

TEST REPORT



Acyltransferase BL1

*(Bacillus licheniformis strain BML780-KLM3'
CAP50)(GICC 3265)*

A 13-WEEK ORAL (GAVAGE) TOXICITY STUDY
IN RATS

LAB Scantox Study No: 62129
Date: 26 October 2006
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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The study described in this report "Acytranferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) - A 13-Week Oral (Gavage) Toxicity Study in Rats" was conducted under my supervision and responsibility and is in compliance with the OECD Principles of Good Laboratory Practice (as revised in 1997), which are in conformity with other international GLP regulations.

The report is a complete and accurate account of the methods employed and the data obtained.



Alan Christensen, MSc
Study Director
LAB Scantox



Date

QUALITY ASSURANCE STATEMENTStudy number: **62129**Study title: **Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) - A 13-Week Oral (Gavage) Toxicity Study in Rats**

A review of the study plan has been performed and reported to the Study Director:

Date of review: 20 March 2006	Reporting date: 20 March 2006
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This study performed by LAB Scantox has been inspected by the Quality Assurance Unit in compliance with the principles of Good Laboratory Practice. Inspection reports have been communicated to the Study Director and to management on the dates stated in the table below. Process and facility inspections are performed on a regular basis in accordance with LAB Scantox procedures. Study-based inspection dates and the most recent inspection dates of the processes applicable to this study are stated in the below table.

Inspection type	Inspection item(s)	Inspection date(s)	Reporting date(s)
Study-based	Housing of animals	03 May 2006 14 June 2006	03 May 2006 14 June 2006
	Dosing	03 May 2006 14 June 2006 10 July 2006	03 May 2006 14 June 2006 10 July 2006
	Observation of animals	03 May 2006 14 June 2006 28 June 2006 10 July 2006	03 May 2006 14 June 2006 28 June 2006 10 July 2006
	Weekly detailed observation of animals	15 May 2006 10 July 2006	15 May 2006 10 July 2006
	Raw data	03 May 2006 28 June 2006 10 July 2006	03 May 2006 28 June 2006 10 July 2006
	Registration and storage of test item	05 May 2006	05 May 2006
	Preparation of dose formulation	19 May 2006	19 May 2006
	Blood sampling	28 June 2006 25 July 2006	28 June 2006 25 July 2006
	Openfield test	13 July 2006	13 July 2006
	Stimuli-induced test	27 July 2006	27 July 2006
	Necropsy	25 July 2006	25 July 2006

Process-based	Arrival and allocation of animals	16 February 2006	16 February 2006
	Re-allocation, weighing of animal and diet	14 February 2006 23 May 2006 07 August 2006	14 February 2006 23 May 2006 07 August 2006
	Sample dispatch	14 August 2006	14 August 2006
	Clinical chemistry analysis	24 February 2006 30 May 2006	24 February 2006 30 May 2006
	Haematology analysis	24 February 2006 30 May 2006	24 February 2006 30 May 2006
	Sampling of urine and urinalysis	29 May 2006	29 May 2006
	Necropsy	26 April 2006 27 July 2006	26 April 2006 28 July 2006
	Histology and pathology	24 March 2006	27 March 2006
	Ophthalmoscopy	16 February 2006 14 June 2006	16 February 2006 14 June 2006

The study report has been audited. As far as can be reasonably established, the methods, procedures and observations have been accurately described, and the results and data presented in the study report accurately reflect the raw data generated during the study.

The study report gives an accurate account of the methods and procedures outlined in the study plan and in LAB Scantox Standard Operating Procedures.

Audit date(s) of Draft Report and data: 20-21 September, 25-29 September, 02-03 October-2006	Reporting date (Study Director and management): 03 October 2006
Audit date of Final Report: 26 October 2006	No report

The part of the study performed by Genencor International Inc. has been inspected and the results reviewed by their Quality Assurance Unit and a test site QA statement has been issued.



Pauline Sylvest Salanti
Head of Quality Assurance
LAB Scantox



Date

PERSONNEL INVOLVED IN THE STUDY

Study Director: Alan Christensen, MSc

Study Supervisor: Thuri Kledal, MSc

Principal Investigator,
Analysis of dose formulation: Christine Rechichi, Genencor International Inc.

Sponsor Monitor: Quang Bui, PhD, Genencor International Inc.

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SUMMARY

This study was conducted at LAB Scantox, Ejby, Denmark with the objective to assess the toxicity of Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) administered daily by oral gavage to rats for at least 90 days. The study was conducted in accordance with the OECD Guideline 408. The rat was selected as the test model because of its suitability in this type of study. Oral treatment was chosen to comply with the intended route of exposure in humans. The doses were selected by the Sponsor.

Eighty-two SPF Sprague Dawley rats (41 males and 41 females) of the stock Ntac:SD were used in this study. Before start of treatment, the animals were allocated to four groups (10 males and 10 females each) and treated once daily by oral gavage for at least 90 days with sterile water containing 3% NaCl (control, Group 1), 4.56 mg total protein/kg b.wt/day (Group 2), 13.68 mg total protein/kg b.wt/day (Group 3) or 41.00 mg total protein/kg b.wt/day (Group 4). One (1) ml stock solution Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) contained 30.40 mg total protein. The dose volume was 5 ml/kg b.wt. The gavage tubing was wiped clean between treatment of each animal. A male and a female from Group 2 had in error been housed together for the first 3 days of the study. Two extra females were added to Group 2. These two introduced animals continued for two extra weeks after the main terminal kill (to give these at least 90 days of dosing).

Clinical signs were recorded daily. Detailed clinical observations were performed once weekly. During Weeks 12 and 13 of the study, the animals were examined for sensory reactivity, grip strength and motor activity. Ophthalmoscopy was performed on all animals before start of treatment, and on the animals of Groups 1 and 4 during Week 12 of the study. Body weight and food consumption were recorded weekly. Water consumption was recorded twice weekly. Before termination of treatment, blood samples were taken for haematology and clinical chemistry, and urine was collected for urinalysis. In addition, on Days 35 + 36 and 65 + 66, blood samples were taken for haematology. The animals were killed and subjected to a macroscopic necropsy. Specified organs/tissues were weighed, fixed and prepared for a histopathological examination.

No treatment-related findings were recorded at the clinical and behavioural examinations, on food or water consumption, body weights or at the ophthalmoscopic examination.

No treatment-related findings were observed on the parameters for serum biochemistry, haematology, urinalysis or organ weights.

Necropsy and the following microscopic examination revealed no test item-related effects.

In conclusion, daily oral administration of Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) to Sprague Dawley rats for at least 90 days at dosages of 4.56, 13.68 and 41.00 mg total protein/kg (corresponding to 13.0, 39.0 and 116.9 mg TOS/kg b.wt./day, respectively) was well-tolerated and did not produce any toxicologically significant changes.

Consequently, in this study, the NOAEL (no observed adverse effect level) was 41.00 mg total protein/kg b.wt./day (corresponding to 116.90 mg TOS/kg b.wt./day).

INTRODUCTION

The objective of this study was to assess the toxicity of Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) administered daily by oral gavage to rats for 13 weeks.

The present study was conducted according to the OECD Guideline 408, adopted on 21 September 1998.

The rat was selected as the test model because of its proven suitability in this type of study. Oral treatment was chosen in order to comply with the possible human route of administration. The doses were selected by the Sponsor.

This study was conducted at LAB Scantox, Hestehavevej 36A, Ejby, DK-4623 Lille Skensved, Denmark according to Study plan dated 30 March 2006 and Amendment No1 dated 01 April 2006, No 2 dated 09 May 2006, No 3 dated 21 June 2006 and No 4 dated 13 September 2006.

The animals arrived on 18 April 2006 and 04 May 2006 (only Nos 101 and 102). Treatment started on 25 April and 09 May 2006 (only Nos 101 and 102). The in-life phase ended on 25 July 2006 and 08 August 2006 (only Nos 101 and 102).

This report describes the procedures used and the results obtained.

MATERIALS AND METHODS

The test item, Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) (Lot No 20068010, expiry date at least 1 year from date of issue), was supplied by the Sponsor. A certificate of analysis is included as Addendum C.

Test item characterisation (identity, purity, stability) was the responsibility of the Sponsor. The test item was stored in a freezer in the dark.

Test item

Name:	Acyltransferase BL1 (<i>Bacillus licheniformis</i> strain BML780-KLM3' CAP50)(GICC 3265)
Lot No:	20068010
Intended use:	Food Processing Aid
Description:	Liquid (Certificate of Analysis is appended)
Storage condition:	Freezer (at approximately -18°C) and thaw in a refrigerator
Total protein:	30.40 mg/ml
Specific gravity:	1.021 g/ml
Vehicle	Sterile water containing 3% NaCl

After finalisation of the report the Sponsor will choose whether remaining test item shall be returned to the Sponsor or destroyed.

Group 1 was dosed with the vehicle (sterile water containing 3% NaCl). The dose formulations for Groups 2, 3 and 4 were prepared weekly by diluting the test item (stock solution) with the vehicle (sterile water containing 3% NaCl).

Animals

The experiment was performed in 41 male and 41 female SPF Sprague Dawley rats of the Ntac:SD strain from Taconic Europe A/S, Ejby, Denmark. At the start of the acclimatisation period, the rats were approximately 5 weeks old and their body weight was within a range of +/- 30 grams for each sex. Eleven (11) extra animals (5 males and 6 females) were available until completion of the acclimatisation period for replacement purposes.

An acclimatisation period of at least 5 days was allowed in order to reject animals in poor condition or at the extremes of the weight range.

Housing

The study took place in animal No 107 room provided with filtered air at a temperature of $21^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and relative humidity of $55\% \pm 15\%$. On a few occasions during the study, the relative humidity was above the specified limits. This was considered not to have affected the outcome of the study. The temperature and relative humidity in the animal room were recorded hourly during the study and the records have been retained.

The ventilation system has been designed to give 10 air changes per hour. The room was illuminated to give a cycle of 12 hours light and 12 hours darkness. Light was on from 06:00 h to 18:00 h.

The rats were kept in transparent polycarbonate cages (floor area: 1500 cm² - height 21 cm) with two in each cage, males and females separated. The cages were cleaned and the bedding changed at least once per week.

Before the animals arrived, the animal room was cleaned and disinfected. During the study, the animal room was cleaned regularly and rinsed with water.

Bedding

The bedding was softwood sawdust "Jeluxyl" from Jelu Werk GmbH, Josef Ehrler GmbH & Co KG, Ludwigsmühle, D-73494 Rosenberg, Germany. Analyses for relevant possible contaminants were performed regularly. Certificates of analysis have been retained.

Environmental enrichment

For environmental enrichment, the animals were offered a supply of Aspen Wood Wool from Tapvei Oy, FIN-73620 Kortteinen, Finland, at each change of bedding. Furthermore, an autoclaved brick of wood was provided to each cage. Analyses for relevant possible contaminants were performed regularly. Certificates of analysis have been retained. Each cage also contained a red transparent Rat House (Noryl, Tecniplast) from Tecniplast Gazzada S.a.r.l., 21020 Buguggiate -Va, Italy. The house allows the animals to show a wide range of natural behaviours.

Diet

A complete pelleted rodent diet "Altromin 1314 Fortified" (for growing animals) was available *ad libitum* until Day 49 of the dosing period. On Day 50 and throughout the study, the animals were offered *ad libitum* "Altromin 1324 Fortified" (for adult animals). Altromin was supplied by Altromin Gesellschaft für Tierernährung mbH, D-32791 Lage, Germany. Analyses for major nutritive components and relevant possible contaminants were performed regularly. Certificates of analysis have been retained.

Drinking water

The animals had free access to bottles with domestic quality drinking water acidified with hydrochloric acid to pH 2.5 in order to prevent microbial growth. Analyses for relevant possible contaminants were performed regularly on the drinking water prior to acidification. Certificates of analysis have been retained.

Animal randomisation and allocation

On the day of arrival, the animals were allocated randomly to 4 groups and a group of extra animals, using a randomisation scheme.

Prior to commencement of treatment, some animals were re-allocated in order to reduce possible inter-group mean body weight differences or due to pre-treatment ophthalmoscopy findings. Data available from pre-treatment observations, clinical signs and laboratory investigations were taken into account when re-allocating animals.

On Day 2, the extra animals were killed, after which they were no longer part of this study.

Animal and cage identification

Each animal was identified by punched earmarks.

Each cage was identified by a colour coded card containing at least; study number; group number; sex and animal number.

Treatment

The groups, dose levels, animal numbers and colour codes were as follows:

Group	Dose* (mg total protein/kg)	Dose concentration* (mg/ml)	Animal Nos		Colour code
			Male	Female	
1	0	0	1 - 10	11 - 20	White
2	4.56	0.91	21 - 30, 31	32 - 40, 101, 102	Blue
3	13.68	2.74	41 - 50	51 - 60	Green
4	41.00	8.20	61 - 70	71 - 80	Red

*Material as supplied

- The daily dose was given by oral gavage according to the most recent body weight data.
- Treatment was performed daily for at least 90 days and until the day before necropsy.
- The dose volume was 5 ml/kg body weight.
- The gavage was wiped clean between each animal.
- The first day of treatment was designated Day 1.
- Formulations for Groups 2-4 were kept on a magnetic stirrer during treatment.

A male and a female had been housed together for the first 3 days of the study. Animal No 31 (male) was in error allocated to the study as a female. Animal No 31 (male) was then housed together with male Nos 29 + 30. Two extra females (Nos 101 + 102) were added to Group 2 (to get at least 10 females in this group). These two introduced animals continued for two extra weeks after the main terminal kill (to give at least 90 days of dosing). Data from these 2 extra animals were excluded from statistical analysis.

Dose formulation preparation

Sodium content in the stock solution equals 3% (30 mg/ml). 1 ml stock solution Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) contains 30.40 mg total protein and 8.67% TOS (see certificate of analysis). The test item (as stock solution) was stored frozen at approximately -18°C until use.

Before use, each bottle of the stock solution was thawed to divide the contents into portions suitable for weekly preparation. The stock solution was thawed overnight(s) in a refrigerator. Before dividing the contents of the original stock bottle into portions, and before preparation of the dose formulations, the stock solution was stirred gently for at least 10 minutes on a magnetic stirrer.

Dose formulations:

Group 1 was dosed with the vehicle (sterile water containing 3% NaCl). The dose formulations for Groups 2, 3 and 4 were prepared weekly by diluting the test item (stock solution) with the vehicle (sterile water containing 3% NaCl).

Dose formulations were prepared as follows:

Group 1: Vehicle (5.0 ml – 3% NaCl solution)

Group 2: 0.15 ml stock solution + 4.85 ml vehicle (3% NaCl solution)

Group 3: 0.45 ml stock solution + 4.55 ml vehicle (3% NaCl solution)

Group 4: 1.35 ml stock solution + 3.65 ml vehicle (3% NaCl solution)

According to the Sponsor, the prepared dose formulations were stable for more than 7 days when stored at refrigerator temperature (approximately +2°C to +8°C) in the dark and for more than 6 hours at room temperature.

Control of dose preparations and usage

Before preparation of dose formulation, the dose calculations were double checked.

Each step of the dose formulation preparation and the dosing, including weight of each dose formulation before and after dosing, were documented by weighing.

After dosing, the amount of dose formulation used for each group was compared with the predicted daily usage.

Analysis of dose formulations

In Weeks 1, 6 and 13, duplicate (2) samples of 1.5 ml of the four dose formulations were taken into a 1.8 ml Cryotube, Nunc and stored frozen at approximately –18°C. In the first instance only the first set of samples was shipped and analysed. The other of each set of duplicate samples was kept by LAB Scantox as a backup. At request of the Sponsor the backup samples were discarded. The samples were sent with dry ice to Christine Rechichi, Genencor Int. for analysis.

These samples were analysed according to Genencor SOP #R-SOP-AL-070-01 and reported to the Study Director at LAB Scantox to verify test item in the samples. The results are included as Addendum B.

Clinical signs

Daily observations

All visible signs of ill health and any behavioural changes were recorded daily during the morning hours. Any deviation from normal was recorded with respect to time of onset, duration and severity. An additional, morbidity/mortality check was performed in the afternoon.

Weekly observations

Beginning prior to start of treatment, detailed clinical observations were performed outside the home cage once per week at similar times. Signs to be recorded included, but were not limited to: changes in skin/fur, eyes, mucous membranes, occurrence of secretions and excretions and autonomic activity (*e.g.*, lacrimation, piloerection, pupil size, and unusual respiratory pattern). Changes in gait, posture and response to handling as well as the presence of clonic or tonic movements, stereotypies (*e.g.* excessive grooming, repetitive circling) or bizarre behaviour (*e.g.* self-mutilation, walking backwards) were also recorded.

Open field and stimuli-induced tests

On one occasion during the last two weeks of the study, all animals were examined with respect to reactivity to different types of stimuli (*e.g.* auditory, visual, tactile), grip strength and motor activity (open field test).

Mortality

Five (5) animals died during the study. The animals were necropsied and subjected to the procedures described in the paragraph "Terminal observations".

Any decision regarding killing for ethical reasons was taken by the Study Director and the Sponsor Monitor was notified immediately by e-mail.

Body weight

All animals were weighed on arrival, on the day of re-allocation, on the first day of treatment (Day 1) and weekly thereafter. Also, the weight at necropsy was recorded.

Food consumption

Starting Day 1, the consumption of food was recorded weekly for each cage.

Water consumption

Starting Day 1, the consumption of water was recorded twice weekly for each cage.

Ophthalmoscopy

Before start of treatment, ophthalmoscopy was performed on all animals. Before termination of treatment, all animals in Groups 1 and 4 were re-examined.

After application of tropicamide 1% solution (Mydracyl, Alcon Universal Ltd., USA), both eyes were examined with an indirect ophthalmoscope (Heine binocular indirect ophthalmoscope, Omega 200, Germany) and a portable slit-lamp microscope (Kowa SL-5, Kowa Company Ltd., Japan).

Clinical pathology

On Days 35 + 36 (haematology only) and 65 + 66 (haematology only) and before termination of treatment (haematology and clinical chemistry), blood samples were taken from all animals. Blood samples were drawn from the orbital venous plexus during CO₂/O₂ anaesthesia.

For haematology, at least 300 µl EDTA stabilised blood was taken. From this sample, a smear was prepared and stained with May-Grünwald and Giemsa for possible later manual differential leucocyte count. In case it is later decided to read all the smears manually, the manual counts will override the results of the ABX Pentra 120.

For the coagulation tests, 500 µl citrate stabilised blood was taken.

Approximately 750 µl blood was taken for clinical chemistry in plain glass tubes for serum.

Before termination of treatment, urine samples were taken from all animals. Urine samples were collected overnight while the animals were placed individually in metabolism cages. During the sampling period, only water was available. The volume of urine samples were recorded and up to 10 ml was saved for analysis.

At necropsy, a bone marrow smear was taken from the femur of all animals (see the table under the heading "Necropsy"). The smears were fixed and stained with May-Grünwald and Giemsa stain. These smears will not be analysed unless suggested by the haematological findings. If the smears will not be analysed, they will be discarded upon finalisation of the study.

