. 058K0684, expiry date: 15/01/2010)

The extracts were applied within the same day and were stored at room temperature until the application.

11.3. Extract Dilutions

The test item was extracted as described above. The extract of the test item was diluted to gain the following concentrations:

Concentration I: 25%

Concentration II: 50%

Concentration III: 100% (undiluted).

The dilution vehicle was AOO (3+1 (v/v) acetone/ olive oil)

(Acetone, Prolabo, lot no. 20066.296, expiry date: 07/2014; olive oil highly refined, Sigma, lot no. 058K0684, expiry date: 15/01/2010)

The preparations were made immediately prior to each dosing.

11.4. Control

The vehicle AOO (3+1 (v/v) acetone/ olive oil) was incubated under agitation at 37 ± 1 °C for 72 ± 2 h and served as negative control.

11.5. Other Materials

³H-methyl thymidine (TRK 300, 20 Ci/mmol; PerkinElmer, lot no. 200907E), diluted to a working concentration of 80 µCi/mL.

Physiological saline 0.9% NaCl, B. Braun Melsungen, lot no. 9435A121, expiry date: 09/2012).

Trichloroacetic acid (TCA), Sigma, lot no. 105K0708, expiry date: 01/2012.

Phosphate buffered saline (PBS), PAN Biotech, lot no. 211209, expiry date: 21/12/2010.

11.6. Test System

Species/strain: healthy mice, CBA/CaOlaHsd

Source: Harlan Winkelmann GmbH, D-33178 Borcheln

Sex: female, nulliparous and non-pregnant

Age at the beginning of the study: 11 – 12 weeks

Number of animals: 5 mice per test group

The animals were derived from a controlled full-barrier maintained breeding system (SPF). According to Art. 9.2, No.7 of the German Act on Animal Welfare the animals were bred for experimental purposes.

11.6.1. Housing and Feeding Conditions

- Full barrier in an air-conditioned room
- Temperature: 22 ± 3 °C
- Relative humidity: $55 \pm 10\%$
- Artificial light, sequence being 12 hours light, 12 hours dark
- Air change: at least 10 x / hour
- Free access to Altromin 1324 maintenance diet for rats and mice (lot no. 0701)
- Free access to tap water, sulphur acidified to a pH of approximately 2.8 (drinking water, municipal residue control, microbiol. controlled periodically)
- The animals were kept in groups of 5 animals in IVC cages, type II L, polysulphone cages on Altromin saw fibre bedding (lot no. 06.06.09)
- Certificates of food, water and bedding are filed at BSL BIOSERVICE
- Adequate acclimatisation period (at least 5 days)

11.7. Preparation of the Animals

The animals were randomly selected.

Identification was ensured by cage number and individual marking (tail).

11.8. Clinical Observation

Prior to the application and once a day thereafter all animals were observed in order to detect signs of toxicity, including dermal irritation at site of application.

11.9. Weight Assessment

The animals were weighed prior to the application and at the end of the test period.

11.10. Dose Groups

3 Test Groups (3 different concentrations) and 1 Negative Control Group (vehicle) were tested.

11.11. Test Regime

Topical Application

Each mouse was treated by topical application of 25 µL of the selected solution to the entire dorsal surface of each ear.

Topical applications were performed once daily over three consecutive days.

Administration of ^3H -methyl thymidine

Five days after the first topical application all mice were dosed with 20 μCi ^3H -methyl thymidine by intravenous injection (tail vein) of 250 μL of ^3H -methyl thymidine, diluted to a working concentration of 80 $\mu\text{Ci}/\text{mL}$.

Preparation of cell suspension

Approximately 5 hours after ^3H -methyl thymidine-injection all mice were sacrificed. The draining "auricular lymph nodes" were excised, pooled for each animal (2 lymph nodes per animal, if technically possible) and collected in PBS. A single cell suspension of pooled lymph node cells was prepared by gentle mechanical disaggregation through polyamide gauze (200 mesh size). After washing the gauze with PBS the cell suspension was pelleted in a centrifuge. The supernatant was discarded and the pellets were resuspended with PBS. This washing procedure was repeated.

After the final wash each pellet was resuspended in approx. 1 mL 5% TCA at approx. 4 °C overnight for precipitation of macromolecules. Each precipitate was once washed again, resuspended in 1 mL 5% TCA and 7 mL scintillation fluid was added. Then this solution was transferred into scintillation vials and stored at room temperature overnight.

Determination of incorporated ^3H -methyl thymidine

The ^3H -methyl thymidine – incorporation was measured in a β -counter and expressed as the number of disintegrations per minute (DPM). Similarly, background ^3H -methyl thymidine levels were also measured (5% TCA). Determination of radioactivity was performed individually for each animal.