The parameters, methods and units for the laboratory investigations are stated below:

Haematology and coagulation parameters

Parameter	Method/Equipment	Unit
Haemoglobin (Hb)	Direct measurement/ABX Pentra 120	mmol/l
Red blood cell count (RBC)	Direct measurement/ABX Pentra 120	$10^{12}/l$
Haematocrit (HT)	Direct measurement/ABX Pentra 120	ml/100 ml
Mean cell volume (MCV)	Calculated/ABX Pentra 120	fl
Mean cell haemoglobin (MCH)	Calculated/ABX Pentra 120	fmol
Mean cell haemoglobin concentration (MCHC)	Calculated/ABX Pentra 120	mmol/l
White blood cell count (WBC)	Direct measurement/ABX Pentra 120	$10^9/l$
Differential leucocyte count (NEUTRO, LYMPHO, EOS, BASO, MONO)	Direct measurement/ABX Pentra 120	% and $10^9/l$
Platelet count (Plt)	Direct measurement/ABX Pentra 120	$10^9/l$
Activated partial thromboplastin time (APTT)	IL Test TM /ACL TM (*)	sec.
Prothrombin time (Pt)	IL Test TM /ACL TM (*)	sec.
Fibrinogen (Fib)	IL Test TM /ACL TM (*)	g/l

(* Instrumentation Laboratories, Automated Coagulation Laboratory)

Clinical chemistry

Parameter	Method	Unit
Alanine aminotransferase (ALAT)	Hitachi 902	μkat/l
Aspartate aminotransferase (ASAT)	Hitachi 902	μkat/l
Alkaline phosphatase (ALKPH)	Hitachi 902	μkat/l
Bilirubin (total) (BILI)	Hitachi 902	μmol/l
Gamma-glutamyl transferase (GGT)	Hitachi 902	μkat/l
Cholesterol (CHOL)	Hitachi 902	mmol/l
Triglycerides (TRIG)	Hitachi 902	mmol/l
Carbamide (UREA)	Hitachi 902	mmol/l
Creatinine (CREAT)	Hitachi 902	μmol/l
Glucose (GLUC)	Hitachi 902	mmol/l
Sodium (Na)	Ion selective electrode/Hitachi 902	mmol/l
Potassium (K)	Ion selective electrode/Hitachi 902	mmol/l
Calcium (Ca)	Hitachi 902	mmol/l
Magnesium (Mg)	Hitachi 902	mmol/l
Inorganic phosphorus (P)	Hitachi 902	mmol/l
Chloride (Cl)	Ion selective electrode/Hitachi 902	mmol/l
Protein (total) (PROTEIN)	Hitachi 902	g/l
Albumin (ALB)	Hitachi 902	g/l
Globulin	Calculated	g/l
Albumin/Globulin (ALB/G) ratio	Calculated	No unit

Urinalysis

Parameter	Method/Equipment	Unit/Range
Volume		ml
Sodium (Na)	Ion selective electrode/ Cobas Mira S	mmol/l
Potassium (K)	Ion selective electrode/ Cobas Mira S	mmol/l
Chloride (Cl)	Ion selective electrode/ Cobas Mira S	mmol/l
Specific gravity (SG)	Ames Multistix 10SG/Clinitek 500	No unit
PH	Ames Multistix 10SG/Clinitek 500	No unit
Colour (COLOUR)	Visual examination	No unit
Protein (PROTEIN)	Ames Multistix 10SG/Clinitek 500	g/l
Leucocytes (LEUC)	Ames Multistix 10SG/Clinitek 500	Cells/ μ l
Nitrite (NITRITE)	Ames Multistix 10SG/Clinitek 500	No unit
Blood (BLOOD)	Ames Multistix 10SG/Clinitek 500	Erythrocytes/ μ l
Glucose (GLUCOSE)	Ames Multistix 10SG/Clinitek 500	mmol/l
Ketones (KETONES)	Ames Multistix 10SG/Clinitek 500	mmol/l
Bilirubin (BILI)	Ames Multistix 10SG/Clinitek 500	No unit
Urobilinogen (UROBIL)	Ames Multistix 10SG/Clinitek 500	μ mol/l

Microscopic examination of spun sediment was performed. A 40 x magnification was used. For the various findings, the incidence is described in the following way:

- "no trace" = no trace in 2-3 visual fields
- (+) "trace" = a few in 2-3 visual fields
- + "slight" = a few in each visual field
- ++ "moderate" = several in each visual field
- +++ "marked" = numerous in each visual field

The elements examined were: erythrocytes, leukocytes, epithelial cells, crystals, urates, hyaline and granular casts and bacteria.

Terminal observations

On the day of necropsy, the animals were weighed, examined externally and placed in a chamber with atmospheric air upon which CO₂ was applied at a steadily increasing concentration for euthanasia. The animals were monitored closely while in the chamber. The animals were sacrificed by exsanguination and necropsied in the sequence of one or two animals/group.

Necropsy

A macroscopic examination was performed after opening the cranial, thoracic and abdominal cavities and by observing the appearance of the organs and tissues *in situ*. Any macroscopic change was recorded with details of the location, colour, shape and size in the PathData computer system.

Organs and tissues

Either whole organs or selected samples of the indicated organs and tissues were subjected to the procedures, itemised in the list given below. Weights were recorded in the PathData computer system.

Paired organs were weighed together. The relative organ weights, i.e. organ weight as a percentage of the body weight, were calculated for each animal.

All tissues were initially fixed in phosphate buffered neutral 4% formaldehyde with the exception of the eyes (Davidson's fixative) and testes (Bouin's fixative). The fixative for long term preservation was phosphate buffered neutral 4% formaldehyde for all tissues. The lungs were infused with fixative at necropsy.

Organs and tissues	W e i g h	F i x	M i c r o	Organs and tissues	W e i g h	F i x	M i c r o
Abnormalities (gross lesions)		x	x	Pituitary		x	x
Adrenals	x	x	x	Prostate		x	x
Aorta (thoracic)		x	x	Salivary gland (right submandibular and sublingual)		x	x
Brain	x	x	x	Sciatic nerve		x	x
Bone marrow smear		x		Seminal vesicles		x	x
Epididymides	x	x	x	Skeletal muscle		x	x
Eyes with lens/optic nerve		x	x	Skin		x	x
Heart	x	x	x	Spinal cord (cervical, thoracic, lumbar)		x	x
Intestine small (duodenum, jejunum, ileum)		x	x	Spleen	x	x	x
Intestine large (caecum, colon, rectum)		x	x	Sternum (for bone marrow)		x	x
Kidneys	x	x	x	Stomach (glandular, non glandular)		x	x
Liver	x	x	x	Testes	x	x	x
Lungs		x	x	Thymus	x	x	x
Lymph nodes (mesenteric and right mandibular)		x	x	Thyroids (incl. parathyroid)		x	x
Mammary gland		x	x	Trachea		x	x
Oesophagus		x	x	Urinary bladder		x	x
Ovaries	x	x	x	Uterus (horn, and cervix)	x	x	x
Pancreas		x	x	Vagina		x	x

Processing and microscopic examination

After fixation, the organs and tissues sampled for microscopic examination were trimmed and representative specimens were taken for histological processing. The specimens were embedded in paraffin and cut at a nominal thickness of approximately 5 µm, stained with haematoxylin and eosin and examined under a light microscope. Paired organs were processed together.

All pathological findings were entered directly onto the PathData computer system.

Histological alterations were graded on a 5 grade system:

- Grade 1 - Minimal/Very few/Very small
- Grade 2 - Slight/Few/Small
- Grade 3 - Moderate/Moderate number/Moderate size
- Grade 4 - Marked/Many/Large
- Grade 5 - Massive/Extensive number/Extensive size
- Present Finding present/Severity not scored

The following organs and tissues were examined microscopically:

1. All organs and tissues from all control (Group 1) and high dose animals (Group 4).
2. All organs and tissues from all animals, dead after initiation of treatment.
3. All gross lesions from all animals.

Submandibular lymph nodes with macroscopic visible signs of accumulation of blood due to blood sampling from the ipsilateral orbital venous plexus were fixed but not processed histologically.

Both eyes were fixed but only the eye opposite the side, used for blood sampling, was examined microscopically.

Tissues not examined microscopically were stored at Scantox held in fixative.

Peer review

A peer review by a LAB Scantox peer reviewing pathologist was performed on selected slides. Diagnostic discrepancies were resolved by discussion.

Deviations

As a deviation to the study plan on Days 35 and 36, animal Nos 101 and 102 were offered Altromin 1324F and not Altromin 1314F as specified in the study plan. As this only happened two days and as Altromin 1324F was going to be offered from Day 50 thereafter, this was considered not to have affected the outcome of the study.

As a deviation to the study plan, extended observation was not made on Day 56 (animal Nos 101 and 102) and 70 (remaining animals). However, the animals were weighed on these days and any major deviations would have been reported. In addition, no findings were seen before or after Days 56 and 70 regarding extended weekly observations in these animals. Therefore, this deviation was considered not to have affected the general outcome of the study.

As a deviation to the study plan, open field was not conducted for animal No 70. As no treatment-related findings were observed in any of these animals, this was considered not to have affected the outcome of the study.

Statistics

Data were processed to give group mean values and standard deviations where appropriate.

Thereafter each continuous variable was tested for homogeneity of variance with Levene's test. If the variance was homogeneous, analysis of variance was carried out for the variable. If any significant differences were detected, possible inter-group differences were assessed with Dunnett's test (comparing treated groups with a control group). If the variance was heterogeneous, each variable was tested for normality by the Shapiro-Wilk method. In case of normal distribution, possible inter-group differences were identified with Student's t-test. Otherwise the possible inter-group differences were assessed by Kruskal-Wallis's test. If any significant inter-group differences were detected, the subsequent identification of the groups was carried out with Wilcoxon Rank-Sum test.

Ranked type of urine analysis data was analysed with Wilcoxon Rank-Sum test.

For all tests, the level of significance was defined as $p < 0.05$.

The statistical analyses were made with SAS[®] procedures (version 8.2) described in "SAS/STAT[®] User's Guide, SAS OnlineDoc[®], 1999, SAS Institute Inc., Cary, North Carolina 27513, USA.

Archives

LAB Scantox

For a period of 10 years, LAB Scantox will be responsible for the archiving of the following materials relating to the study:

Study plan, study plan amendments and correspondence, test material receipts, sample of test item, animal records, all original data, wet tissues, blocks and slides and final report.

At the end of the storage period, LAB Scantox will contact the Sponsor for instructions whether the material should be transferred, retained or destroyed.

Genencor International Inc. (Analysis of dose formulation)

For a period of 10 years, the raw data pertaining to formulation analysis, shipping documents, correspondence and the analytical report will be archived at Genencor International Inc. At the end of the storage period, Genencor International Inc. will contact the Sponsor for instructions whether the material should be transferred, retained or destroyed.

RESULTS

Mortality

There were 4 deaths distributed between Groups 3 (one male and two females) and 4 (one male) in the course of the study. One male (group 2) was killed moribund:

Low dose male No 21 was killed moribund on Day 74. Clinical signs: 'Forced respiration, gasping for air, wheezing sound at respiration, subdued, dehydrated. Animal killed moribund'. Serum biochemistry revealed increased values for aspartate aminotransferase, cholesterol, urea, creatinine, glucose, magnesium and phosphor and decreased value for chloride. However, as these increases and decreases were seen in one animal in the low dose level only, this was considered not to be related to treatment with the test item. Macroscopic examination revealed haemorrhage of the thymus. Microscopic examination of animal No 21 revealed changes mainly in the liver and the kidneys. These changes were considered incidental.

Mid dose male No 44 was found dead on Day 73. No clinical signs were seen in this animal before this day. No abnormal macroscopic findings were seen. Microscopic examination of animal No 44 showed changes (seen as foreign material in the lungs) probably related to a gavage error accident.

Mid dose female No 53 was found dead on Day 29. Clinical signs: '10 minutes post dose forced respiration, passive. Animal found dead in the afternoon'. Macroscopic examination revealed a high amount of reddened Peyer's patches in the small intestines and, in addition, red discoloration of the lungs. Microscopic examination of animal No 53 showed pleuritis on the lungs and this change was probably related to a gavage error accident.

Mid dose female No 59 was found dead on Day 12. No clinical signs were seen in this animal before this day. No abnormal macroscopic findings were seen. Microscopic examination of animal No 59 showed changes (seen as foreign material in the lungs) probably related to a gavage error accident.

High dose male No 69 was found dead on Day 37. No clinical signs were seen in this animal before this day. The rat was autolysed and no abnormal macroscopic findings were seen. Microscopic examination of animal No 69 did not reveal any changes related to treatment or the dosing procedure.

Therefore, based on available information (clinical signs, clinical pathology (only one animal), and/or the macro- and microscopic examination) and in the absence of a dose response relationship, the death of the 5 animals could not conclusively be treatment related.

Clinical signs (Appendix I)

No clinical signs were seen in the study that could be considered to be related to treatment.

Open field and stimuli-induced tests (Tables 1-2, Appendices II-III)

No treatment-related effects were observed on parameters from the open field test and the reflex test series.

Body weight (Figure 1, Table 3, Appendix IV)

All animals gained expected body weight during the study and no treatment-related effects were observed on body weights or body weight gain.

A statistically significant increase in body weight gain (Days 1-91) was seen in Group 2 females, compared to the control group. As this was seen in the low dose level and with no similar tendencies for males, this was not considered treatment related.

Food consumption (Table 4, Appendix V)

No treatment-related effects were observed in food consumption.

In Weeks 5, 7 and 13, the females of Group 2 had statistically significantly higher food consumption when compared with the females of the control group. Since this finding was sporadic, without clear dose dependency and without a similar tendency in the opposite sex, it was considered to be incidental.

Water consumption (Table 5, Appendix VI)

No treatment-related effects were observed in water consumption.

On Days 8-11, 36-39, 74-78 and 81-85, the males of Groups 2, 4, 3 and 3 + 4, respectively had statistically significantly lower water consumption when compared with the males of the control group. Since this finding was sporadic, without any clear dose dependency and without a similar tendency in the opposite sex, it was considered to be incidental.

Ophthalmoscopy (Appendix VII)

The ophthalmoscopic examination revealed no treatment-related effects.

Haematology (Tables 6-8, Appendices VIII-X)

No treatment-related findings were observed in the parameters for haematology.

Haematology revealed a statistically significant decrease in haemoglobin in Group 4 males on Days 35 and 36 when compared with the males of the control group. A statistically significant increase was seen in fibrinogen of Group 2 males on Days 65 and 66 when compared with the males of the control group. As the above findings were restricted to one sex only, seen in the low dose level only (fibrinogen), or not seen consistently throughout the study they were considered not to be attributable to treatment.

Clinical chemistry (Table 9, Appendix XI)

No treatment-related findings were observed on the parameters for clinical chemistry.

Animal No 21 (Group 2), moribund and killed on Day 74, had increased values for aspartate aminotransferase, cholesterol, urea, creatinine, glucose, magnesium and phosphor compared with LAB Scantox Historical data (see Addendum D). Decreased value was seen for chloride compared with LAB Scantox Historical data. However, as these increases and decreases were seen in one animal in the low dose level only, this was not considered to be related to treatment with the test item. Microscopic examination of animal No 21 revealed changes mainly in the liver and the kidneys. These changes were considered incidental.

At termination, a statistically significant increase for urea was seen in Group 4 males compared with the control group. As this was seen in one sex only, and with no clear dose relationship, it was not considered to be attributable to treatment.

Urinalysis (Tables 10-11, Appendices XII-XIII)

No treatment-related findings were seen in the urinalysis or in the microscopic examination of the urine.

Organ weight (Table 12, Appendix XIV)

There were no treatment-related differences in organ weights between treated and control animals.

Macroscopic findings (Addendum A)

No treatment-related findings were reported at post mortem.

Microscopic findings (Addendum A)Decedent animals (+1 and +2 in the PathData report)

During the study, four animals died and one animal was killed moribund before termination of the in life phase:

- Animal No 21, male, low dose group was sacrificed moribund on Day 74 of the study
- Animal No 44, male, intermediate dose group was found dead on Day 73 of the study
- Animal No 53, female, intermediate dose group was found dead on Day 29 of the study
- Animal No 59, female, intermediate dose group was found dead on Day 12 of the study
- Animal No 69, male, high dose group was found dead on Day 37 of the study

Microscopic examination of the decedents showed changes probably related to gavage error accidents in animal Nos 44, 53 and 59. These changes were foreign material in the lungs of animal Nos 44 and 59 and pleuritis in animal No 53.

Microscopic examination of animal No 21 revealed changes mainly in the liver and the kidneys. These changes were considered incidental.

Microscopic examination of animal No 69 did not reveal any changes related to treatment or to the dosing procedure.

Terminal kill (K0 in the PathData report)

No treatment-related findings were reported at the microscopic examination of tissues, available for histological examination from terminal kill animals in the high dose group.

All findings reported were within the background of findings reported in this age and strain of laboratory maintained rat and as such considered to be of no toxicological significance.

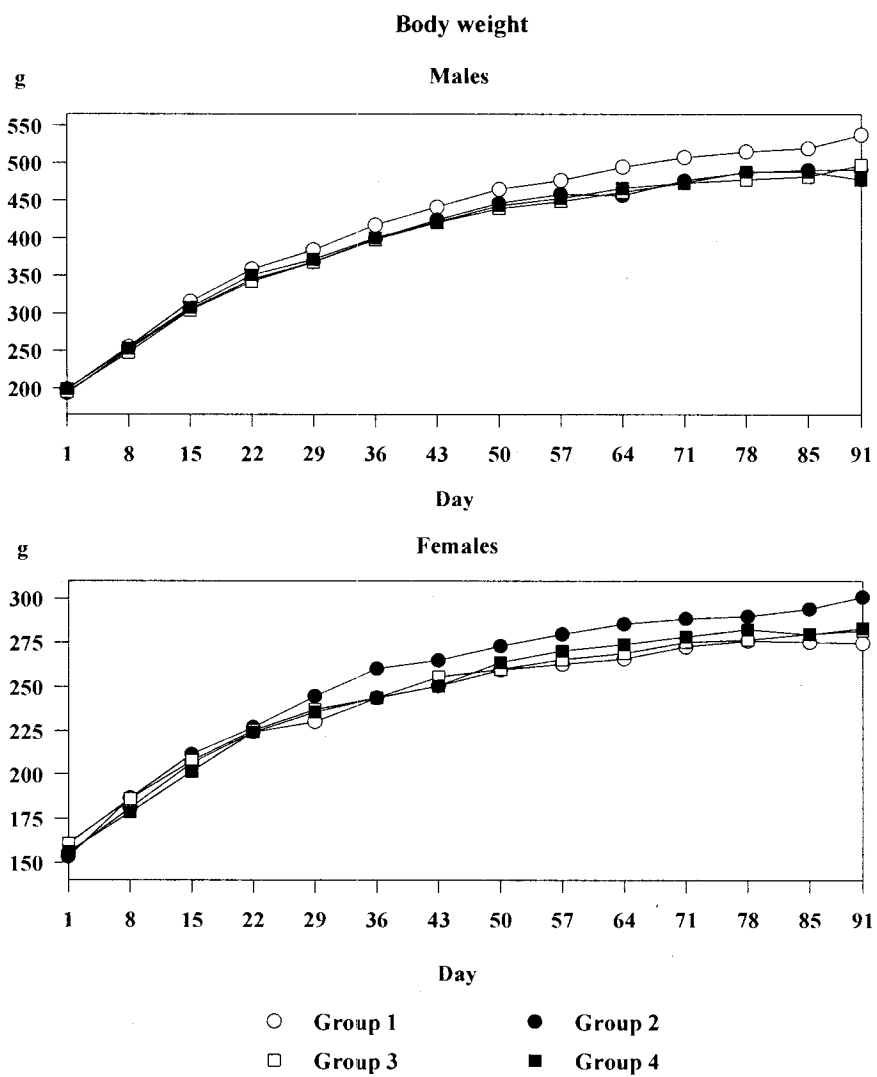
CONCLUSION

Daily oral administration of Acyltransferase BL1 (*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265) to Sprague Dawley rats for at least 90 days at dosages of 4.56, 13.68 and 41.00 mg total protein/kg (corresponding to 13.0, 39.0 and 116.9 mg TOS/kg b.wt./day, respectively) was well-tolerated and did not produce any toxicologically significant changes.

Consequently, in this study, the NOAEL (no observed adverse effect level) was 41.00 mg total protein/kg b.wt./day (corresponding to 116.90 mg TOS/kg b.wt./day).

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats



ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Group mean values

Males

GROUP	TIME MOVING				TOTAL DISTANCE (m)				NO. OF REARINGS				TIME CENTRE			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	238.3	11.0	10		37.1	6.3	10		43.5	27.5	10		12.2	11.2	10	
2	243.4	11.5	10		43.5	10.3	10		50.0	16.3	10		14.1	5.7	10	
3	239.7	7.3	9		40.0	5.1	9		43.4	20.8	9		17.3	13.1	9	
4	242.9	14.1	8		39.2	7.3	8		42.0	18.2	8		8.9	5.9	8	

GROUP	TIME PERIPHERY				TOTAL CORNER VISITS				MOVES/COUNTS				FAECES			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	287.8	11.2	10		18.7	6.2	10		1190.7	55.8	10		3.4	2.7	10	
2	285.9	5.7	10		22.1	5.9	10		1217.0	56.9	10		2.5	3.2	10	
3	282.7	13.1	9		21.4	4.3	9		1198.0	36.3	9		0.7	1.1	9	
4	291.1	5.9	8		17.6	2.9	8		1214.9	71.6	8		1.9	2.1	8	

p>0.05, versus control group

S.D. = standard deviation N = numbers of cages

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Group mean values

Females

GROUP	TIME MOVING				TOTAL DISTANCE (m)				NO. OF REARINGS				TIME CENTRE			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	238.4	11.1	10		44.7	7.0	10		33.2	6.9	10		7.6	4.5	10	
2	244.2	7.4	9		46.2	5.2	9		40.6	10.3	9		6.1	3.4	9	
3	240.1	12.0	8		48.4	7.9	8		35.5	7.2	8		6.1	4.7	8	
4	247.1	3.9	10		50.7	6.8	10		42.9	8.3	10		8.0	5.2	10	

GROUP	TIME PERIPHERY				TOTAL CORNER VISITS				MOVES/COUNTS				FAECES			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	292.4	4.5	10		25.5	5.1	10		1192.1	55.2	10		0.0	0.0	10	
2	293.9	3.4	9		26.4	3.1	9		1220.9	36.9	9		0.1	0.3	9	
3	293.9	4.7	8		27.6	4.5	8		1200.1	60.5	8		0.5	1.4	8	
4	292.0	5.2	10		28.3	3.6	10		1235.8	19.8	10		0.0	0.0	10	

p>0.05, versus control group

S.D. = standard deviation N = numbers of cages

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Males

GROUP	PUPIL REFLEX		Total	p
	Proper reaction	Failed reaction		
1	9	1	10	
2	10	0	10	
3	9	1	10	
4	9	0	9	
Total	37	2	39	

GROUP	TOE PINCH REACTION	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	GRASP RESPONSE		Total	p
	Proper reaction	Failed reaction		
1	10	0	10	
2	9	1	10	
3	10	0	10	
4	9	0	9	
Total	38	1	39	

GROUP	GRIP STRENGTH	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Males

GROUP	EYELID REFLEX	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	STARTLE RESPONSE	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	HEAD SHAKE RESPONSE	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	RIGHTING REFLEX, TABLE	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Males

GROUP	RIGHTING REFLEX, HAND	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	PLACING REFLEX	Total	p
	Proper reaction		
1	10	10	
2	10	10	
3	10	10	
4	9	9	
Total	39	39	

GROUP	NEGATIVE GEOTAXIS		Total	p
	Proper reaction	Failed reaction		
1	9	1	10	
2	8	2	10	
3	10	0	10	
4	7	2	9	
Total	34	5	39	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Females

GROUP	PUPIL REFLEX	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	TOE PINCH REACTION	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	GRASP RESPONSE	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	GRIP STRENGTH	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

p>0.05 versus control group

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Females

GROUP	EYELID REFLEX	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	STARTLE RESPONSE	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	HEAD SHAKE RESPONSE	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	RIGHTING REFLEX, TABLE	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Incidence of findings

Females

GROUP	RIGHTING REFLEX, HAND	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	PLACING REFLEX	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	NEGATIVE GEOTAXIS	Total	p
	Proper reaction		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Group mean values - Day of arrival to Day 91

Males

GROUP	ON ARRIVAL				DAY OF RE- ALLOCATION				DAY 1				DAY 8				DAY 15			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	131.9	4.1	10		185.1	7.4	10		198.6	8.4	10		255.0	13.9	10		315.2	19.8	10	
2	133.5	5.7	11		183.6	9.4	11		193.4	15.1	11		251.6	14.1	11		305.4	18.4	11	
3	131.7	3.7	10		183.3	6.0	10		195.1	7.6	10		247.8	14.6	10		303.7	18.7	10	
4	134.3	4.2	10		187.3	4.8	10		199.0	4.9	10		253.4	8.3	10		307.4	14.0	10	

GROUP	DAY 22				DAY 29				DAY 36				DAY 43				DAY 50			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	358.1	29.8	10		384.0	38.8	10		417.1	40.0	10		440.9	40.7	10		464.8	42.8	10	
2	344.6	20.4	11		368.0	20.8	11		398.5	23.2	11		424.2	25.4	11		446.4	28.2	11	
3	341.9	24.5	10		367.5	31.6	10		397.5	35.6	10		420.3	40.8	10		439.0	40.0	10	
4	350.5	17.5	10		371.2	19.7	10		400.1	22.1	10		421.1	25.3	9		443.0	25.0	9	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Group mean values - Day of arrival to Day 91

Males

GROUP	DAY 57				DAY 64				DAY 71				DAY 78				DAY 85			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	476.6	45.2	10		494.4	48.8	10		507.1	51.4	10		514.8	51.4	10		519.2	54.9	10	
2	458.3	30.6	11		456.2	36.0	11		476.4	30.0	11		487.0	32.8	10		490.6	32.8	10	
3	448.6	44.2	10		461.1	43.4	10		472.9	44.7	10		477.6	46.6	9		481.7	44.5	9	
4	452.3	28.7	9		466.3	29.2	9		473.7	33.7	9		488.0	32.1	9		488.0	33.9	9	

GROUP	DAY 91				BODY WT GAIN 1-91			
	Mean	S.D.	N	p	Mean	S.D.	N	p
1	520.0	55.0	10		321.4	48.0	10	
2	491.3	35.6	10		299.0	35.7	10	
3	485.2	44.1	9		290.7	39.0	9	
4	490.6	33.0	9		292.3	32.6	9	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Group mean values - Day of arrival to Day 91

Females

GROUP	ON ARRIVAL				DAY OF RE- ALLOCATION				DAY 1				DAY 8				DAY 15			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	122.0	4.7	10		148.8	3.3	10		155.2	3.8	10		180.9	7.3	10		206.2	12.4	10	
2	124.7	5.7	9		148.8	11.7	9		153.2	14.7	9		186.6	11.4	9		211.2	11.4	9	
3	123.1	9.2	10		152.6	5.8	10		160.8	6.2	10		186.1	11.1	10		207.6	10.7	9	
4	123.2	8.0	10		150.2	4.8	10		156.1	8.6	10		178.4	9.2	10		201.5	12.4	10	

GROUP	DAY 22				DAY 29				DAY 36				DAY 43				DAY 50			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	224.2	16.8	10		230.1	12.6	10		243.5	13.9	10		250.4	12.6	10		259.5	11.3	10	
2	227.0	15.8	9		244.7	20.8	9		260.1	24.9	9		264.8	18.6	9		273.0	22.7	9	
3	225.2	15.8	9		237.0	15.1	9		243.8	14.2	8		255.5	11.4	8		259.8	15.8	8	
4	224.2	20.1	10		235.6	20.1	10		243.6	15.7	10		250.4	13.5	10		263.7	16.0	10	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Group mean values - Day of arrival to Day 91

Females

GROUP	DAY 57				DAY 64				DAY 71				DAY 78				DAY 85			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	262.7	9.9	10		265.8	11.7	10		272.6	9.9	10		275.9	12.5	10		275.2	11.2	10	
2	279.7	26.6	9		285.4	27.5	9		288.4	24.3	9		289.8	21.8	9		294.0	24.2	9	
3	265.4	14.9	8		268.9	13.4	8		275.3	13.7	8		276.5	15.7	8		279.9	12.7	8	
4	270.2	18.5	10		273.9	17.4	10		278.2	17.3	10		282.3	18.6	10		279.6	17.1	10	

GROUP	DAY 91				BODY WT GAIN 1-91			
	Mean	S.D.	N	p	Mean	S.D.	N	p
1	275.8	10.4	10		120.6	10.0	10	
2	297.1	23.6	9		143.9	27.4	9	*
3	284.0	15.3	8		123.6	13.9	8	
4	279.7	15.9	10		123.6	15.2	10	

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Group mean values per animal - Week 1 - Week 13

Males

GROUP	WEEK 1				WEEK 2				WEEK 3				WEEK 4				WEEK 5			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	173.9	10.3	5		189.2	15.2	5		195.6	15.6	5		188.4	17.4	5		198.2	15.6	5	
2	171.0	5.9	4		177.6	10.1	5		185.5	4.3	5		177.6	7.3	5		186.1	6.1	5	
3	166.0	10.3	5		179.2	7.0	5		183.8	7.4	5		178.5	8.4	5		185.3	7.0	5	
4	169.7	8.6	5		180.7	12.1	5		190.6	14.5	5		180.2	13.7	5		186.4	10.4	5	

GROUP	WEEK 6				WEEK 7				WEEK 8				WEEK 9				WEEK 10			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	193.6	8.9	5		187.0	9.4	5		206.7	12.1	5		205.9	13.8	5		207.7	15.4	5	
2	186.6	8.2	5		181.1	9.0	5		199.3	10.5	5		181.8	24.0	5		203.8	22.3	4	
3	185.8	9.0	5		179.0	8.4	5		194.9	11.6	5		191.6	9.4	5		192.4	5.4	5	
4	184.3	13.9	4		179.4	6.1	4		195.9	7.5	5		196.1	7.8	5		194.2	11.9	3	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Group mean values per animal - Week 1 - Week 13

Males

GROUP	WEEK 11				WEEK 12				WEEK 13 #				TOTAL, WEEK 1 TO WEEK 13			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	195.6	11.5	5		205.8	16.0	5		157.3	9.0	5		2505.9	155.9	5	
2	196.3	18.1	4		195.3	12.8	5		153.0	11.2	5		2410.3	102.7	3	
3	191.3	7.0	4		189.3	9.6	5		147.9	9.0	5		2387.4	94.9	4	
4	196.8	16.3	4		193.9	7.8	4		153.0	7.5	4		2383.0	136.3	3	

= only 6 days

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3⁺ CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Group mean values per animal - Week 1 - Week 13

Females

GROUP	WEEK 1				WEEK 2				WEEK 3				WEEK 4				WEEK 5			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	120.8	2.5	5		121.8	7.4	5		127.9	6.8	5		117.9	7.7	5		125.9	7.0	5	
2	124.5	4.1	4		128.2	7.9	5		131.6	8.2	5		132.6	14.3	5		141.7	10.2	4	*
3	120.2	3.9	5		122.5	6.7	4		121.7	10.5	5		125.3	5.7	5		121.5	4.5	3	
4	117.2	5.4	5		119.0	3.0	5		126.3	12.8	5		115.4	24.9	5		122.5	8.1	5	

GROUP	WEEK 6				WEEK 7				WEEK 8				WEEK 9				WEEK 10			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	121.7	5.5	5		115.3	3.9	5		130.0	6.8	5		128.0	7.1	5		128.1	5.4	5	
2	124.9	6.9	4		122.0	1.8	4	*	144.1	9.0	4		138.9	9.2	4		135.4	2.6	4	
3	124.6	10.1	3		114.2	2.3	3		131.1	1.3	3		130.7	6.3	3		123.5	3.8	3	
4	119.6	7.1	5		118.7	9.4	5		143.0	11.3	5		136.3	9.5	5		125.8	12.2	5	

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Group mean values per animal - Week 1 - Week 13

Females

GROUP	WEEK 11				WEEK 12				WEEK 13 #				TOTAL, WEEK 1 TO WEEK 13			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	129.3	8.7	5		122.8	7.3	5		98.5	5.8	5		1588.0	51.8	5	
2	127.2	6.6	4		134.8	5.4	4		112.6	3.9	4	**	1694.1	58.5	4	
3	124.2	6.4	3		128.5	2.4	3		97.3	2.8	3		1591.2	15.1	3	
4	128.6	12.5	5		128.3	9.1	5		98.8	3.0	5		1599.5	91.5	5	

#= only 6 days

** means $p < 0.01$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Males

GROUP	DAY 1-4				DAY 4-8				DAY 8-11				DAY 11-15				DAY 15-18			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	87.8	5.9	5		115.3	31.0	5		96.2	6.0	5		134.7	11.3	5		97.9	6.9	5	
2	87.4	4.3	4		117.7	7.7	5		86.6	4.5	5	*	125.7	12.5	5		98.7	5.1	5	
3	87.1	7.0	5		114.4	17.1	5		91.2	5.0	5		132.3	12.1	5		98.3	8.2	5	
4	84.8	6.4	5		121.2	5.6	5		95.1	3.6	5		129.6	15.9	5		95.8	6.3	5	

GROUP	DAY 18-22				DAY 22-25				DAY 25-29				DAY 29-32				DAY 32-36			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	144.2	4.4	5		103.8	3.6	4		112.4	10.3	5		108.3	7.3	5		142.7	8.5	5	
2	138.9	6.1	5		96.0	4.5	5		109.2	2.4	5		102.6	3.4	5		138.6	5.9	5	
3	137.3	16.8	5		96.2	9.7	5		106.6	3.9	5		100.1	9.6	5		137.0	15.0	5	
4	138.9	8.4	5		93.3	6.1	5		107.9	8.8	5		101.8	9.4	5		136.5	8.7	5	

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Males

GROUP	DAY 36-39				DAY 39-43				DAY 43-46				DAY 46-50				DAY 50-53			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	107.3	4.4	5		128.7	6.3	5				0		152.7	15.5	5		112.1	6.9	5	
2	101.3	5.2	5		133.1	16.0	5				0		140.9	11.4	5		102.3	2.5	5	
3	102.8	9.9	5		127.7	9.6	5				0		139.1	13.4	5		97.9	11.7	5	
4	97.0	5.2	4	*	127.3	7.4	5				0		131.7	9.9	5		97.7	10.1	5	

GROUP	DAY 53-57				DAY 57-60				DAY 60-64				DAY 64-67				DAY 67-71			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	162.3	7.3	5		90.4	4.2	5		131.6	3.5	5		116.9	5.7	5		141.9	7.0	5	
2	156.3	15.4	5		86.3	5.4	5		108.7	52.5	5		125.4	24.3	5		136.2	13.6	5	
3	145.2	14.5	5		82.1	8.3	5		121.7	15.2	5		102.7	14.3	5		128.8	9.7	5	
4	148.4	7.5	5		86.3	9.0	5		123.0	10.0	5		85.9	22.0	4		130.8	22.5	4	

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Males

GROUP	DAY 71-74				DAY 74-78				DAY 78-81				DAY 81-85				DAY 85-88			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1			0		130.8	8.0	5		94.3	8.4	5		140.8	5.0	5		116.2	7.0	5	
2			0		122.7	8.0	5		92.8	16.2	5		125.3	15.1	5		101.8	14.9	5	
3			0		113.7	10.4	5	*	84.8	10.5	5		116.8	9.7	5	*	103.9	9.2	5	
4			0		116.3	7.3	4		91.1	11.4	4		109.6	13.5	4	**	100.8	12.0	4	

GROUP	DAY 88-91			
	Mean	S.D.	N	p
1	93.7	16.1	5	
2	84.8	5.0	5	
3	79.3	4.7	5	
4	79.6	5.6	4	

* means $p < 0.05$, versus control group

** means $p < 0.01$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Females

GROUP	DAY 1-4				DAY 4-8				DAY 8-11				DAY 11-15				DAY 15-18			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	68.4	3.9	5		95.4	4.9	5		72.2	8.2	5		102.1	12.7	5		76.8	8.8	5	
2	74.3	7.8	4		110.1	12.6	5		82.4	10.0	5	*	121.1	22.2	5		84.7	16.2	5	
3	64.6	10.2	5		111.7	38.0	5		78.4	12.9	5		106.5	10.6	4		73.3	5.2	5	
4	68.3	1.6	5		92.5	5.5	4		88.1	36.6	5		100.9	9.1	5		70.3	6.7	5	

GROUP	DAY 18-22				DAY 22-25				DAY 25-29				DAY 29-32				DAY 32-36			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	109.4	16.9	5		73.4	8.2	5		77.3	6.8	5		102.5	55.6	5		103.5	12.9	5	
2	125.8	23.3	5		93.3	17.4	5		86.4	13.1	5		95.6	17.1	4		121.3	11.2	4	
3	105.5	7.3	5		78.3	5.7	5		84.4	6.5	5		72.0	7.9	3		90.2	5.5	3	
4	106.6	11.7	4		74.6	3.5	4		80.4	4.3	5		68.6	6.6	5		98.6	8.0	5	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Females

GROUP	DAY 36-39				DAY 39-43				DAY 43-46				DAY 46-50				DAY 50-53			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	70.1	8.4	5		91.5	9.8	5				0		96.5	5.2	5		70.0	8.6	5	
2	76.6	3.6	4		100.7	4.5	4				0		108.8	10.5	4		86.3	7.9	4	
3	75.8	13.9	3		93.0	18.1	3				0		99.3	2.9	3		72.2	6.9	3	
4	71.2	6.1	5		91.0	7.8	5				0		103.0	10.9	5		78.2	12.2	5	

GROUP	DAY 53-57				DAY 57-60				DAY 60-64				DAY 64-67				DAY 67-71			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	110.7	15.9	5		60.0	7.0	5		90.7	11.6	5		82.6	12.7	5		95.6	8.5	5	
2	128.0	20.9	4		64.2	9.9	4		109.7	10.5	4		92.2	9.6	4		107.2	4.7	4	
3	113.4	6.7	3		64.8	2.3	3		96.6	11.2	3		75.9	5.7	3		97.1	7.9	3	
4	110.9	15.4	4		65.1	6.6	5		92.9	7.1	5		99.8	25.8	5		91.7	5.2	5	

$p > 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Group mean values per animal - Day 1 - Day 91

Females

GROUP	DAY 71-74				DAY 74-78				DAY 78-81				DAY 81-85				DAY 85-88			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1			0		89.3	10.0	5		65.1	12.7	5		92.0	6.4	5		80.6	11.2	5	
2			0		98.1	10.3	4		72.9	0.4	4		97.0	7.2	4		86.4	1.9	4	
3			0		79.6	1.8	3		72.8	1.9	3		89.9	4.5	3		68.2	11.7	3	
4			0		89.9	4.4	5		75.6	5.3	5		91.9	7.5	5		73.1	5.3	5	

GROUP	DAY 88-91			
	Mean	S.D.	N	p
1	63.8	9.1	5	
2	80.4	10.1	4	
3	62.7	10.1	3	
4	67.2	8.1	3	

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Males

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.64	0.24	10		8.35	0.40	10		47.3	1.2	10		56.7	2.2	10		1.16	0.05	10	
2	9.70	0.32	11		8.38	0.25	11		47.5	1.8	11		56.5	1.6	11		1.15	0.05	11	
3	9.50	0.32	10		8.28	0.43	10		46.9	1.4	10		56.5	1.9	10		1.15	0.05	10	
4	9.33	0.21	10	*	8.23	0.40	10		45.9	1.3	10		55.8	1.5	10		1.14	0.05	10	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.4	0.2	10		16.95	2.14	10		7.1	4.8	10		1.17	0.77	10		92.2	5.2	10	
2	20.5	0.2	11		16.19	2.93	11		5.7	3.2	11		0.95	0.63	11		93.6	3.0	11	
3	20.4	0.1	10		17.42	4.40	10		5.0	3.1	10		0.85	0.53	10		94.1	3.4	10	
4	20.3	0.1	10		14.90	3.54	10		4.3	2.4	10		0.57	0.26	10		95.0	2.9	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Males

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	15.66	2.50	10		0.0	0.0	10		0.00	0.00	10		0.0	0.0	10		0.00	0.00	10	
2	15.15	2.63	11		0.5	0.5	11		0.07	0.09	11		0.0	0.0	11		0.00	0.00	11	
3	16.41	4.14	10		0.6	0.7	10		0.11	0.13	10		0.0	0.0	10		0.00	0.00	10	
4	14.22	3.74	10		0.3	0.9	10		0.03	0.09	10		0.0	0.0	10		0.00	0.00	10	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	0.7	0.8	10		0.12	0.15	10		569	28	10		15.0	2.2	10		13.4	0.5	10	
2	0.2	0.4	11		0.04	0.08	11		590	41	11		14.8	2.3	11		13.5	0.4	11	
3	0.3	0.5	10		0.07	0.12	10		547	65	10		16.4	4.3	10		13.7	0.5	10	
4	0.4	0.7	10		0.05	0.08	10		581	51	10		18.5	7.2	10		13.7	0.4	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Males

GROUP	Fib			
	Mean	S.D.	N	p
1	2.56	0.21	10	
2	2.66	0.35	11	
3	2.51	0.20	10	
4	2.38	0.16	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Females

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.38	0.33	10		8.24	0.28	10		45.2	1.7	10		54.7	1.1	10		1.13	0.05	10	
2	9.36	0.21	9		8.22	0.25	9		44.9	1.1	9		54.8	1.3	9		1.14	0.05	9	
3	9.19	0.39	8		8.03	0.47	8		44.0	1.9	8		54.5	1.4	8		1.16	0.05	8	
4	9.27	0.28	10		8.21	0.28	10		44.7	1.6	10		54.2	1.2	10		1.14	0.05	10	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.8	0.2	10		14.77	2.43	10		7.9	2.5	10		1.16	0.37	10		91.0	3.0	10	
2	20.8	0.2	9		13.49	1.92	9		6.2	2.6	9		0.83	0.34	9		91.9	3.3	9	
3	21.0	0.1	8		14.14	2.00	8		7.1	3.4	8		1.01	0.53	8		91.5	3.9	8	
4	20.8	0.2	10		13.42	4.20	10		5.5	2.8	10		0.77	0.58	10		92.4	5.3	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Females

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	13.46	2.36	10		0.8	1.1	10		0.11	0.16	10		0.0	0.0	10		0.00	0.00	10	
2	12.38	1.79	9		1.4	2.9	9		0.20	0.45	9		0.0	0.0	9		0.00	0.00	9	
3	12.94	1.93	8		0.8	0.9	8		0.11	0.12	8		0.0	0.0	8		0.00	0.00	8	
4	12.27	3.16	10		1.9	3.2	10		0.35	0.75	10		0.0	0.0	10		0.00	0.00	10	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	0.3	0.7	10		0.04	0.10	10		559	116	10		15.7	1.9	10		14.0	0.4	10	
2	0.4	0.7	9		0.07	0.11	9		585	46	9		14.5	1.2	9		13.8	0.5	9	
3	0.6	1.1	8		0.09	0.15	8		580	71	8		13.5	2.4	8		13.5	0.6	8	
4	0.2	0.4	10		0.03	0.07	10		605	115	10		14.4	2.1	9		13.6	0.2	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML7B0-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 35 and 36

Females

GROUP	Fib			
	Mean	S.D.	N	p
1	1.95	0.38	10	
2	2.11	0.20	9	
3	2.08	0.17	8	
4	2.13	0.19	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Day 65 + 66