11.12. Evaluation of Results

The proliferative response of lymph node cells was expressed as the number of radioactive disintegrations per minute per lymph node (DPM/NODE) and as the ratio of ^3H -methyl thymidine - incorporation into lymph node cells of test group animals relative to that recorded for control group animals (STIMULATION INDEX). Before DPM/NODE values were determined, background values were subtracted.

EC3 values, calculated concentrations which induce stimulation indices of three, are determined by linear interpolation $\{\text{EC3} = c + [(3-d) / (b-d)] \times (a-c)\}$, between two points of the stimulation indices axis, one above (a,b) and one below (c,d) the stimulation index of three. If all measured points are above or below the stimulation index of three, no EC3 value can be stated.

A substance is regarded as a 'sensitiser' in the LLNA if at least one concentration of the test item results in a 3 fold or greater increase in ^3H -methyl thymidine - incorporation into lymph node cells of the lymph nodes of the test group animals, relative to that recorded for the lymph nodes of control group animals (**Stimulation Index equal to or greater than 3.0**).

11.13. Reliability Check

The recent reliability check was performed in October 2009. The raw data of this study are kept in the BSL archives (BSL Project ID 093140 L). The reliability checks were audited by the QA unit periodically.

Positive-control substance: P-Phenylenediamine (CAS 106-50-3, Sigma GmbH, purity > 98%; Lot 128K0093) 1%

Vehicle: AOO (3+1 (v/v) Acetone/Olive Oil)

Species/strain: Healthy CBA/CaOlaHsd mice

Source: Harlan Winkelmann GmbH, D-33178 Borcheln

Concentrations: 1% on three consecutive days

Table 1: Radioactive Determination of the Positive-Control Group of the Recent Study

POS	CPM	Test Item	Conc. [%]	Animal number	DPM	DPM-mean back-ground	DPM/Node	Stimulation Index
18	498.0	Negative Control		16	1013.0	996.4	498.2	
19	692.0			17	1397.0	1380.4	690.2	
20	769.0			18	1563.0	1546.4	773.2	
21	548.0			19	1102.0	1085.4	542.7	
22	510.0			20	1026.0	1009.4	504.7	
MV	603.4			MV	1220.2	1203.6	601.8	1.0
SD	107.9			SD	220.6	220.6	110.3	
114	7845.0	Phenylene-Diamine	1	96	16140.0	16123.4	8061.7	13.4
115	7244.0			97	14730.0	14713.4	7356.7	12.2
116	10993*			97	22369*	n.d.	n.d.	n.d.
117	6277.0			99	12784.0	12767.4	6383.7	10.6
118	7229.0			100	14769.0	14752.4	7376.2	12.3
MV	7148.8			MV	14605.8	14589.2	7294.6	12.1
SD	561.3			SD	1195.3	1195.3	597.6	1.0
121	11.0	Background Szinti and TCA			22.0			
122	7.0				15.0			
123	6.0				13.0			
124	11.0				21.0			
125	6.0				12.0			
MV	8.2			MV	16.6	0.0	0.0	0.0
SD	2.3			SD	4.1			

* = outlier, failed Grubbs, Nalimov and Dixon

If not noted individually, the results include both lymph nodes of an animal.

POS = position in counter; CPM = counts per minute; Conc. = concentration;
DPM = disintegrations per minute; SD = standard deviation; MV = mean value;
Szinti = scintillation fluid; TCA = trichloroacetic acid

12. Deviations from the Study Plan

There was no deviation from the study plan.

13. Results

The ratio of ^3H -methyl thymidine - incorporation into lymph node cells of test group animals, relative to that recorded for control group animals (stimulation index) for the test item

at an extract concentration of	25%	was	1.1
at an extract concentration of	50%	was	1.3
at an extract concentration of	100%	was	1.2

All animals survived throughout the test period without showing any clinical signs.

All animals showed the expected weight development which includes a weight loss of up to 2 g throughout the study.

For individual data see the tables in the appendix.

The EC3 value (derived by linear interpolation) could not be stated, as all measure points were below the stimulation index of three.

13.1. Conclusions

Under the conditions of the present study it can be stated that the test item PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System) causes no reactions identified as sensitisation, as the stimulation index was below 3.0 for each concentration tested.

14. Distribution of the Report

1 original (paper):	Sponsor
1 copy (paper):	BSL Bioservice

15. References

BSL BIOSERVICE, Standard Operating Procedures (SOP) No. 11-3-3

Commission Regulation (EC) No 440/2008, L 142, Annex Part B, 30 May 2008

ISO 10993-1: 2009 "Evaluation and testing within a risk management process"

DIN EN ISO 10993-10: 2007 (ISO 10993-10: 2002 + Amendment 1: 2006) "Tests for irritation and delayed-type hypersensitivity"

ISO 10993-12: 2007 "Sample preparation and reference materials"

OECD Guidelines for Testing of Chemicals, number 429 "Skin Sensitisation: Local Lymph Node Assay" (adopted: 24th April 2002)