Males

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.56	0.28	10		8.84	0.39	10		47.2	1.8	10		53.5	2.3	10		1.09	0.07	10	
2	9.51	0.38	11		8.71	0.40	11		47.3	2.1	11		54.1	1.8	11		1.11	0.03	11	
3	9.54	0.21	10		8.86	0.36	10		47.3	1.2	10		53.3	2.2	10		1.09	0.06	10	
4	9.49	0.38	9		8.91	0.50	9		47.1	2.1	9		52.6	1.3	9		1.06	0.05	9	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.3	0.2	10		15.60	2.13	10		5.6	0.8	10		0.88	0.19	10		93.3	0.9	10	
2	20.2	0.2	11		13.52	1.75	11		6.1	0.9	11		0.82	0.17	11		93.1	1.3	11	
3	20.2	0.1	10		15.52	3.15	10		6.0	1.2	10		0.92	0.25	10		93.3	1.8	10	
4	20.2	0.2	9		15.57	3.72	9		6.1	0.3	9		0.97	0.25	9		92.8	0.8	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 65 and 66

Males

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	14.57	1.95	10		0.6	0.5	10		0.09	0.06	10		0.0	0.0	10		0.00	0.00	10	
2	12.57	1.68	11		0.5	0.5	11		0.08	0.04	11		0.0	0.0	11		0.00	0.00	11	
3	14.43	2.97	10		0.6	0.7	10		0.11	0.03	10		0.0	0.0	10		0.00	0.00	10	
4	14.42	3.49	9		0.8	0.4	9		0.10	0.05	9		0.0	0.0	9		0.00	0.00	9	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	0.5	0.5	10		0.09	0.03	10		548	73	10		16.0	1.7	10		13.2	0.3	10	
2	0.5	0.5	11		0.06	0.05	11		521	71	11		16.3	2.2	11		13.5	0.5	11	
3	0.4	0.5	10		0.06	0.05	10		496	93	10		16.8	3.4	10		13.3	0.4	10	
4	0.3	0.5	9		0.09	0.06	9		529	60	9		20.9	9.6	9		13.6	0.5	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 65 and 66

Males

GROUP	Fib			
	Mean	S.D.	N	p
1	2.51	0.09	10	
2	2.91	0.37	11	*
3	2.82	0.37	10	
4	2.55	0.35	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 65 and 66

Females

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.54	0.20	10		8.56	0.31	10		46.1	1.0	10		53.7	1.3	10		1.11	0.03	10	
2	9.63	0.32	9		8.76	0.27	9		47.0	1.7	9		53.7	1.7	9		1.10	0.00	9	
3	9.28	0.50	8		8.30	0.44	8		44.8	2.6	8		54.3	1.8	8		1.11	0.04	8	
4	9.43	0.20	10		8.58	0.20	10		45.7	1.3	10		53.1	1.4	10		1.10	0.00	10	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.8	0.2	10		13.90	2.82	10		7.5	3.4	10		1.08	0.64	10		91.7	3.9	10	
2	20.5	0.2	9		11.79	2.85	9		7.4	3.4	9		0.86	0.42	9		91.6	3.8	9	
3	20.6	0.2	8		12.63	2.24	8		6.0	1.4	8		0.75	0.24	8		93.0	1.3	8	
4	20.7	0.4	10		12.49	3.04	10		6.4	1.5	10		0.76	0.26	10		92.5	1.9	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 65 and 66

Females

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	12.69	2.40	10		1.0	0.8	10		0.13	0.11	10		0.0	0.0	10		0.00	0.00	10	
2	10.80	2.69	9		1.0	0.5	9		0.10	0.05	9		0.0	0.0	9		0.00	0.00	9	
3	11.73	2.03	8		0.9	0.4	8		0.10	0.05	8		0.0	0.0	8		0.00	0.00	8	
4	11.52	2.81	10		1.1	0.3	10		0.13	0.05	10		0.0	0.0	10		0.00	0.00	10	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	0.1	0.3	10		0.05	0.05	10		583	68	10		15.0	1.6	10		13.4	0.4	10	
2	0.2	0.4	9		0.04	0.05	9		591	69	9		15.2	0.8	9		13.1	0.2	9	
3	0.1	0.4	8		0.04	0.05	8		581	24	8		16.1	5.6	8		13.6	0.3	7	
4	0.4	0.5	10		0.06	0.07	10		568	74	10		15.2	3.9	10		13.6	0.3	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Days 65 and 66

Females

GROUP	Fib			
	Mean	S.D.	N	p
1	2.04	0.22	10	
2	2.10	0.15	9	
3	2.03	0.17	7	
4	2.08	0.36	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Males

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.99	0.47	10		9.35	0.44	10		48.5	2.2	10		52.1	1.9	10		1.06	0.05	10	
2	9.99	0.49	10		9.28	0.43	10		48.3	2.3	10		52.1	1.7	10		1.09	0.06	10	
3	9.86	0.62	9		9.24	0.64	9		48.1	2.7	9		52.1	2.0	9		1.07	0.05	9	
4	9.94	0.45	8		9.45	0.60	8		48.8	2.0	8		51.4	1.6	8		1.06	0.05	8	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.5	0.3	10		14.55	2.34	10		8.1	2.2	10		1.18	0.37	10		89.2	2.4	10	
2	20.6	0.4	10		14.65	4.27	10		8.0	2.1	10		1.18	0.41	10		89.0	3.1	10	
3	20.4	0.2	9		14.52	4.18	9		7.4	1.7	9		1.09	0.42	9		89.4	3.2	9	
4	20.5	0.2	8		15.19	3.72	8		8.3	1.9	8		1.25	0.45	8		89.4	2.4	8	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Males

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	12.98	2.17	10		1.1	0.9	10		0.15	0.12	10		0.0	0.0	10		0.00	0.00	10	
2	13.01	3.88	10		1.1	0.9	10		0.14	0.12	10		0.0	0.0	10		0.00	0.00	10	
3	13.01	3.78	9		1.1	0.8	9		0.14	0.10	9		0.0	0.0	9		0.00	0.00	9	
4	13.54	3.30	8		0.9	0.6	8		0.14	0.07	8		0.0	0.0	8		0.00	0.00	8	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	1.8	0.9	10		0.24	0.13	10		609	155	10		17.3	2.9	10		14.8	0.8	10	
2	2.3	0.9	10		0.33	0.21	10		553	103	10		19.5	3.0	9		14.7	0.5	10	
3	2.1	1.3	9		0.28	0.17	9		534	91	9		18.3	3.8	9		14.7	0.5	9	
4	2.0	0.8	8		0.31	0.15	8		525	95	8		21.2	7.8	9		14.9	0.5	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Males

GROUP	Fib			
	Mean	S.D.	N	p
1	3.38	0.40	10	
2	3.48	0.61	10	
3	3.35	0.26	9	
4	3.12	0.60	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Females

GROUP	Hb				RBC				HT				MCV				MCH			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	9.54	0.29	10		8.56	0.37	10		46.0	1.5	10		53.7	1.5	10		1.11	0.03	10	
2	9.34	0.42	9		8.37	0.32	9		44.9	1.9	9		53.7	1.1	9		1.11	0.03	9	
3	9.30	0.55	8		8.38	0.32	8		45.0	2.5	8		53.9	1.6	8		1.09	0.04	8	
4	9.22	0.35	10		8.39	0.35	10		44.6	1.8	10		52.9	1.3	10		1.09	0.03	10	

GROUP	MCHC				WBC				% NEUTRO				NEUTRO				% LYMPHO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	20.8	0.2	10		12.92	1.08	10		8.2	2.9	10		1.07	0.37	10		89.3	2.5	10	
2	20.8	0.3	9		12.74	3.46	9		8.3	3.4	9		1.01	0.36	9		89.3	4.2	9	
3	20.6	0.5	8		15.61	4.66	8		7.9	3.3	8		1.19	0.52	8		90.4	3.9	8	
4	20.7	0.2	10		11.92	2.46	10		7.5	2.0	10		0.91	0.37	10		90.6	2.0	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Females

GROUP	LYMPHO				% EOS				EOS				% BASO				BASO			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	11.52	1.10	10		1.5	0.8	10		0.20	0.12	10		0.0	0.0	10		0.00	0.00	10	
2	11.40	3.42	9		1.7	1.0	9		0.18	0.11	9		0.0	0.0	9		0.00	0.00	9	
3	14.11	4.29	8		1.3	0.9	8		0.16	0.09	8		0.0	0.0	8		0.00	0.00	8	
4	10.76	2.12	10		1.4	1.1	10		0.14	0.13	10		0.0	0.0	10		0.00	0.00	10	

GROUP	% MONO				MONO				Plt				APTT				Pt			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	1.1	0.3	10		0.13	0.07	10		594	66	10		17.2	1.3	10		14.6	0.6	10	
2	1.1	0.8	9		0.14	0.11	9		577	75	9		16.3	2.0	9		14.4	0.4	9	
3	1.0	0.8	8		0.15	0.09	8		550	50	8		19.1	8.9	8		14.6	0.6	8	
4	1.0	0.0	10		0.12	0.04	10		602	86	10		16.8	4.7	10		14.6	0.7	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Group mean values - Before termination of treatment

Females

GROUP	Fib			
	Mean	S.D.	N	p
1	2.49	0.21	10	
2	2.52	0.24	9	
3	2.56	0.20	8	
4	2.37	0.26	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical chemistry

Group mean values - Before termination of treatment

Males

GROUP	ALAT				ASAT				ALKPH				BILI				GGT			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	1.58	0.13	10		1.50	0.21	10		3.13	0.33	10		<1.40	>0.23	10		<0.04	>0.0	10	
2	1.63	0.31	10		1.54	0.25	10		3.09	0.72	10		<1.36	>0.13	10		<0.04	>0.0	10	
3	1.74	0.63	9		1.73	0.59	9		3.60	0.58	9		<1.31	>0.03	9		<0.04	>0.0	9	
4	1.75	0.42	9		1.72	0.64	9		2.99	0.63	9		<1.38	>0.18	9		<0.04	>0.0	9	

GROUP	CHOL				TRIG				UREA				CREAT				GLUC			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	3.04	0.57	10		2.70	1.05	10		6.82	0.27	10		24.9	2.1	10		7.00	1.08	10	
2	3.04	0.26	10		2.43	0.83	10		7.30	1.14	10		26.9	2.1	10		6.55	0.89	10	
3	2.78	0.46	9		1.95	0.40	9		6.63	1.12	9		26.1	2.5	9		6.79	0.37	9	
4	3.07	0.56	9		2.23	0.47	9		7.24	0.54	9 *		26.6	2.2	9		6.70	0.67	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI is 1.3 - this value is used in the calculation
Limit of detection for GGT is 0.04 - this value is used in the calculation

* means $0.01 < p < 0.05$, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Group mean values - Before termination of treatment

Males

GROUP	Na				K				Ca				Mg				P			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	149.1	2.4	10		6.94	0.31	10		2.98	0.08	10		1.09	0.08	10		2.90	0.44	10	
2	149.4	2.2	10		6.72	0.43	10		2.98	0.08	10		1.07	0.11	10		2.72	0.19	10	
3	148.4	2.1	9		6.61	0.31	9		2.91	0.08	9		1.01	0.07	9		2.66	0.21	9	
4	150.8	1.1	9		6.52	0.36	9		2.94	0.08	9		1.00	0.08	9		2.68	0.18	9	

GROUP	Cl				PROTEIN				ALB				GLOBULIN				ALB/G Ratio			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	101.0	1.4	10		73.5	3.3	10		45.2	1.5	10		28.3	2.8	10		1.61	0.16	10	
2	100.3	1.0	10		73.0	3.0	10		44.7	2.7	10		28.3	2.0	10		1.59	0.15	10	
3	100.3	1.3	9		71.8	3.0	9		44.7	1.9	9		27.2	2.0	9		1.65	0.12	9	
4	101.9	1.3	9		72.8	3.3	9		45.2	2.1	9		27.6	2.1	9		1.65	0.13	9	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Group mean values - Before termination of treatment

Females

GROUP	ALAT				ASAT				ALKPH				BILI				GGT			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	1.27	0.22	10		1.58	0.32	10		2.36	0.38	10		<1.65	>0.39	10		<0.04	>0.0	10	
2	1.41	0.15	9		1.51	0.20	9		2.53	0.55	9		<1.63	>0.49	9		<0.04	>0.0	9	
3	1.47	0.37	8		1.66	0.19	8		2.47	0.64	8		<1.81	>0.41	8		<0.04	>0.0	8	
4	1.37	0.36	10		1.71	0.70	10		2.37	0.43	10		<1.54	>0.32	10		<0.04	>0.0	10	

GROUP	CHOL				TRIG				UREA				CREAT				GLUC			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	2.83	0.33	10		0.99	0.42	10		6.87	1.46	10		26.6	2.4	10		6.74	0.78	10	
2	2.88	0.54	9		1.35	0.76	9		7.21	0.67	9		28.4	1.3	9		6.94	1.21	9	
3	2.68	0.31	8		1.02	0.25	8		6.27	0.61	8		27.5	2.6	8		6.61	0.58	8	
4	2.57	0.32	10		1.04	0.25	10		6.49	1.25	10		27.0	2.3	10		7.09	0.38	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI is 1.3 - this value is used in the calculation

Limit of detection for GGT is 0.04 - this value is used in the calculation

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical chemistry

Group mean values - Before termination of treatment

Females

GROUP	Na				K				Ca				Mg				P			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	147.8	3.6	10		6.41	0.35	10		3.01	0.11	10		1.15	0.08	10		2.69	0.30	10	
2	148.9	4.4	9		6.40	0.50	9		3.04	0.15	9		1.16	0.12	9		2.73	0.50	9	
3	148.9	3.4	8		6.30	0.30	8		3.01	0.06	8		1.15	0.05	8		2.83	0.25	8	
4	147.6	3.9	10		6.13	0.47	10		2.92	0.08	10		1.09	0.06	10		2.64	0.40	10	

GROUP	Cl				PROTEIN				ALB				GLOBULIN				ALB/G Ratio			
	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p	Mean	S.D.	N	p
1	101.5	2.2	10		72.1	3.8	10		48.4	2.7	10		23.7	1.6	10		2.05	0.12	10	
2	101.9	2.8	9		72.6	4.1	9		48.6	2.8	9		24.1	2.7	9		2.04	0.23	9	
3	101.1	2.8	8		72.4	3.8	8		48.4	2.6	8		24.0	1.5	8		2.02	0.09	8	
4	101.6	1.8	10		69.9	3.4	10		47.6	1.9	10		22.3	2.6	10		2.16	0.25	10	

Abbreviations and units are explained in subsection 'Clinical pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Group mean values - Before termination

Males

GROUP	VOLUME				Na				K				Cl			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	14.6	4.7	10		79.1	18.4	10		117.9	24.2	10		80.7	15.4	10	
2	13.6	3.7	10		74.2	16.8	10		117.6	22.0	10		87.7	15.7	10	
3	15.0	4.7	9		66.1	22.6	9		112.4	35.6	9		79.9	19.4	9	
4	14.1	3.9	9		58.6	18.6	9		121.7	22.2	9		79.3	18.2	9	

Abbreviations and units are explained in subsection 'Clinical Pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Males

GROUP	SPECIFIC GRAVITY					Total	p
	1.010	1.015	1.020	1.025	≥1.030		
1	1	2	5	2	0	10	
2	0	4	4	0	2	10	
3	0	5	2	2	0	9	
4	0	4	4	1	0	9	
Total	1	15	15	5	2	38	

GROUP	pH					Total	p
	6.5	7.0	7.5	8.0	8.5		
1	0	2	6	0	2	10	
2	1	2	3	3	1	10	
3	0	2	6	1	0	9	
4	0	2	4	2	1	9	
Total	1	8	19	6	4	38	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Males

GROUP	COLOUR		Total	p
	Light yellow	Yellow		
1	2	8	10	
2	5	5	10	
3	6	3	9	
4	1	8	9	
Total	14	24	38	

GROUP	PROTEIN			Total	p
	0.3 g/l	1.0 g/l	>3.0 g/l		
1	4	5	1	10	
2	5	3	2	10	
3	6	2	1	9	
4	5	2	2	9	
Total	20	12	6	38	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Males

GROUP	LEUCOCYTES				Total	p
	15 cells/ μ l	70 cells/ μ l	125 cells/ μ l	500 cells/ μ l		
1	1	5	2	2	10	
2	0	7	1	2	10	
3	0	7	1	1	9	
4	1	6	2	0	9	
Total	2	25	6	5	38	

GROUP	NITRITE		Total	p
	No trace	Positive		
1	8	2	10	
2	8	2	10	
3	7	2	9	
4	9	0	9	
Total	32	6	38	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Males

GROUP	BLOOD	Total	p
	No trace		
1	10	10	
2	10	10	
3	9	9	
4	9	9	
Total	38	38	

GROUP	GLUCOSE	Total	p
	No trace		
1	10	10	
2	10	10	
3	9	9	
4	9	9	
Total	38	38	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Males

GROUP	KETONES			Total	p
	No trace	Trace	1.5 mmol/l		
1	0	5	5	10	
2	0	6	4	10	
3	1	3	5	9	
4	0	4	5	9	
Total	1	18	19	38	

GROUP	BILI- RUBIN	Total	p
	No trace		
1	10	10	
2	10	10	
3	9	9	
4	9	9	
Total	38	38	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Before termination

Incidence of findings

Males

GROUP	UROBILI- NOGEN	Total	p
	3.2 μmol/l		
1	10	10	
2	10	10	
3	9	9	
4	9	9	
Total	38	38	

p>0.05, versus control group

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Before termination

Group mean values

Females

GROUP	VOLUME				Na				K				Cl			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	10.7	6.1	10		73.1	18.7	10		96.9	37.7	10		83.8	20.1	10	
2	12.3	4.3	9		66.8	13.6	9		94.2	21.4	9		78.7	14.7	9	
3	10.8	2.0	8		68.6	18.2	8		88.5	11.9	8		80.0	14.0	8	
4	8.9	2.4	10		74.6	22.4	10		115.1	34.3	10		82.6	21.0	10	

Abbreviations and units are explained in subsection 'Clinical Pathology'

p>0.05, versus control group

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	SPECIFIC GRAVITY					Total	p
	1.010	1.015	1.020	1.025	≥1.030		
1	1	1	2	4	2	10	
2	0	2	3	4	0	9	
3	0	1	3	3	1	8	
4	0	1	3	4	2	10	
Total	1	5	11	15	5	37	

GROUP	pH				Total	p
	6.0	6.5	7.0	7.5		
1	1	3	6	0	10	
2	0	2	7	0	9	
3	1	3	3	1	8	
4	1	3	5	1	10	
Total	3	11	21	2	37	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	COLOUR		Total	p
	Light yellow	Yellow		
1	2	8	10	
2	3	6	9	
3	1	7	8	
4	0	10	10	
Total	6	31	37	

GROUP	PROTEIN				Total	p
	No trace	Trace	0.3 g/l	1.0 g/l		
1	2	4	1	3	10	
2	1	3	1	4	9	
3	1	7	0	0	8	
4	0	3	4	3	10	
Total	4	17	6	10	37	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	LEUCOCYTES				Total	p
	No trace	15 cells/ μ l	70 cells/ μ l	125 cells/ μ l		
1	4	4	2	0	10	
2	2	3	3	1	9	
3	6	2	0	0	8	
4	2	6	2	0	10	
Total	14	15	7	1	37	

GROUP	NITRITE		Total	p
	No trace	Positive		
1	10	0	10	
2	9	0	9	
3	7	1	8	
4	10	0	10	
Total	36	1	37	

$p > 0.05$, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	BLOOD	Total	p
	No trace		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

GROUP	GLUCOSE	Total	p
	No trace		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	KETONES		Total	p
	No trace	Trace		
1	9	1	10	
2	9	0	9	
3	8	0	8	
4	10	0	10	
Total	36	1	37	

GROUP	BILI- RUBIN	Total	p
	No trace		
1	10	10	
2	9	9	
3	8	8	
4	10	10	
Total	37	37	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Incidence of findings - Before termination

Females

GROUP	UROBILINOGEN		Total	p
	3.2 $\mu\text{mol/l}$	16 $\mu\text{mol/l}$		
1	9	1	10	
2	9	0	9	
3	8	0	8	
4	9	1	10	
Total	35	2	37	

p>0.05, versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Males

GROUP	ERYTHROCYTES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	1	5	4	0	0	10	
2	2	5	3	0	0	10	
3	2	7	0	0	0	9	
4	2	7	0	0	0	9	
Total	7	24	7	0	0	38	

GROUP	LEUCOCYTES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	9	1	0	0	0	10	
2	9	1	0	0	0	10	
3	8	1	0	0	0	9	
4	8	1	0	0	0	9	
Total	34	4	0	0	0	38	

p>0.05 versus control group

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Males

GROUP	EPITHELIAL CELLS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	1	6	3	0	0	10	
2	2	5	3	0	0	10	
3	5	3	1	0	0	9	
4	3	6	0	0	0	9	
Total	11	20	7	0	0	38	

GROUP	CRYSTALS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	0	0	0	6	4	10	
2	0	0	1	7	2	10	
3	0	0	0	7	2	9	
4	0	0	0	4	5	9	
Total	0	0	1	24	13	38	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Males

GROUP	URATES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	1	3	5	1	0	10	
2	1	2	7	0	0	10	
3	3	2	3	1	0	9	
4	1	4	2	2	0	9	
Total	6	11	17	4	0	38	

GROUP	HYALINE CASTS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	10	0	0	0	0	10	
2	10	0	0	0	0	10	
3	9	0	0	0	0	9	
4	9	0	0	0	0	9	
Total	38	0	0	0	0	38	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Males

GROUP	GRANULAR CASTS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	10	0	0	0	0	10	
2	10	0	0	0	0	10	
3	9	0	0	0	0	9	
4	9	0	0	0	0	9	
Total	38	0	0	0	0	38	

GROUP	BACTERIA					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	0	0	0	0	10	10	
2	0	0	0	0	10	10	
3	0	0	0	0	9	9	
4	0	0	0	1	8	9	
Total	0	0	0	1	37	38	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Females

GROUP	ERYTHROCYTES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	7	3	0	0	0	10	
2	5	4	0	0	0	9	
3	5	3	0	0	0	8	
4	5	5	0	0	0	10	
Total	22	15	0	0	0	37	

GROUP	LEUCOCYTES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	9	1	0	0	0	10	
2	8	1	0	0	0	9	
3	7	1	0	0	0	8	
4	9	1	0	0	0	10	
Total	33	4	0	0	0	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Females

GROUP	EPITHELIAL CELLS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	3	7	0	0	0	10	
2	2	5	2	0	0	9	
3	3	5	0	0	0	8	
4	3	7	0	0	0	10	
Total	11	24	2	0	0	37	

GROUP	CRYSTALS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	0	0	2	6	2	10	
2	0	0	2	5	2	9	
3	0	0	2	3	3	8	
4	0	0	1	7	2	10	
Total	0	0	7	21	9	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Females

GROUP	URATES					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	5	2	3	0	0	10	
2	1	3	4	1	0	9	
3	2	2	4	0	0	8	
4	5	3	2	0	0	10	
Total	13	10	13	1	0	37	

GROUP	HYALINE CASTS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	10	0	0	0	0	10	
2	9	0	0	0	0	9	
3	8	0	0	0	0	8	
4	10	0	0	0	0	10	
Total	37	0	0	0	0	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain 8ML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Incidence of findings - Before termination

Females

GROUP	GRANULAR CASTS					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	10	0	0	0	0	10	
2	9	0	0	0	0	9	
3	8	0	0	0	0	8	
4	10	0	0	0	0	10	
Total	37	0	0	0	0	37	

GROUP	BACTERIA					Total	p
	No trace	Traces	Slight	Moderate	Marked		
1	0	0	0	3	7	10	
2	0	0	0	3	6	9	
3	0	0	0	2	6	8	
4	0	0	0	2	8	10	
Total	0	0	0	10	27	37	

p>0.05 versus control group

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Absolute (mg) and relative (% of body wt) organ weight

Group mean values

Males

GROUP	BODY WT, g				ADRENALS				ADRENALS				BRAIN				BRAIN			
					ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	520.3	54.4	10		55.1	12.0	10		0.0107	0.0027	10		2309	121	10		0.446	0.030	10	
2	491.9	35.4	10		50.2	12.6	10		0.0102	0.0022	10		2295	102	10		0.468	0.029	10	
3	486.0	45.5	9		50.9	7.7	9		0.0105	0.0014	9		2285	106	9		0.472	0.028	9	
4	490.8	33.9	9		54.7	7.4	9		0.0111	0.0014	9		2257	117	9		0.461	0.031	9	

GROUP	EPIDIDYIMIDES				EPIDIDYIMIDES				HEART				HEART				KIDNEYS			
	ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE				ABSOLUTE			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	1448	116	10		0.281	0.036	10		1690	164	10		0.326	0.022	10		3437	324	10	
2	1385	270	10		0.281	0.050	10		1694	111	10		0.346	0.032	10		3303	294	10	
3	1486	203	9		0.309	0.057	9		1683	180	9		0.346	0.014	9		3269	309	9	
4	1395	130	9		0.285	0.023	9		1623	53	9		0.332	0.021	9		3239	236	9	

p>0.05, versus group 1

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Absolute (mg) and relative (% of body wt) organ weight

Group mean values

Males

GROUP	KIDNEYS				LIVER				LIVER				SPLEEN				SPLEEN			
	RELATIVE				ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	0.664	0.066	10		18627	2553	10		3.58	0.25	10		1025	128	10		0.198	0.024	10	
2	0.673	0.051	10		17798	1995	10		3.62	0.29	10		980	149	10		0.200	0.030	10	
3	0.674	0.039	9		17356	2561	9		3.56	0.25	9		1035	184	9		0.213	0.036	9	
4	0.661	0.044	9		18146	2070	9		3.69	0.25	9		990	66	9		0.202	0.017	9	

GROUP	TESTES				TESTES				THYMUS				THYMUS			
	ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p	MEAN	S.D.	N	p
1	3868	295	10		0.75	0.08	10		423	106	10		0.081	0.017	10	
2	3705	629	10		0.75	0.12	10		455	94	10		0.093	0.022	10	
3	3849	450	9		0.79	0.08	9		436	84	9		0.090	0.017	9	
4	3918	178	9		0.80	0.06	9		439	170	9		0.089	0.031	9	

p>0.05, versus group 1

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Absolute (mg) and relative (% of body wt) organ weight

Group mean values

Females

GROUP	BODY WT, g				ADRENALS				ADRENALS				BRAIN				BRAIN			
					ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p
1	275.8	11.1	10		68.9	6.0	10		0.0250	0.0026	10		2094	97	10		0.760	0.041	10	
2	299.1	24.9	9	*	66.9	8.2	9		0.0225	0.0030	9		2127	106	9		0.714	0.046	9	
3	282.8	15.8	8		70.4	7.9	8		0.0250	0.0030	8		2107	65	8		0.747	0.045	8	
4	277.5	16.8	10		70.3	9.8	10		0.0255	0.0040	10		2107	112	10		0.762	0.055	10	

GROUP	HEART				HEART				KIDNEYS				KIDNEYS				LIVER			
	ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE				ABSOLUTE			
	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p
1	1124	101	10		0.408	0.037	10		1946	136	10		0.706	0.042	10		9208	617	10	
2	1162	119	9		0.390	0.038	9		1985	160	9		0.664	0.029	9		10254	958	9	
3	1073	133	8		0.379	0.039	8		1950	133	8		0.691	0.049	8		9635	1024	8	
4	1072	99	10		0.387	0.034	10		2000	140	10		0.721	0.046	10		9671	652	10	

* means $0.01 < p < 0.05$, versus group 1

S.D. = standard deviation N = number of animals

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Absolute (mg) and relative (% of body wt) organ weight

Group mean values

Females

GROUP	LIVER				OVARIES				OVARIES				SPLEEN				SPLEEN			
	RELATIVE				ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p
1	3.34	0.18	10		99.7	10.2	10		0.0362	0.0039	10		643	58	10		0.233	0.017	10	
2	3.43	0.15	9		100.2	22.2	9		0.0333	0.0051	9		704	85	9		0.236	0.024	9	
3	3.41	0.32	8		98.0	12.7	8		0.0347	0.0044	8		653	80	8		0.232	0.030	8	
4	3.49	0.24	10		107.3	18.4	10		0.0389	0.0081	10		665	105	10		0.241	0.045	10	

GROUP	THYMUS				THYMUS				UTERUS				UTERUS			
	ABSOLUTE				RELATIVE				ABSOLUTE				RELATIVE			
	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p	Mean	S.D	N	p
1	341	63	10		0.124	0.023	10		663	169	10		0.242	0.066	10	
2	336	85	9		0.112	0.027	9		681	285	9		0.228	0.088	9	
3	342	51	8		0.121	0.017	8		672	141	8		0.237	0.043	8	
4	304	62	10		0.110	0.023	10		695	121	10		0.252	0.048	10	

p>0.05, versus group 1

S.D. = standard deviation N = number of animals

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical signs

Individual values

Group 1 – Control

MALES

Animal Nos 1-8

No adverse clinical signs.

Animal No 9

Day 57-58: Red discharge from both eyes.

Animal No 10

No adverse clinical signs.

FEMALES

Animal No 11

Day 58-76: Scarce fur on the loin.

Day 76: Afternoon: Slightly scarce fur on the loin.

Animal Nos 12-15

No adverse clinical signs.

Animal No 16

Day 47-55: Scarce fur on the posterior part of the back.

Animal Nos 17-20

No adverse clinical signs.

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical signs

Individual values

Group 2 – 4.56 mg total protein/kg

MALES

Animal No 21

Day 74: Forced and wheezing respiration.
Gasping for air. Subdued. Slightly
dehydrated. Killed moribund.

Animal No 22

Days 70-72: Red discharge from right eye. Washed
with 0.9% NaCl.

Animal Nos 23-29

No adverse clinical signs.

Animal No 30

Days 29-32: Red discharge from left eye.
Day 34: Appeared less active.
Days 41-83: Red discharge from left eye. From
Day 54-80 eye washed with 0.9%
NaCl.

Animal No 31

Days 65-76: Hairless on both forepaws.

FEMALES

Animal No 32

Day 39: Scarce fur on the left foreleg.
Days 40-76: Scarce fur on both forelegs.

Animal Nos 33-34

No adverse clinical signs.

Animal No 35

Days 41-47: Scarce fur on the middle part of the
back. and on the loin

Animal Nos 36-40, 101

No adverse clinical signs.

Animal No 102

Day 56: Morning: Wheezing respiration
approximately 10 min after dosing.

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical signs

Individual values

Group 3 – 13.68 mg total protein/kg

MALES

Animal No 41

Day 19: Two small bites on the tail. Washed with 0.9% NaCl.

Day 20: Four small bites on the tail. Washed with 0.9% NaCl.

Animal No 42

Days 56-61: Scarce fur on the right side of the posterior part of the chest and abdomen.

Days 63-66: Slightly scarce fur on the right side of the posterior part of the chest and abdomen.

Animal No 43

No adverse clinical signs.

Animal No 44

Day 73: Found dead. Necropsied.

Animal No 45

No adverse clinical signs.

Animal No 46

Days 45-46: Red discharge from right eye. Day 45 washed with 0.9% NaCl.

Animal Nos 47-50

No adverse clinical signs.

FEMALES

Animal Nos 51-52

No adverse clinical signs.

Animal No 53

Day 29: Forced respiration 10 min after dosing.

Day 29: Forced respiration. Very passive.
(Noon) Flaccid. Dark and wet eyes (13:00 h).
Found dead (13:10 h).

Animal Nos 54-57

No adverse clinical signs.

Animal No 58

Day 23-25: Red discharge from left eye.

Animal No 59

Day 12: Found dead at the morning observation. Necropsied.

Animal No 60

No adverse clinical sign

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical signs

Individual values

Group 4 – 41.00 mg total protein/kg

MALES

Animal Nos 61-68

No adverse clinical signs.

Animal No 69

Day 37: Found dead. Necropsied.

Animal No 70

No adverse clinical signs.

FEMALES

Animal Nos 71-73

No adverse clinical signs.

Animal No 74

Days 48-49: Scarce fur on the posterior part of the back.

Animal Nos 75-80

No adverse clinical signs.

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Individual values

Males

GROUP	ANIMAL NO	TIME MOVING	TOTAL DISTANCE (m)	NO. OF REARINGS	TIME CENTRE	TIME PERIPHERY	TOTAL CORNER VISITS	MOVES/ COUNTS	FAECES
1	1	247	35.1	24	38	262	12	1233	0
	2	226	32.6	39	20	280	14	1129	3
	3	222	28.3	25	0	300	15	1108	5
	4	247	43.2	34	12	288	21	1233	0
	5	244	39.9	46	11	289	17	1222	7
	6	247	47.0	110	10	290	33	1236	0
	7	241	38.5	38	5	295	19	1206	7
	8	249	43.5	70	5	295	24	1244	5
	9	239	32.4	32	2	298	18	1193	4
	10	221	30.5	17	19	281	14	1103	3
2	21	d	d	d	d	d	d	d	d
	22	243	43.4	45	10	290	21	1214	0
	23	236	36.2	44	11	289	18	1179	2
	24	257	62.6	58	9	291	21	1284	3
	25	245	38.2	35	19	281	19	1227	9
	26	255	55.8	67	16	284	32	1274	5
	27	249	41.9	34	12	288	26	1243	0
	28	221	29.2	38	12	288	15	1106	6
	29	229	32.5	84	11	289	15	1147	0
	30	249	47.3	38	13	287	30	1246	0
	31	250	47.4	57	28	272	24	1250	0
3	41	255	42.9	53	21	279	21	1274	3
	42	233	37.4	36	49	251	17	1163	2
	43	243	45.7	44	14	286	30	1214	0
	44	d	d	d	d	d	d	d	d
	45	242	48.5	24	10	290	22	1211	0
	46	231	33.7	46	18	282	20	1157	0
	47	244	42.1	93	15	285	25	1219	1
	48	235	36.9	27	14	286	16	1175	0
	49	236	38.6	38	14	286	19	1178	0
	50	238	34.2	30	1	299	23	1191	0

d = dead before termination of treatment

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Individual values

Males

GROUP	ANIMAL NO	TIME MOVING	TOTAL DISTANCE (m)	NO. OF REARINGS	TIME CENTRE	TIME PERIPHERY	TOTAL CORNER VISITS	MOVES/ COUNTS	FAECES
4	61	253	40.4	64	11	289	20	1267	3
	62	252	43.1	48	11	289	22	1261	0
	63	241	48.0	34	13	287	19	1206	0
	64	261	43.2	39	18	282	18	1306	6
	65	249	40.6	46	11	289	18	1245	0
	66	218	25.3	23	2	298	15	1088	3
	67	241	42.1	67	4	296	13	1206	2
	68	228	31.2	15	1	299	16	1140	1
	69	d	d	d	d	d	d	d	d
	70

d = dead before termination of treatment

. = not recorded in error

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Individual values

Females

GROUP	ANIMAL NO	TIME MOVING	TOTAL DISTANCE (m)	NO. OF REARINGS	TIME CENTRE	TIME PERIPHERY	TOTAL CORNER VISITS	MOVES/ COUNTS	FAECES
1	11	236	43.8	23	7	293	26	1182	0
	12	246	39.0	35	13	287	21	1228	0
	13	244	47.5	28	8	292	36	1218	0
	14	251	45.1	41	11	289	27	1255	0
	15	244	52.3	30	2	298	26	1219	0
	16	234	50.9	39	13	287	28	1172	0
	17	252	55.3	40	4	296	29	1261	0
	18	231	39.4	39	10	290	22	1157	0
	19	230	40.8	34	8	292	18	1148	0
	20	216	32.5	23	0	300	22	1081	0
2	32	246	44.4	35	6	294	21	1228	0
	33	245	47.3	49	12	288	30	1227	0
	34	252	44.9	41	7	293	28	1258	1
	35	240	59.5	61	6	294	27	1200	0
	36	244	42.1	30	7	293	22	1219	0
	37	229	44.8	28	0	300	30	1145	0
	38	248	42.9	35	4	296	26	1239	0
	39	240	43.9	46	9	291	27	1201	0
	40	254	46.1	40	4	296	27	1271	0
	101	1 245	46.5	40	12	288	26	1223	0
	102	1 246	42.9	30	28	272	18	1232	0
3	51	238	45.7	42	4	296	21	1189	0
	52	214	38.5	28	14	286	22	1068	0
	53	d	d	d	d	d	d	d	d
	54	247	48.9	24	4	296	29	1236	0
	55	245	43.4	41	0	300	25	1223	0
	56	238	65.8	29	12	288	33	1191	0
	57	245	47.8	41	7	293	28	1223	0
	58	239	46.6	39	3	297	31	1196	4
	59	d	d	d	d	d	d	d	d
	60	255	50.6	40	5	295	32	1275	0

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Open field testing

Individual values

Females

GROUP	ANIMAL NO	TIME MOVING	TOTAL DISTANCE (m)	NO. OF REARINGS	TIME CENTRE	TIME PERIPHERY	TOTAL CORNER VISITS	MOVES/ COUNTS	FAECES
4	71	246	49.8	38	10	290	22	1231	0
	72	251	44.8	45	11	289	27	1254	0
	73	244	65.1	40	5	295	30	1220	0
	74	255	56.1	61	8	292	33	1277	0
	75	249	57.9	37	10	290	27	1244	0
	76	249	43.9	44	3	297	24	1245	0
	77	243	46.7	46	20	280	28	1214	0
	78	247	45.7	33	6	294	28	1236	0
	79	243	48.3	35	4	296	33	1216	0
	80	244	48.5	50	3	297	31	1221	0

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Individual values

Males

GROUP	ANIMAL NO	TOE		GRASP RESPONSE	GRIP STRENGTH	EYELID REFLEX	STARTLE RESPONSE	HEAD SHAKE RESPONSE	RIGHTING REFLEX TABLE	RIGHTING REFLEX HAND	PLACING REFLEX	NEGA-TIVE GEOTAXIS
		PUPIL REFLEX	PINCH REACT.									
1	1	1	1	1	1	1	1	1	1	1	1	0
	2	1	1	1	1	1	1	1	1	1	1	1
	3	0	1	1	1	1	1	1	1	1	1	1
	4	1	1	1	1	1	1	1	1	1	1	1
	5	1	1	1	1	1	1	1	1	1	1	1
	6	1	1	1	1	1	1	1	1	1	1	1
	7	1	1	1	1	1	1	1	1	1	1	1
	8	1	1	1	1	1	1	1	1	1	1	1
	9	1	1	1	1	1	1	1	1	1	1	1
	10	1	1	1	1	1	1	1	1	1	1	1
2	21	d	d	d	d	d	d	d	d	d	d	d
	22	1	1	1	1	1	1	1	1	1	1	1
	23	1	1	1	1	1	1	1	1	1	1	1
	24	1	1	1	1	1	1	1	1	1	1	1
	25	1	1	1	1	1	1	1	1	1	1	1
	26	1	1	1	1	1	1	1	1	1	1	0
	27	1	1	1	1	1	1	1	1	1	1	1
	28	1	1	1	1	1	1	1	1	1	1	0
	29	1	1	1	1	1	1	1	1	1	1	1
	30	1	1	0	1	1	1	1	1	1	1	1
	31	1	1	1	1	1	1	1	1	1	1	1
3	41	1	1	1	1	1	1	1	1	1	1	1
	42	1	1	1	1	1	1	1	1	1	1	1
	43	1	1	1	1	1	1	1	1	1	1	1
	44	1	1	1	1	1	1	1	1	1	1	1
	45	1	1	1	1	1	1	1	1	1	1	1
	46	1	1	1	1	1	1	1	1	1	1	1
	47	1	1	1	1	1	1	1	1	1	1	1
	48	1	1	1	1	1	1	1	1	1	1	1
	49	1	1	1	1	1	1	1	1	1	1	1
	50	0	1	1	1	1	1	1	1	1	1	1

d = dead before termination of dosing

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Individual values

Males

GROUP	ANIMAL NO	TOE		GRASP RESPONSE	GRIP STRENGTH	EYELID REFLEX	STARTLE RESPONSE	HEAD SHAKE RESPONSE	RIGHTING REFLEX TABLE	RIGHTING REFLEX HAND	PLACING REFLEX	NEGA- TIVE GEOTAXIS
		PUPIL REFLEX	PINCH REACT.									
4	61	1	1	1	1	1	1	1	1	1	1	0
	62	1	1	1	1	1	1	1	1	1	1	1
	63	1	1	1	1	1	1	1	1	1	1	1
	64	1	1	1	1	1	1	1	1	1	1	1
	65	1	1	1	1	1	1	1	1	1	1	1
	66	1	1	1	1	1	1	1	1	1	1	0
	67	1	1	1	1	1	1	1	1	1	1	1
	68	1	1	1	1	1	1	1	1	1	1	1
	69	d	d	d	d	d	d	d	d	d	d	d
	70	1	1	1	1	1	1	1	1	1	1	1

d = dead before termination of dosing

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Individual values

Females

GROUP	ANIMAL NO	TOE		GRASP RESPONSE	GRIP STRENGTH	EYELID REFLEX	STARTLE RESPONSE	HEAD SHAKE RESPONSE	RIGHTING REFLEX TABLE	RIGHTING REFLEX HAND	PLACING REFLEX	NEGA-TIVE GEOTAXIS
		PUPIL REFLEX	PINCH REACT.									
1	11	1	1	1	1	1	1	1	1	1	1	1
	12	1	1	1	1	1	1	1	1	1	1	1
	13	1	1	1	1	1	1	1	1	1	1	1
	14	1	1	1	1	1	1	1	1	1	1	1
	15	1	1	1	1	1	1	1	1	1	1	1
	16	1	1	1	1	1	1	1	1	1	1	1
	17	1	1	1	1	1	1	1	1	1	1	1
	18	1	1	1	1	1	1	1	1	1	1	1
	19	1	1	1	1	1	1	1	1	1	1	1
	20	1	1	1	1	1	1	1	1	1	1	1
2	32	1	1	1	1	1	1	1	1	1	1	1
	33	1	1	1	1	1	1	1	1	1	1	1
	34	1	1	1	1	1	1	1	1	1	1	1
	35	1	1	1	1	1	1	1	1	1	1	1
	36	1	1	1	1	1	1	1	1	1	1	1
	37	1	1	1	1	1	1	1	1	1	1	1
	38	1	1	1	1	1	1	1	1	1	1	1
	39	1	1	1	1	1	1	1	1	1	1	1
	40	1	1	1	1	1	1	1	1	1	1	1
	101	1	1	0	1	1	1	1	1	1	1	1
	102	1	1	1	1	1	1	1	1	1	1	1
3	51	1	1	1	1	1	1	1	1	1	1	1
	52	1	1	1	1	1	1	1	1	1	1	1
	53	d	d	d	d	d	d	d	d	d	d	d
	54	1	1	1	1	1	1	1	1	1	1	1
	55	1	1	1	1	1	1	1	1	1	1	1
	56	1	1	1	1	1	1	1	1	1	1	1
	57	1	1	1	1	1	1	1	1	1	1	1
	58	1	1	1	1	1	1	1	1	1	1	1
	59	d	d	d	d	d	d	d	d	d	d	d
	60	1	1	1	1	1	1	1	1	1	1	1