16. Appendix – Individual Data

Table 2:Radioactive Determination of the Test-Substance Groups

POS	CPM	Test Item	Conc. [%]	Animal number	DPM	DPM-mean back-ground	DPM/Node	Stimulation Index
18	503.0	Negative Control		16	1007.0	995.0	497.5	1.0
19	416.0			17	842.0	830.0	415.0	
20	660.0			18	1327.0	1315.0	657.5	
21	350.0			19	710.0	698.0	349.0	
22	474.0			20	959.0	947.0	473.5	
MV	480.6			MV	969.0	957.0	478.5	
SD	103.9			SD	206.4	206.4	103.2	
25	694.0	Extract of PA 2200 Reused powder	25	1	1400.0	1388.0	694.0	1.5
26	689.0			2	1408.0	1396.0	698.0	1.5
27	371.0			3	747.0	735.0	367.5	0.8
28	482.0			4	968.0	956.0	478.0	1.0
29	442.0			5	886.0	874.0	437.0	0.9
MV	535.6			MV	1081.8	1069.8	534.9	1.1
SD	132.2			SD	272.4	272.4	136.2	0.3
30	618.0	Extract of PA 2200 Reused powder	50	6	1242.0	1230.0	615.0	1.3
31	885.0			7	1772.0	1760.0	880.0	1.8
32	493.0			8	997.0	985.0	492.5	1.0
33	370.0			9	738.0	726.0	363.0	0.8
34	740.0			10	1499.0	1487.0	743.5	1.6
MV	621.2			MV	1249.6	1237.6	618.8	1.3
SD	180.7			SD	363.5	363.5	181.8	0.4
37	583.0	Extract of PA 2200 Reused powder	100	11	1183.0	1171.0	585.5	1.2
38	555.0			12	1118.0	1106.0	553.0	1.2
39	958.0*			13	1934.0	n.d.	n.d.	n.d.
40	419.0			14	847.0	835.0	417.5	0.9
41	426.0			15	863.0	851.0	425.5	0.9
MV	495.8			MV	1189.0	1177.0	588.5	1.2
SD	74.0			SD	395.8	149.6	74.8	0.2
49	5.0	Background Szinti and TCA			10.0			
50	5.0				11.0			
51	6.0				13.0			
52	6.0				13.0			
53	7.0				13.0			
MV	5.8			MV	12.0	0.0	0.0	0.0
SD	0.7			SD	1.3			

* = outlier, failed Grubbs, Nalimov and Dixon; n.d. = not determined

If not noted individually, the results include both lymph nodes of an animal.

POS = position in counter; CPM = counts per minute; Conc. = concentration;
DPM = disintegrations per minute; SD = standard deviation; MV = mean value;
Szinti = scintillation fluid; TCA = trichloroacetic acid

Table 3:Body Weight Gain (g)

<i>Group</i>	<i>Animal No.</i>	<i>Start of study</i>	<i>End of study</i>	<i>Weight gain</i>
<i>Extract of PA 2200 Reused powder 25% in AOO</i>	1	22	22	0
	2	22	22	0
	3	22	22	0
	4	18	19	1
	5	23	23	0
<i>Extract of PA 2200 Reused powder 50% in AOO</i>	6	22	23	1
	7	22	22	0
	8	21	21	0
	9	17	17	0
	10	23	24	1
<i>Extract of PA 2200 Reused powder 100%</i>	11	24	24	0
	12	22	22	0
	13	19	19	0
	14	21	21	0
	15	26	26	0
<i>Negative control 100% AOO</i>	16	20	20	0
	17	22	22	0
	18	22	22	0
	19	22	22	0
	20	21	22	1

Table 4: Clinical Observation

<i>Time of observation after the application</i>	<i>Systemic effects</i>	<i>Local effects</i>
Group 1, animals no. 1 – 5 / test item at a concentration of 25% in AOO		
1 day	nsf	nsf
2 days	nsf	nsf
3 days	nsf	nsf
4 days	nsf	nsf
5 days	nsf	nsf
6 days	nsf	nsf
Group 2, animals no. 6 – 10 / test item at a concentration of 50% in AOO		
1 day	nsf	nsf
2 days	nsf	nsf
3 days	nsf	nsf
4 days	nsf	nsf
5 days	nsf	nsf
6 days	nsf	nsf
Group 3, animals no. 11 – 15 / test item at a concentration of 100%		
1 day	nsf	nsf
2 days	nsf	nsf
3 days	nsf	nsf
4 days	nsf	nsf
5 days	nsf	nsf
6 days	nsf	nsf
Group 4, animals no. 16 – 20 / negative control AOO		
1 day	nsf	nsf
2 days	nsf	nsf
3 days	nsf	nsf
4 days	nsf	nsf
5 days	nsf	nsf
6 days	nsf	nsf

nsf = no specific findings