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(*Bacillus licheniformis* strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Stimuli-induced clinical observations

Individual values

Females

[illegible]

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Individual values - Day of arrival to Day 91

Males

																			BODY WT	
GROUP	ANIMAL NO	ON ARRIVAL	DAY OF RE-ALLOCATION	DAY 1	DAY 8	DAY 15	DAY 22	DAY 29	DAY 36	DAY 43	DAY 50	DAY 57	DAY 64	DAY 71	DAY 78	DAY 85	DAY 91	GAIN 1-91		
1	1	131	179	191	247	295	332	360	389	414	439	445	466	471	483	499	506	315		
	2	131	172	185	232	292	324	338	367	389	406	417	427	436	446	447	449	264		
	3	132	189	205	263	325	382	413	453	478	513	531	538	562	570	581	576	371		
	4	124	176	186	234	282	316	333	362	386	405	415	427	437	439	432	432	246		
	5	129	185	199	251	314	358	392	425	448	470	483	508	526	536	540	553	354		
	6	139	197	209	271	339	399	444	479	502	524	542	578	592	596	607	610	401		
	7	134	189	200	257	315	333	339	382	401	431	443	464	478	481	485	483	283		
	8	131	190	205	269	335	380	404	428	454	473	485	495	510	524	524	518	313		
	9	137	186	204	267	335	388	417	452	474	498	513	530	535	540	539	534	330		
	10	131	188	202	259	320	369	400	434	463	489	492	511	524	533	538	539	337		
2	21	135	191	204	256	322	340	377	412	442	473	487	497	506	d	d	d	d		
	22	135	185	196	250	308	355	381	416	447	469	482	491	499	506	507	509	313		
	23	133	191	201	265	332	378	400	427	452	474	489	500	508	524	525	528	327		
	24	137	184	198	249	287	324	336	358	378	397	406	413	426	432	440	429	231		
	25	138	190	204	257	313	357	376	405	430	459	471	410	486	505	504	507	303		
	26	136	189	203	261	317	357	387	421	445	465	481	417	490	512	519	521	318		
	27	144	197	211	275	319	363	380	412	438	461	470	485	493	503	512	510	299		
	28	128	173	177	232	275	316	343	376	398	422	429	443	450	461	458	458	281		
	29	131	180	191	256	309	341	361	387	415	431	444	458	469	486	493	495	304		
	30	129	173	183	228	279	313	340	366	389	403	411	424	425	435	438	440	257		
	31	123	167	159	239	298	347	367	403	432	456	471	480	488	506	510	516	357		
	3	41	132	187	202	246	309	358	390	425	452	478	489	502	514	524	521	529	327	
42		130	180	190	224	274	300	315	345	362	383	390	407	415	421	422	428	238		
43		130	176	187	237	281	310	327	350	372	391	391	403	412	419	428	423	236		
44		132	188	200	259	318	364	403	427	455	471	485	498	518	d	d	d	d		
45		133	179	190	248	307	347	375	411	438	457	474	483	491	509	506	507	317		
46		127	181	193	251	312	365	394	436	461	477	494	502	508	521	520	521	328		
47		139	197	212	278	337	367	397	428	467	475	484	501	515	524	531	531	319		
48		131	181	192	247	302	334	354	372	396	413	419	433	449	459	467	479	287		
49		136	182	190	235	287	320	339	364	373	390	396	407	418	424	432	440	250		
50		127	182	195	253	310	354	381	417	427	455	464	475	489	497	508	509	314		

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Individual values - Day of arrival to Day 91

Males

BODY WT																			
ANIMAL	ON	DAY OF	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	GAIN
GROUP	NO	ARRIVAL	RE-ALLOCATION	1	8	15	22	29	36	43	50	57	64	71	78	85	91	1-91	
4	61	137	187	197	256	318	370	391	430	455	480	497	514	530	541	547	548	351	
	62	127	186	196	243	301	337	357	386	401	421	424	439	460	460	469	470	274	
	63	137	191	200	257	306	362	392	425	455	477	492	507	523	530	535	533	333	
	64	133	191	203	255	301	353	378	405	431	452	461	478	485	496	492	494	291	
	65	136	179	191	241	288	322	340	365	393	420	424	445	453	461	464	462	271	
	66	142	191	202	253	293	332	342	368	391	415	424	436	448	455	457	460	258	
	67	133	187	204	258	310	347	375	405	428	450	458	463	455	479	468	474	270	
	68	129	180	193	247	305	342	363	392	401	421	431	442	432	464	457	463	270	
	69	135	194	206	270	338	375	390	410	d	d	d	d	d	d	d	d	d	
	70	134	187	198	254	314	365	384	415	435	451	460	473	477	506	503	511	313	

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Individual values - Day of arrival to Day 91

Females

GROUP	ANIMAL NO	ON ARRIVAL	DAY OF RE-ALLOCATION	BODY WT																GAIN 1-91
				DAY 1	DAY 8	DAY 15	DAY 22	DAY 29	DAY 36	DAY 43	DAY 50	DAY 57	DAY 64	DAY 71	DAY 78	DAY 85	DAY 91			
1	11	122	147	153	176	202	216	221	242	248	251	253	263	267	265	265	273	120		
	12	117	146	154	175	196	216	218	226	240	249	254	249	263	276	269	275	121		
	13	125	151	155	169	197	205	221	231	238	244	254	255	254	260	265	257	102		
	14	116	152	158	189	233	260	257	271	280	280	285	287	283	295	296	292	134		
	15	127	151	158	187	213	234	241	262	258	272	269	281	281	282	285	288	130		
	16	127	149	153	178	198	206	229	239	243	254	255	255	265	260	264	263	110		
	17	118	143	148	176	201	234	230	243	252	263	266	265	275	278	282	279	131		
	18	121	149	157	189	222	229	239	240	257	262	267	264	278	295	286	280	123		
	19	129	154	162	190	201	231	229	248	249	267	261	269	276	272	272	275	113		
	20	118	146	154	180	199	211	216	233	239	253	263	270	284	276	268	276	122		
2	32	132	125	123	183	214	227	253	272	289	301	301	302	309	318	316	320	197		
	33	126	150	154	182	200	211	226	240	246	249	255	264	262	270	280	293	139		
	34	129	160	169	192	213	225	249	273	278	277	291	297	297	289	306	298	129		
	35	131	150	150	180	192	218	228	237	252	260	265	269	271	274	277	283	133		
	36	114	135	140	176	208	233	250	257	265	270	276	283	293	297	296	295	155		
	37	119	154	162	192	224	235	256	269	271	272	280	277	290	291	291	299	137		
	38	124	161	170	213	229	263	288	313	291	317	336	347	335	328	342	345	175		
	39	123	150	155	177	206	215	223	236	243	252	257	255	257	263	266	270	115		
	40	124	154	156	184	215	216	229	244	248	259	256	275	282	278	272	271	115		
	101	1	132	151	169	190	219	218	225	231	245	241	247	249	247	242	243	92		
	102	1	133	150	173	192	210	215	229	223	242	236	246	242	238	256	252	102		
	3	51	129	155	161	192	210	223	237	257	268	264	265	267	275	283	277	285	124	
52		135	155	166	194	212	223	236	247	257	255	269	272	271	274	275	279	113		
53		117	156	168	206	225	251	269	d	d	d	d	d	d	d	d	d	d		
54		139	161	170	185	207	226	232	239	254	256	266	260	273	270	279	283	113		
55		117	145	153	180	205	224	241	254	257	263	275	277	286	290	296	288	135		
56		115	150	158	190	212	224	239	249	251	267	283	278	276	270	283	282	124		
57		123	159	165	190	207	228	237	251	266	277	264	286	294	295	292	309	144		
58		124	153	158	184	206	237	232	241	260	271	269	269	280	285	283	292	134		
59		123	149	157	174	d	d	d	d	d	d	d	d	d	d	d	d	d		
60		109	143	152	166	184	191	210	212	212	231	225	232	242	247	245	254	102		

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Body weight and body weight gain (g)

Individual values - Day of arrival to Day 91

Females

BODY WT																			
ANIMAL	ON	DAY OF	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	DAY	GAIN
GROUP	NO	ARRIVAL	RE-ALLOCATION	1	8	15	22	29	36	43	50	57	64	71	78	85	91	1-91	
4	71	130	153	159	180	206	233	244	237	255	265	255	269	268	276	270	270	111	
	72	118	144	147	169	195	213	233	239	244	261	267	268	272	277	276	272	125	
	73	115	144	152	174	203	223	231	238	264	274	276	275	289	290	293	294	142	
	74	121	147	144	172	192	210	226	246	247	241	257	263	263	259	267	269	125	
	75	118	150	155	182	206	221	238	250	255	271	278	281	289	292	291	254	99	
	76	135	148	150	167	184	190	195	212	221	243	255	258	257	256	253	296	146	
	77	113	148	174	194	228	263	262	266	268	292	312	314	310	306	297	303	129	
	78	124	156	161	172	191	212	218	232	242	248	249	251	258	265	257	265	104	
	79	122	156	161	191	211	239	249	262	261	276	282	285	285	294	298	285	124	
	80	136	156	158	183	199	238	260	254	247	266	271	275	291	308	294	289	131	

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Values per animal - Week 1 - Week 13

Males

GROUP	CAGE NO	WEEK													TOTAL WEEK 1 TO WEEK 13
		1	2	3	4	5	6	7	8	9	10	11	12	13#	
1	1	159.5	169.0	177.0	176.0	182.0	184.0	176.5	189.5	187.5	186.5	182.5	189.5	145.5	2305.0
	2	168.5	177.5	186.0	181.5	184.5	186.5	182.0	202.5	199.0	203.5	190.5	196.5	152.5	2411.0
	3	175.0	200.0	214.5	217.5	219.0	201.5	201.5	216.5	223.0	229.0	213.0	228.0	169.0	2707.5
	4	186.0	204.0	192.0	176.0	197.5	192.0	186.0	205.0	205.0	213.0	200.0	201.5	157.5	2515.5
	5	180.5	195.5	208.5	191.0	208.0	204.0	189.0	220.0	215.0	206.5	192.0	218.5	162.0	2590.5
2	11	164.0	182.5	181.5	183.5	190.5	193.5	186.0	205.0	198.5	198.0	d	192.0	151.0	d
	12	173.0	180.5	186.5	176.5	188.5	192.0	177.5	195.0	195.5	193.0	187.5	199.0	155.0	2399.5
	13	178.0	185.5	191.5	186.0	191.5	192.0	192.5	215.0	140.0	236.5	223.5	215.0	171.0	2518.0
	14	169.0	160.0	187.0	174.0	183.5	179.5	181.0	190.5	191.0	187.5	188.0	181.0	141.5	2313.5
	15	.	179.3	181.0	168.0	176.7	176.0	168.7	191.0	184.0	.	186.3	189.3	146.7	.
3	21	150.5	177.5	178.0	167.5	179.0	176.5	175.5	190.0	188.0	189.5	184.5	180.0	145.5	2282.0
	22	163.0	171.5	178.5	175.5	180.0	180.0	169.5	184.0	180.5	185.5	d	181.0	135.0	d
	23	170.0	179.5	196.0	190.5	196.5	199.5	189.5	210.0	203.5	194.0	197.5	197.0	156.5	2480.0
	24	178.5	190.5	185.5	181.5	184.0	189.5	186.0	204.5	199.0	200.0	197.0	201.5	156.5	2454.0
	25	168.0	177.0	181.0	177.5	187.0	183.5	174.5	186.0	187.0	193.0	186.0	187.0	146.0	2333.5
4	31	162.0	189.0	195.0	187.5	192.5	192.5	179.0	191.0	199.0	202.5	193.5	202.0	161.0	2446.5
	32	175.0	170.0	204.0	193.5	193.5	199.5	185.0	205.5	202.0	199.5	197.0	198.5	153.0	2476.0
	33	161.5	166.5	170.5	157.5	169.0	171.5	171.0	189.5	182.5	180.5	178.5	185.0	143.0	2226.5
	34	168.5	183.5	181.0	181.0	184.5	173.5	182.5	202.5	197.0	.	218.0	190.0	155.0	.
	35	181.5	194.5	202.5	181.5	192.5	d	.	191.0	200.0					

d = cage-mate dead before termination of treatment

= only 6 days

. = not recorded in error

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Food consumption (g)

Values per animal - Week 1 - Week 13

Females

															TOTAL WEEK 1 TO WEEK 13
GROUP	CAGE NO	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10	WEEK 11	WEEK 12	WEEK 13 #	
1	6	120.0	115.0	120.0	114.0	129.5	116.0	109.5	127.0	124.5	127.0	136.0	120.5	101.5	1560.5
	7	119.5	131.5	137.5	127.0	131.0	129.5	118.5	140.5	133.0	129.5	135.0	133.5	103.0	1669.0
	8	118.5	123.0	129.0	125.5	129.5	125.0	118.0	128.0	137.0	125.0	125.0	126.5	100.0	1610.0
	9	121.0	125.5	130.0	111.0	114.0	119.5	117.5	122.5	119.0	122.5	134.5	118.5	88.5	1544.0
	10	125.0	114.0	123.0	112.0	125.5	118.5	113.0	132.0	126.5	136.5	116.0	115.0	99.5	1556.5
2	16	.	132.0	137.0	141.0										
	17	121.5	114.5	123.5	126.0	133.3	128.0	121.0	133.7	129.7	131.7	125.7	134.3	109.0	1631.9
	18	127.0	128.5	139.0	130.5	137.0	132.0	124.0	141.0	139.0	136.5	133.0	136.0	111.0	1714.5
	19	129.0	133.0	136.5	151.5	156.5	116.0	123.0	155.0	151.5	136.0	118.5	141.0	118.0	1765.5
	20	120.5	133.0	122.0	114.0	140.0	123.5	120.0	146.5	135.5	137.5	131.5	128.0	112.5	1664.5
	46	112.0	118.5	123.0	111.5	113.5	108.0	120.5	114.5	117.5	123.0	109.0	120.5	115.5	1507.0
3	26	122.5	114.5	114.0	125.5	126.5	134.5	113.5	132.0	136.0	123.5	131.5	131.0	100.5	1605.5
	27	120.0	122.0	127.0	130.5										
	28	122.5	131.0	123.0	130.5	117.7	114.3	116.7	131.7	123.7	119.7	120.3	128.3	96.0	1575.4
	29	122.5	122.5	135.5	123.0	120.3	125.0	112.3	129.7	132.3	127.3	120.7	126.3	95.3	1592.7
	30	113.5	d	109.0	117.0										
4	36	109.5	119.0	125.5	124.0	110.0	116.0	114.0	126.0	129.0	126.0	124.5	120.5	97.0	1541.0
	37	117.5	118.5	121.5	123.5	129.5	127.5	122.5	138.0	132.0	123.0	125.0	138.0	97.5	1614.0
	38	115.0	114.5	108.0	72.5	119.0	110.0	104.5	153.5	133.0	110.5	116.0	120.0	98.5	1475.0
	39	123.5	122.5	141.0	119.5	128.5	125.5	126.5	152.0	153.0	125.0	128.0	125.0	104.0	1674.0
	40	120.5	120.5	135.5	137.5	125.5	119.0	126.0	145.5	134.5	144.5	149.5	138.0	97.0	1693.5

d = cage-mate dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

= only 6 days

. = not recorded in error

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Values per animal - Day 1 - Day 91

		Males													
GROUP	CAGE NO	DAY 1-4	DAY 4-8	DAY 8-11	DAY 11-15	DAY 15-18	DAY 18-22	DAY 22-25	DAY 25-29	DAY 29-32	DAY 32-36	DAY 36-39	DAY 39-43	DAY 43-46	
1	1	84.5	123.5	89.5	128.0	93.0	141.5	100.0	112.5	99.0	141.5	110.5	135.0	.	
	2	80.0	125.5	93.5	120.5	97.5	142.5	r	109.5	103.5	140.0	102.0	132.0	.	
	3	90.0	61.0	93.5	136.5	105.0	143.0	106.0	124.0	115.0	150.5	110.5	123.5	.	
	4	89.0	127.0	100.0	150.5	89.5	142.0	101.5	97.0	108.0	130.5	103.0	120.5	.	
	5	95.5	139.5	104.5	138.0	104.5	152.0	107.5	119.0	116.0	151.0	110.5	132.5	.	
2	11	91.5	106.5	86.5	126.5	101.0	130.0	100.5	111.5	100.0	139.5	100.0	134.5	.	
	12	87.5	120.0	81.5	135.5	93.5	140.0	90.5	105.5	98.0	128.5	94.5	120.0	.	
	13	89.0	128.0	90.0	126.0	100.0	137.5	100.5	111.0	105.0	141.5	108.5	151.5	.	
	14	81.5	116.0	83.0	105.0	93.5	140.0	93.0	109.0	105.5	140.0	103.5	114.0	.	
	15		118.0	92.0	135.7	105.3	147.0	95.7	109.0	104.7	143.7	100.0	145.3	.	
3	21	83.0	95.5	92.5	128.5	98.5	139.5	96.0	105.0	91.5	124.5	95.5	123.0	.	
	22	80.5	97.5	83.5	116.0	89.0	114.0	90.5	101.5	92.0	124.0	92.0	119.0	.	
	23	98.5	124.5	97.0	145.5	111.0	161.0	113.0	112.0	115.0	160.5	115.0	144.0	.	
	24	88.0	120.5	90.0	143.0	99.0	133.5	89.5	106.0	99.5	134.5	100.5	125.0	.	
	25	85.5	134.0	93.0	128.5	94.0	138.5	92.0	108.5	102.5	141.5	111.0	127.5	.	
4	31	74.5	112.0	90.5	128.0	88.0	131.5	89.0	98.5	90.0	128.5	94.0	118.0	.	
	32	83.5	124.0	93.0	104.0	95.5	139.5	100.0	117.0	109.5	133.5	104.5	138.0	.	
	33	88.5	120.0	94.5	132.5	91.5	134.5	87.0	98.5	95.5	129.0	96.5	125.5	.	
	34	86.5	124.5	99.0	136.5	100.5	136.0	91.0	113.5	101.5	146.0	93.0	125.0	.	
	35	91.0	125.5	98.5	147.0	103.5	153.0	99.5	112.0	112.5	145.5	d	130.0	.	

d = cage-mate dead before termination of treatment

r = water bottle had run

. = not recorded in error

ACYLTRANFERASE BL1
(Bacillus licheniformis strain 8ML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Values per animal - Day 1 - Day 91

Males														
GROUP	CAGE NO	DAY 46-50	DAY 50-53	DAY 53-57	DAY 57-60	DAY 60-64	DAY 64-67	DAY 67-71	DAY 71-74	DAY 74-78	DAY 78-81	DAY 81-85	DAY 85-88	DAY 88-91
1	1	133.0	113.5	153.0	86.0	132.0	123.5	137.5	.	136.0	108.0	148.0	120.0	121.5
	2	146.5	103.5	159.0	94.5	136.5	114.0	152.5	.	131.0	92.5	142.5	114.5	86.0
	3	147.0	107.5	170.5	87.0	133.0	121.5	144.0	.	117.0	95.0	137.5	126.0	90.0
	4	170.5	114.5	160.0	89.5	128.0	116.0	141.5	.	133.5	85.5	135.0	108.0	80.0
	5	166.5	121.5	169.0	95.0	128.5	109.5	134.0	.	136.5	90.5	141.0	112.5	91.0
2	11	140.0	102.5	167.0	89.0	129.0	120.5	142.0	d	113.0	93.0	102.0	105.0	89.0
	12	134.0	98.5	142.5	79.0	120.0	108.0	123.5	.	116.5	71.5	118.0	78.5	80.0
	13	158.0	102.5	177.0	93.5	16.0	167.5	155.5	.	132.0	117.0	134.5	114.0	85.0
	14	144.5	105.5	152.5	84.5	141.0	110.0	137.0	.	123.0	91.0	137.5	97.0	90.5
	15	128.0	102.3	142.3	85.7	137.7	121.0	123.0	.	129.0	91.3	134.7	114.7	79.7
3	21	130.0	88.0	144.5	82.0	120.0	97.0	126.0	.	107.0	74.5	105.5	98.5	76.0
	22	123.0	88.0	134.0	78.5	102.0	89.5	118.5	d	106.0	85.0	118.0	101.0	75.0
	23	152.5	116.5	167.0	96.5	144.0	126.5	144.5	.	131.5	100.5	131.0	117.5	87.0
	24	137.0	96.5	150.0	76.5	125.5	104.0	125.0	.	113.0	76.0	119.0	108.5	79.0
	25	153.0	100.5	130.5	77.0	117.0	96.5	130.0	.	111.0	88.0	110.5	94.0	79.5
4	31	117.0	82.5	137.0	75.0	121.5	99.5	102.0	.	106.0	74.5	115.5	99.5	74.0
	32	132.0	108.5	155.5	96.5	138.5	107.5	135.0	.	122.5	97.0	123.0	85.0	81.0
	33	129.0	94.5	146.5	79.0	117.5	77.5	129.5	.	116.5	93.0	91.5	113.5	76.5
	34	143.5	105.0	155.0	89.0	125.5	59.0	156.7	.	120.3	100.0	108.3	105.0	86.7
	35	137.0	98.0	148.0	92.0	112.0								

d = cage-mate dead before termination of treatment

r = water bottle had run

. = not recorded in error

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Values per animal - Day 1 - Day 91

Females

GROUP	CAGE NO	DAY 1-4	DAY 4-8	DAY 8-11	DAY 11-15	DAY 15-18	DAY 18-22	DAY 22-25	DAY 25-29	DAY 29-32	DAY 32-36	DAY 36-39	DAY 39-43	DAY 43-46
1	6	71.5	94.0	70.5	95.0	73.5	97.0	67.5	85.0	198.5	110.5	63.5	97.0	.
	7	72.5	93.0	82.0	116.5	91.0	136.0	86.0	79.5	95.5	112.5	75.0	100.0	.
	8	66.0	103.0	79.0	114.5	79.5	116.0	77.0	80.0	90.0	113.0	82.5	98.5	.
	9	63.0	90.0	62.0	96.5	69.5	96.0	66.5	75.0	60.5	83.0	65.5	78.5	.
	10	69.0	97.0	67.5	88.0	70.5	102.0	70.0	67.0	68.0	98.5	64.0	83.5	.
2	16		121.0	86.0	144.0	110.0	162.0	111.0	97.0					
	17	71.5	90.0	65.5	86.0	66.0	97.0	74.0	77.0	72.0	108.3	74.7	95.3	.
	18	83.0	107.0	82.5	125.0	77.5	126.5	84.5	87.0	99.0	119.0	80.5	103.0	.
	19	65.0	120.0	86.5	116.0	83.0	121.0	112.5	101.0	113.0	135.5	72.5	105.5	.
	20	77.5	112.5	91.5	134.5	87.0	122.5	84.5	70.0	98.5	122.5	78.5	99.0	.
	46	1	69.5	90.5	.	80.0	106.0	75.5	83.5	.	100.0	75.0	105.0	70.0
3	26	79.0	109.5	92.0	117.0	80.0	110.5	78.0	89.5	80.0	96.0	91.0	113.0	.
	27	52.5	100.0	79.5	99.5	69.5	108.5	73.0	82.0					.
	28	57.5	177.0	90.0	114.0	77.5	105.5	73.5	93.0	71.7	89.7	72.7	88.3	.
	29	67.5	91.5	65.0	95.5	71.5	110.0	80.0	78.5	64.3	85.0	63.7	77.7	.
	30	66.5	80.5	65.5	d	68.0	93.0	87.0	79.0					.
4	36	67.5	.	153.0	95.0	68.0	109.5	75.5	83.5	59.5	100.5	69.5	99.5	.
	37	69.5	97.5	74.0	102.0	66.5	101.0	76.0	81.5	66.0	103.5	79.0	96.5	.
	38	70.5	95.5	71.0	100.0	65.5	94.5	69.5	75.0	69.0	96.5	70.5	88.5	.
	39	66.5	92.0	77.5	115.5	82.0	121.5	77.5	77.0	77.5	106.5	74.5	91.0	.
	40	67.5	85.0	65.0	92.0	69.5	.	.	85.0	71.0	86.0	62.5	79.5	.

d = cage-mate dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

. = not recorded in error

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Water consumption (g)

Values per animal - Day 1 - Day 91

Females

GROUP	CAGE NO	DAY 46-50	DAY 50-53	DAY 53-57	DAY 57-60	DAY 60-64	DAY 64-67	DAY 67-71	DAY 71-74	DAY 74-78	DAY 78-81	DAY 81-85	DAY 85-88	DAY 88-91
1	6	94.5	62.5	114.0	60.5	91.5	79.0	98.0	.	97.5	71.0	90.0	86.5	63.5
	7	92.5	80.5	123.5	63.0	104.0	97.5	107.0	.	96.5	70.0	99.0	92.0	64.5
	8	101.0	74.5	127.0	69.5	100.0	93.5	90.5	.	93.5	77.0	98.0	85.0	77.0
	9	91.5	60.0	90.0	51.0	78.5	67.0	84.5	.	85.5	44.0	84.0	63.5	51.5
	10	103.0	72.5	99.0	56.0	79.5	76.0	98.0	.	73.5	63.5	89.0	76.0	62.5
2	16													
	17	104.7	74.7	99.3	54.7	97.3	78.3	103.3	.	84.0	72.7	97.0	84.7	71.7
	18	119.5	92.0	127.5	72.5	114.5	95.5	105.5	.	107.0	72.5	106.0	85.5	85.0
	19	115.0	88.0	148.5	56.5	121.5	100.5	106.0	.	104.5	73.0	88.5	89.0	92.5
	20	96.0	90.5	136.5	73.0	105.5	94.5	114.0	.	97.0	73.5	96.5	86.5	72.5
	46 1	98.0	67.5	85.5	.	82.5	64.0	96.0	67.0	82.5	70.5	65.0	.	92.0
3	26	100.5	80.0	121.0	67.5	109.5	82.5	106.0	.	77.5	75.0	95.0	78.0	70.5
	27
	28	96.0	70.0	108.3	63.3	88.7	73.3	91.0	.	80.7	71.7	86.7	71.3	66.3
	29	101.3	66.7	111.0	63.7	91.7	72.0	94.3	.	80.7	71.7	88.0	55.3	51.3
	30													
4	36	100.0	62.5	103.0	67.0	91.0	83.0	86.5	.	84.0	74.5	89.5	77.0	.
	37	104.0	86.0	93.5	57.5	90.0	107.0	87.0	.	87.5	84.5	94.5	67.5	65.5
	38	112.5	88.0	127.0	68.0	92.0	142.0	94.0	.	95.5	70.5	93.0	75.0	.
	39	112.5	87.0	120.0	73.5	105.0	80.0	99.0	.	91.0	73.0	101.5	67.5	76.0
	40	86.0	67.5	.	59.5	86.5	87.0	92.0	.	91.5	75.5	81.0	78.5	60.0

d = cage-mate dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

. = not recorded in error

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Ophthalmoscopy

Group	Animal No/Sex	Before start of treatment	Before termination of treatment
1	1, male	No abnormal findings	No abnormal findings
	2, male	No abnormal findings	No abnormal findings
	3, male	No abnormal findings	Both eyes: Superficial corneal opacities
	4, male	Right eye: No abnormal findings Left eye: Superficial corneal opacities	No abnormal findings
	5, male	No abnormal findings	No abnormal findings
	6, male	No abnormal findings	No abnormal findings
	7, male	No abnormal findings	No abnormal findings
	8, male	No abnormal findings	Right eye: Pupil could not be dilated Left eye: No abnormal findings
	9, male	No abnormal findings	No abnormal findings
	10, male	Right eye: Pupil could not be dilated Left eye: No abnormal findings	No abnormal findings
	11, female	No abnormal findings	No abnormal findings
	12, female	No abnormal findings	Both eyes: Superficial corneal opacities
	13, female	No abnormal findings	No abnormal findings
	14, female	No abnormal findings	No abnormal findings
	15, female	Both eyes: Superficial corneal opacities	No abnormal findings
	16, female	No abnormal findings	No abnormal findings
	17, female	No abnormal findings	No abnormal findings
	18, female	No abnormal findings	No abnormal findings
	19, female	No abnormal findings	No abnormal findings
	20, female	No abnormal findings	No abnormal findings

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Ophthalmoscopy

Group	Animal No/Sex	Before start of treatment	Before termination of treatment
2	21, male	No abnormal findings	
	22, male	No abnormal findings	
	23, male	No abnormal findings	
	24, male	No abnormal findings	
	25, male	No abnormal findings	
	26, male	No abnormal findings	
	27, male	No abnormal findings	
	28, male	No abnormal findings	
	29, male	No abnormal findings	
	30, male	No abnormal findings	
	31, male	Both eyes: Slight central lenticular opacities	
	32, female	No abnormal findings	
	33, female	No abnormal findings	
	34, female	No abnormal findings	
	35, female	Both eyes: Superficial corneal opacities	
	36, female	No abnormal findings	
	37, female	No abnormal findings	
	38, female	No abnormal findings	
	39, female	No abnormal findings	
	40, female	No abnormal findings	
	101, female	No abnormal findings	
	102, female	No abnormal findings	

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Ophthalmoscopy

Group	Animal No/Sex	Before start of treatment	Before termination of treatment
3	41, male	No abnormal findings	
	42, male	No abnormal findings	
	43, male	Both eyes: Superficial corneal opacities	
	44, male	No abnormal findings	
	45, male	No abnormal findings	
	46, male	No abnormal findings	
	47, male	No abnormal findings	
	48, male	Both eyes: Superficial corneal opacities	
	49, male	No abnormal findings	
	50, male	No abnormal findings	
	51, female	No abnormal findings	
	52, female	No abnormal findings	
	53, female	No abnormal findings	
	54, female	No abnormal findings	
	55, female	No abnormal findings	
	56, female	No abnormal findings	
	57, female	No abnormal findings	
	58, female	No abnormal findings	
	59, female	No abnormal findings	
	60, female	No abnormal findings	

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Ophthalmoscopy

Group	Animal No/Sex	Before start of treatment	Before termination of treatment
4	61, male	No abnormal findings	No abnormal findings
	62, male	No abnormal findings	No abnormal findings
	63, male	No abnormal findings	Both eyes: Superficial corneal opacities
	64, male	No abnormal findings	No abnormal findings
	65, male	No abnormal findings	No abnormal findings
	66, male	No abnormal findings	No abnormal findings
	67, male	No abnormal findings	No abnormal findings
	68, male	No abnormal findings	No abnormal findings
	69, male	No abnormal findings	d
	70, male	No abnormal findings	No abnormal findings
	71, female	No abnormal findings	No abnormal findings
	72, female	No abnormal findings	No abnormal findings
	73, female	No abnormal findings	No abnormal findings
	74, female	No abnormal findings	No abnormal findings
	75, female	No abnormal findings	No abnormal findings
	76, female	Both eyes: Superficial corneal opacities	No abnormal findings
	77, female	Both eyes: Superficial corneal opacities	No abnormal findings
	78, female	No abnormal findings	No abnormal findings
	79, female	No abnormal findings	No abnormal findings
	80, female	Both eyes: Superficial corneal opacities	No abnormal findings

d = dead

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Males

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO	NEUTRO	% LYMPHO	LYMPHO
1	1	9.9	8.78	48	55	1.1	20.5	15.7	5	0.8	95	14.9
	2	9.8	8.27	48	58	1.2	20.5	15.2	2	0.3	98	14.9
	3	9.9	8.65	49	57	1.2	20.2	18.2	10	1.8	89	16.2
	4	9.7	8.54	47	55	1.1	20.5	21.2	1	0.2	99	21.0
	5	9.3	8.41	46	54	1.1	20.2	16.5	7	1.2	91	15.0
	6	9.5	8.33	47	57	1.2	20.2	18.9	3	0.6	96	18.1
	7	9.6	8.74	47	54	1.1	20.5	14.6	9	1.3	90	13.1
	8	9.8	7.93	48	60	1.2	20.4	14.3	15	2.1	85	12.2
	9	9.2	7.48	45	60	1.2	20.6	17.3	5	0.9	95	16.4
	10	9.7	8.40	48	57	1.2	20.2	17.6	14	2.5	84	14.8
2	21	9.9	8.49	49	57	1.2	20.4	16.1	6	1.0	93	15.0
	22	9.5	8.39	46	55	1.1	20.6	15.5	4	0.6	96	14.9
	23	10.0	8.57	48	56	1.2	20.6	17.0	2	0.3	98	16.7
	24	10.1	8.87	50	56	1.1	20.3	16.0	2	0.3	96	15.4
	25	9.5	8.36	46	55	1.1	20.6	14.1	8	1.1	91	12.8
	26	9.3	8.29	46	55	1.1	20.4	12.0	3	0.4	96	11.5
	27	9.5	8.30	46	55	1.1	20.7	15.1	8	1.2	91	13.7
	28	9.3	7.91	45	57	1.2	20.7	23.7	9	2.1	91	21.6
	29	9.8	8.54	49	57	1.2	20.3	14.7	9	1.3	91	13.4
	30	9.6	8.07	47	58	1.2	20.4	16.0	2	0.3	97	15.5
	31	10.2	8.34	50	60	1.2	20.3	17.9	10	1.8	90	16.1
3	41	9.3	7.63	46	60	1.2	20.3	15.4	8	1.2	92	14.2
	42	9.2	8.48	46	54	1.1	20.2	20.5	3	0.6	97	19.9
	43	9.3	7.97	46	58	1.2	20.2	13.3	11	1.5	87	11.6
	44	9.7	8.62	48	55	1.1	20.3	18.7	7	1.3	92	17.2
	45	9.3	8.31	46	56	1.1	20.3	15.3	3	0.5	96	14.7
	46	9.5	7.96	47	59	1.2	20.3	10.9	3	0.3	96	10.5
	47	9.6	8.28	47	56	1.2	20.6	16.3	5	0.8	95	15.5
	48	10.1	9.04	50	55	1.1	20.4	18.4	4	0.7	95	17.5
	49	9.9	8.65	48	56	1.1	20.5	27.0	6	1.6	92	24.8
	50	9.1	7.89	45	56	1.2	20.4	18.4	0	0.0	99	18.2

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Males

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO		% LYMPHO	
4	61	9.2	7.77	45	58	1.2	20.4	10.7	7	0.7	90	9.6
	62	9.5	8.65	47	54	1.1	20.3	12.7	5	0.6	94	11.9
	63	9.0	7.89	44	56	1.1	20.4	14.4	3	0.4	97	14.0
	64	9.3	8.01	45	57	1.2	20.6	20.4	2	0.4	98	20.0
	65	9.4	8.59	47	55	1.1	20.1	16.8	3	0.5	97	16.3
	66	9.7	8.95	48	53	1.1	20.2	13.7	9	1.2	91	12.5
	67	9.2	8.07	45	56	1.1	20.3	18.9	1	0.2	98	18.5
	68	9.4	8.41	46	55	1.1	20.4	11.9	5	0.6	95	11.3
	69	9.5	8.14	47	57	1.2	20.4	10.9	5	0.5	93	10.1
	70	9.1	7.84	45	57	1.2	20.3	18.6	3	0.6	97	18.0

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Males

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
1	1	0	0.0	0	0	0	0.0	553	14.4	13.4	2.50
	2	0	0.0	0	0	0	0.0	624	16.5	13.9	2.41
	3	0	0.0	0	0	1	0.2	544	14.9	13.9	2.65
	4	0	0.0	0	0	0	0.0	574	17.7	14.3	2.53
	5	0	0.0	0	0	2	0.3	566	19.2	13.4	2.44
	6	0	0.0	0	0	1	0.2	562	14.2	12.9	2.62
	7	0	0.0	0	0	1	0.1	610	13.4	13.1	2.44
	8	0	0.0	0	0	0	0.0	536	12.4	13.2	2.52
	9	0	0.0	0	0	0	0.0	556	15.2	12.9	2.39
	10	0	0.0	0	0	2	0.4	563	12.2	13.2	3.09
2	21	0	0.0	0	0	1	0.2	535	12.9	13.9	2.89
	22	0	0.0	0	0	0	0.0	590	13.9	13.9	2.83
	23	0	0.0	0	0	0	0.0	600	15.7	13.9	2.75
	24	1	0.2	0	0	1	0.2	538	14.2	13.2	2.48
	25	1	0.1	0	0	0	0.0	645	19.5	13.2	2.43
	26	1	0.1	0	0	0	0.0	620	15.2	13.8	1.95
	27	1	0.2	0	0	0	0.0	556	15.9	13.2	2.42
	28	0	0.0	0	0	0	0.0	654	15.4	12.9	3.19
	29	0	0.0	0	0	0	0.0	605	16.7	13.2	2.49
	30	1	0.2	0	0	0	0.0	546	11.4	13.5	2.86
	31	0	0.0	0	0	0	0.0	597	12.2	13.5	3.00
3	41	0	0.0	0	0	0	0.0	520	13.4	13.2	2.55
	42	0	0.0	0	0	0	0.0	521	16.7	13.5	2.37
	43	2	0.3	0	0	0	0.0	481	19.0	13.7	2.53
	44	0	0.0	0	0	1	0.2	492	27.2	13.4	2.64
	45	0	0.0	0	0	1	0.2	545	12.7	12.8	2.22
	46	1	0.1	0	0	0	0.0	609	15.4	13.4	2.23
	47	0	0.0	0	0	0	0.0	542	15.4	14.1	2.84
	48	1	0.2	0	0	0	0.0	506	15.7	13.8	2.59
	49	1	0.3	0	0	1	0.3	551	12.7	14.3	2.68
	50	1	0.2	0	0	0	0.0	699	15.4	14.4	2.42

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Males

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
4	61	3	0.3	0	0	0	0.0	583	16.2	14.1	2.26
	62	0	0.0	0	0	1	0.1	612	15.9	14.4	2.41
	63	0	0.0	0	0	0	0.0	574	14.7	13.2	2.28
	64	0	0.0	0	0	0	0.0	689	28.0	13.2	2.46
	65	0	0.0	0	0	0	0.0	515	17.5	13.2	2.10
	66	0	0.0	0	0	0	0.0	534	19.0	13.5	2.55
	67	0	0.0	0	0	1	0.2	604	34.5	13.9	2.36
	68	0	0.0	0	0	0	0.0	588	11.2	13.8	2.64
	69	0	0.0	0	0	2	0.2	521	14.7	13.8	2.46
	70	0	0.0	0	0	0	0.0	591	13.4	13.9	2.23

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Females

GROUP	ANIMAL									% NEUTRO		% LYMPHO	
	NO		Hb	RBC	HT	MCV	MCH	MCHC	WBC	NEUTRO	NEUTRO	LYMPHO	LYMPHO
1	11		9.6	8.36	46	55	1.2	20.8	19.0	10	1.9	90	17.1
	12		9.4	8.40	46	54	1.1	20.7	17.5	6	1.1	94	16.5
	13		9.4	8.05	46	57	1.2	20.5	13.1	4	0.5	94	12.3
	14		10.1	8.82	49	55	1.1	20.7	12.0	12	1.4	88	10.6
	15		9.3	8.06	44	55	1.2	20.9	16.2	7	1.1	89	14.4
	16		9.3	8.32	44	53	1.1	21.0	13.6	10	1.4	86	11.7
	17		8.9	7.79	43	55	1.1	20.6	15.3	8	1.2	92	14.1
	18		9.4	8.24	45	54	1.1	21.0	11.5	10	1.2	89	10.2
	19		9.4	8.34	45	54	1.1	20.9	16.0	6	1.0	94	15.0
	20		9.0	8.04	44	55	1.1	20.6	13.5	6	0.8	94	12.7
2	32		9.1	8.00	44	55	1.1	20.7	13.1	10	1.3	88	11.5
	33		9.2	8.38	45	53	1.1	20.7	14.4	8	1.2	91	13.1
	34		9.5	8.27	45	55	1.2	20.9	11.3	5	0.6	93	10.5
	35		9.3	8.25	44	54	1.1	20.9	12.1	7	0.8	93	11.3
	36		9.5	8.20	45	55	1.2	21.3	13.3	4	0.5	95	12.6
	37		9.0	7.88	43	55	1.1	20.7	12.8	10	1.3	89	11.4
	38		9.6	8.04	46	57	1.2	20.7	15.4	4	0.6	87	13.4
	39		9.5	8.20	46	56	1.2	20.6	17.3	4	0.7	95	16.4
	40		9.5	8.76	46	53	1.1	20.5	11.7	4	0.5	96	11.2
	101	1	9.6	8.67	47	54	1.1	20.4	16.9	5	0.9	94	15.8
	102	1	10.1	8.55	49	57	1.2	20.8	19.6	5	0.9	94	18.4
	3	51		8.7	7.51	42	55	1.2	21.0	13.9	4	0.6	96
52			9.3	8.11	45	55	1.2	20.9	16.0	13	2.1	85	13.6
53			d	d	d	d	d	d	d	d	d	d	d
54			10.0	9.06	48	52	1.1	21.0	16.0	8	1.3	91	14.6
55			8.9	8.05	43	53	1.1	20.7	14.6	3	0.4	94	13.7
56			9.3	8.13	44	54	1.1	21.0	12.5	6	0.8	91	11.4
57			9.0	7.69	43	56	1.2	20.9	10.4	11	1.1	87	9.0
58			9.2	7.79	43	56	1.2	21.2	13.6	5	0.7	95	12.9
59			d	d	d	d	d	d	d	d	d	d	d
60			9.1	7.89	44	55	1.2	20.9	16.1	7	1.1	93	15.0

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Females

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO		% LYMPHO	
4	71	9.2	8.50	44	52	1.1	20.7	13.5	2	0.3	98	13.2
	72	9.1	8.10	44	54	1.1	20.9	9.8	4	0.4	96	9.4
	73	9.6	8.44	47	55	1.1	20.6	24.2	9	2.2	81	19.6
	74	9.4	8.16	45	55	1.2	20.8	15.2	5	0.8	94	14.3
	75	9.1	7.86	44	56	1.2	20.6	13.1	1	0.1	98	12.8
	76	9.3	8.45	45	53	1.1	20.8	11.5	6	0.7	94	10.8
	77	8.9	7.72	42	55	1.2	21.2	9.0	8	0.7	90	8.1
	78	8.9	8.09	43	53	1.1	20.7	12.9	4	0.5	95	12.3
	79	9.5	8.24	46	55	1.2	20.8	11.8	8	0.9	91	10.7
	80	9.7	8.58	47	54	1.1	20.9	13.2	8	1.1	87	11.5

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Females

GROUP	ANIMAL NO	% EOS	% EOS	% BASO	% BASO	% MONO	% MONO	Plt	APTT	Pt	Fib
1	11	0	0.0	0	0	0	0.0	613	15.7	13.4	2.10
	12	0	0.0	0	0	0	0.0	552	18.2	13.9	2.22
	13	2	0.3	0	0	0	0.0	293	18.7	14.6	1.03
	14	0	0.0	0	0	0	0.0	556	14.7	14.1	2.39
	15	2	0.3	0	0	2	0.3	661	15.9	13.8	2.12
	16	3	0.4	0	0	1	0.1	688	17.5	13.7	1.73
	17	0	0.0	0	0	0	0.0	626	14.2	14.3	1.84
	18	1	0.1	0	0	0	0.0	586	12.4	14.1	2.22
	19	0	0.0	0	0	0	0.0	440	14.9	14.3	1.88
	20	0	0.0	0	0	0	0.0	573	15.2	13.5	1.96
2	32	0	0.0	0	0	2	0.3	567	17.0	13.9	2.44
	33	1	0.1	0	0	0	0.0	576	15.0	14.6	2.06
	34	1	0.1	0	0	1	0.1	633	15.2	14.1	1.94
	35	0	0.0	0	0	0	0.0	553	14.9	13.8	1.82
	36	1	0.1	0	0	0	0.0	634	13.7	13.1	1.91
	37	1	0.1	0	0	0	0.0	646	14.2	14.1	2.19
	38	9	1.4	0	0	0	0.0	500	14.4	13.8	2.33
	39	0	0.0	0	0	1	0.2	581	13.2	13.2	2.16
	40	0	0.0	0	0	0	0.0	572	12.9	13.5	2.13
	101	1	0.2	0	0	0	0.1	554	20.2	13.9	2.60
3	102	1	0.1	0	0	1	0.2	587	20.7	14.7	2.46
	51	0	0.0	0	0	0	0.0	643	14.2	14.4	1.89
	52	1	0.2	0	0	1	0.2	681	15.9	13.1	1.89
	53	d	d	d	d	d	d	d	d	d	d
	54	1	0.2	0	0	0	0.0	520	11.9	12.4	2.16
	55	2	0.3	0	0	1	0.1	551	10.9	13.4	1.94
	56	0	0.0	0	0	3	0.4	642	15.2	13.5	2.19
	57	2	0.2	0	0	0	0.0	500	11.2	13.9	2.03
	58	0	0.0	0	0	0	0.0	598	11.4	13.8	2.30
	59	d	d	d	d	d	d	d	d	d	d
	60	0	0.0	0	0	0	0.0	501	17.2	13.5	2.26

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 35 and 36

Females

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
4	71	0	0.0	0	0	0	0.0	579	14.2	13.5	2.14
	72	0	0.0	0	0	0	0.0	524	13.2	13.5	2.21
	73	10	2.4	0	0	0	0.0	603	14.9	13.5	2.11
	74	0	0.0	0	0	1	0.2	550	14.7	13.5	1.91
	75	0	0.0	0	0	1	0.1	528	.	13.7	2.22
	76	0	0.0	0	0	0	0.0	630	14.2	13.4	1.76
	77	2	0.2	0	0	0	0.0	523	13.9	13.9	2.26
	78	1	0.1	0	0	0	0.0	907	15.4	13.8	.
	79	1	0.1	0	0	0	0.0	642	10.4	13.7	2.23
	80	5	0.7	0	0	0	0.0	559	18.5	13.8	2.37

Abbreviations and units are explained in subsection 'Clinical pathology'

. = measuring error or not possible to measure

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3⁺ CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Males

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO	NEUTRO	% LYMPHO	LYMPHO
1	1	9.8	9.34	48	51	1.1	20.3	15.9	6	1.0	92	14.6
	2	9.5	8.52	47	55	1.1	20.3	16.0	5	0.8	94	15.1
	3	10.0	9.24	50	54	1.1	20.2	16.7	5	0.9	94	15.7
	4	9.7	9.07	47	52	1.1	20.5	20.4	6	1.2	93	19.0
	5	9.1	8.69	45	51	1.0	20.4	16.2	6	1.0	93	15.1
	6	9.3	8.96	46	52	1.0	20.1	13.7	6	0.8	93	12.8
	7	9.3	8.93	46	52	1.0	20.0	15.2	6	0.9	93	14.1
	8	9.8	8.55	49	58	1.2	20.0	14.8	5	0.7	94	13.9
	9	9.4	8.05	45	56	1.2	20.7	12.3	4	0.5	95	11.7
	10	9.7	9.01	49	54	1.1	20.0	14.8	7	1.0	92	13.7
2	21	9.8	8.90	49	55	1.1	20.1	13.5	7	0.9	92	12.4
	22	9.3	8.74	46	53	1.1	20.3	13.2	5	0.6	95	12.5
	23	9.8	8.88	48	54	1.1	20.5	13.9	7	1.0	92	12.8
	24	10.0	9.21	50	54	1.1	20.1	15.9	7	1.1	93	14.7
	25	9.4	8.84	47	53	1.1	20.2	13.7	5	0.6	95	13.0
	26	9.5	8.97	46	51	1.1	20.6	12.7	5	0.6	94	12.0
	27	9.2	8.76	46	52	1.1	20.2	11.6	7	0.8	92	10.7
	28	8.7	7.68	43	56	1.1	20.3	16.9	5	0.9	94	15.8
	29	9.5	8.80	48	54	1.1	20.0	10.6	7	0.8	91	9.6
	30	9.4	8.39	47	56	1.1	20.1	13.0	6	0.8	93	12.1
	31	10.0	8.65	50	57	1.2	20.1	13.7	6	0.9	93	12.7
3	41	9.5	8.23	47	57	1.2	20.4	12.5	5	0.6	95	11.8
	42	9.3	9.09	46	50	1.0	20.3	18.2	6	1.1	93	16.9
	43	9.4	8.47	47	55	1.1	20.2	13.5	9	1.2	89	12.0
	44	9.3	8.88	46	52	1.1	20.1	17.2	5	0.8	95	16.2
	45	9.6	9.05	48	53	1.1	20.3	15.1	6	0.8	94	14.1
	46	9.8	8.72	48	56	1.1	20.2	11.2	5	0.6	94	10.5
	47	9.6	8.86	47	53	1.1	20.2	13.1	5	0.7	94	12.3
	48	9.8	9.51	49	51	1.0	20.1	14.6	7	1.0	92	13.4
	49	9.8	9.13	49	53	1.1	20.1	21.0	6	1.2	94	19.6
	50	9.3	8.69	46	53	1.1	20.2	18.8	6	1.2	93	17.5

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Days 65 and 66

Males

GROUP	ANIMAL								%		%	
	NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	NEUTRO	NEUTRO	LYMPHO	LYMPHO
4	61	9.3	8.47	46	54	1.1	20.3	10.8	6	0.7	92	9.9
	62	9.4	9.09	47	52	1.0	20.1	11.1	6	0.7	93	10.3
	63	9.7	9.04	48	53	1.1	20.1	13.6	6	0.8	93	12.7
	64	10.0	9.16	50	54	1.1	20.1	22.1	6	1.4	93	20.6
	65	9.4	9.19	47	51	1.0	19.9	17.2	6	1.0	93	16.0
	66	10.0	9.64	50	51	1.0	20.1	17.3	7	1.3	91	15.7
	67	9.5	8.76	47	53	1.1	20.3	18.5	6	1.1	93	17.2
	68	9.3	8.97	46	51	1.0	20.3	13.0	6	0.8	93	12.0
	69	d	d	d	d	d	d	d	d	d	d	d
	70	8.8	7.88	43	54	1.1	20.4	16.5	6	0.9	94	15.4

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Males

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
1	1	1	0.2	0	0	1	0.1	517	15.9	12.9	2.39
	2	1	0.1	0	0	1	0.1	613	15.9	12.9	2.37
	3	1	0.1	0	0	1	0.1	479	16.5	13.5	2.65
	4	0	0.1	0	0	0	0.1	439	15.9	12.9	2.54
	5	0	0.0	0	0	0	0.1	576	19.7	13.4	2.58
	6	0	0.0	0	0	0	0.1	670	13.2	13.1	2.42
	7	0	0.1	0	0	1	0.1	603	14.7	12.6	2.50
	8	1	0.1	0	0	1	0.1	585	16.5	13.7	2.54
	9	1	0.1	0	0	0	0.1	470	17.0	13.2	2.55
	10	1	0.1	0	0	0	0.0	532	14.4	13.5	2.58
2	21	0	0.0	0	0	1	0.1	554	11.9	12.9	3.10
	22	0	0.1	0	0	0	0.0	498	16.7	14.7	2.60
	23	1	0.1	0	0	0	0.0	556	13.7	13.1	2.79
	24	0	0.0	0	0	1	0.1	363	17.0	13.4	2.39
	25	1	0.1	0	0	0	0.0	474	18.7	13.9	2.50
	26	0	0.1	0	0	0	0.1	517	16.7	13.8	2.69
	27	0	0.1	0	0	1	0.1	553	17.7	13.5	2.99
	28	1	0.1	0	0	0	0.1	641	19.7	13.1	3.22
	29	1	0.1	0	0	1	0.1	537	16.5	13.2	2.84
	30	1	0.1	0	0	1	0.1	468	14.4	13.7	3.19
	31	1	0.1	0	0	0	0.0	568	16.5	13.4	3.67
3	41	1	0.1	0	0	0	0.0	538	16.2	13.4	2.68
	42	0	0.1	0	0	0	0.0	501	17.5	12.8	2.32
	43	2	0.2	0	0	1	0.1	265	20.5	12.9	2.73
	44	0	0.1	0	0	0	0.0	502	24.5	13.9	2.37
	45	0	0.1	0	0	0	0.1	573	14.9	12.8	2.47
	46	1	0.1	0	0	1	0.1	486	14.4	13.1	3.07
	47	1	0.1	0	0	0	0.0	564	12.9	13.5	3.49
	48	1	0.1	0	0	1	0.1	458	16.5	13.2	3.06
	49	0	0.1	0	0	0	0.1	473	14.4	13.7	2.86
	50	0	0.1	0	0	1	0.1	598	16.5	13.9	3.10

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Males

GROUP	ANIMAL NO	% EOS	% EOS	% BASO	% BASO	% MONO	% MONO	Plt	APTT	Pt	Fib
4	61	1	0.1	0	0	1	0.1	500	16.2	13.8	2.58
	62	1	0.1	0	0	0	0.0	514	17.5	14.3	2.49
	63	0	0.0	0	0	0	0.1	453	15.4	13.7	2.15
	64	0	0.1	0	0	0	0.1	599	40.0	12.9	2.73
	65	1	0.1	0	0	1	0.1	470	15.9	12.8	2.27
	66	1	0.1	0	0	1	0.2	470	26.5	14.1	3.18
	67	1	0.2	0	0	0	0.1	564	31.2	13.8	2.96
	68	1	0.1	0	0	0	0.0	593	10.9	13.4	2.21
	69	d	d	d	d	d	d	d	d	d	d
	70	1	0.1	0	0	0	0.1	599	14.2	13.9	2.42

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Females

ANIMAL									%		%		
GROUP	NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	NEUTRO	NEUTRO	LYMPHO	LYMPHO	
1	11	9.8	8.64	47	54	1.1	21.0	16.3	15	2.5	82	13.3	
	12	9.7	8.83	47	54	1.1	20.6	19.6	10	1.9	90	17.5	
	13	9.2	7.90	45	57	1.2	20.4	11.7	10	1.2	90	10.5	
	14	9.7	8.90	48	53	1.1	20.4	12.6	6	0.8	93	11.7	
	15	9.3	8.26	45	54	1.1	20.9	13.2	7	0.9	93	12.3	
	16	9.5	8.73	46	52	1.1	20.7	12.7	3	0.4	96	12.2	
	17	9.5	8.45	46	54	1.1	20.8	13.3	6	0.8	94	12.5	
	18	9.7	8.79	46	53	1.1	21.0	9.5	8	0.8	91	8.7	
	19	9.6	8.69	46	53	1.1	20.9	13.9	5	0.7	94	13.0	
	20	9.4	8.41	45	53	1.1	20.8	16.2	5	0.8	94	15.2	
2	32	9.8	8.87	48	54	1.1	20.5	15.2	10	1.5	89	13.6	
	33	9.3	8.67	45	52	1.1	20.6	11.8	11	1.4	88	10.4	
	34	9.8	8.75	48	55	1.1	20.6	8.3	14	1.2	84	7.0	
	35	9.5	8.80	46	52	1.1	20.6	8.8	5	0.4	93	8.2	
	36	9.4	8.50	46	54	1.1	20.6	11.8	6	0.7	93	11.0	
	37	9.2	8.42	45	54	1.1	20.2	12.9	6	0.7	93	12.0	
	38	10.2	8.99	50	56	1.1	20.4	14.9	6	0.8	93	13.8	
	39	9.6	8.54	47	55	1.1	20.5	14.4	5	0.7	95	13.6	
	40	9.9	9.29	48	51	1.1	20.8	8.0	4	0.3	96	7.6	
	101	1	9.7	8.86	48	54	1.1	20.3	14.7	10	1.4	87	12.8
	102	1	10.2	8.84	50	56	1.2	20.6	16.4	7	1.2	92	15.1
3	51	8.7	7.75	42	55	1.1	20.5	13.6	7	0.9	92	12.5	
	52	9.2	8.14	44	55	1.1	20.6	13.4	8	1.0	92	12.3	
	53	d	d	d	d	d	d	d	d	d	d	d	
	54	9.7	9.06	47	51	1.1	20.8	10.7	4	0.5	95	10.1	
	55	8.5	7.91	41	52	1.1	20.5	10.7	6	0.6	93	10.0	
	56	9.1	7.99	43	54	1.1	21.0	9.1	6	0.5	93	8.4	
	57	10.0	8.70	48	56	1.2	20.6	14.2	7	1.0	92	13.1	
	58	9.5	8.38	47	56	1.1	20.3	13.4	4	0.5	95	12.8	
	59	d	d	d	d	d	d	d	d	d	d	d	
	60	9.5	8.45	46	55	1.1	20.5	15.9	6	1.0	92	14.6	

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Females

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO	NEUTRO	% LYMPHO	LYMPHO
4	71	9.2	8.69	45	51	1.1	20.7	10.0	7	0.7	93	9.2
	72	9.2	8.48	43	51	1.1	21.5	11.1	8	0.9	91	10.1
	73	9.4	8.44	46	54	1.1	20.6	10.7	6	0.6	93	9.9
	74	9.6	8.52	47	55	1.1	20.6	18.2	8	1.4	90	16.4
	75	9.4	8.44	47	55	1.1	20.2	15.6	5	0.8	93	14.5
	76	9.6	8.50	46	53	1.1	21.0	13.3	6	0.7	94	12.5
	77	9.2	8.35	44	53	1.1	20.8	8.5	9	0.7	89	7.5
	78	9.4	8.94	46	52	1.1	20.3	15.4	5	0.8	93	14.4
	79	9.5	8.51	46	54	1.1	20.6	11.5	5	0.5	95	10.8
	80	9.8	8.90	47	53	1.1	20.7	10.6	5	0.5	94	9.9

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Females

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
1	11	3	0.4	0	0	0	0.1	685	16.5	13.2	2.11
	12	1	0.1	0	0	0	0.1	578	16.2	13.8	2.20
	13	0	0.0	0	0	0	0.0	616	12.4	13.5	1.95
	14	1	0.1	0	0	1	0.1	499	15.4	13.9	2.37
	15	1	0.1	0	0	0	0.0	561	14.4	13.8	2.18
	16	1	0.1	0	0	0	0.0	629	17.2	13.4	1.70
	17	0	0.1	0	0	0	0.0	659	15.2	13.1	1.75
	18	1	0.1	0	0	0	0.0	529	12.7	13.1	2.29
	19	1	0.1	0	0	0	0.1	478	14.4	12.6	1.94
	20	1	0.2	0	0	0	0.1	600	15.4	13.2	1.94
2	32	1	0.1	0	0	0	0.1	537	16.5	13.1	2.08
	33	1	0.1	0	0	0	0.1	560	15.7	13.2	2.13
	34	1	0.1	0	0	0	0.0	664	15.2	13.2	2.17
	35	2	0.1	0	0	0	0.0	620	13.4	12.8	2.02
	36	1	0.1	0	0	0	0.0	599	15.4	12.9	1.89
	37	1	0.1	0	0	1	0.1	493	15.2	13.5	2.04
	38	1	0.2	0	0	1	0.1	512	14.9	13.1	2.44
	39	1	0.1	0	0	0	0.0	648	14.7	12.9	2.01
	40	0	0.0	0	0	0	0.0	687	15.4	13.2	2.11
	101	1	0.1	0	0	3	0.4	703	20.2	14.4	2.90
	102	1	0.1	0	0	1	0.1	696	23.5	15.2	2.48
3	51	1	0.1	0	0	0	0.1	566	10.4	13.5	2.13
	52	1	0.1	0	0	0	0.0	605	16.2	13.2	1.98
	53	d	d	d	d	d	d	d	d	d	d
	54	1	0.1	0	0	0	0.0	616	14.7	13.1	1.79
	55	1	0.1	0	0	0	0.0	539	13.9	13.9	1.99
	56	1	0.1	0	0	0	0.0	583	14.7	13.5	2.24
	57	0	0.0	0	0	0	0.1	566	14.9	13.8	1.85
	58	1	0.1	0	0	0	0.0	577	14.9	13.9	2.21
	59	d	d	d	d	d	d	d	d	d	d
	60	1	0.2	0	0	1	0.1	592	29.2	.	.

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

. = measuring error or not possible to measure

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Day 65 + 66

Females

GROUP	ANIMAL NO	%		%		%		Plt	APTT	Pt	Fib
		EOS	EOS	BASO	BASO	MONO	MONO				
4	71	1	0.1	0	0	0	0.0	668	13.2	13.1	2.39
	72	1	0.1	0	0	1	0.1	551	14.2	13.4	2.10
	73	1	0.1	0	0	0	0.0	579	11.7	13.5	2.03
	74	1	0.2	0	0	1	0.2	561	16.2	14.1	2.35
	75	1	0.2	0	0	1	0.1	488	13.2	13.9	2.19
	76	1	0.1	0	0	0	0.0	450	13.9	13.4	1.16
	77	2	0.2	0	0	0	0.0	497	13.2	13.4	2.45
	78	1	0.1	0	0	1	0.1	651	15.7	13.4	1.95
	79	1	0.1	0	0	0	0.1	640	15.2	13.8	2.15
	80	1	0.1	0	0	0	0.0	599	25.5	13.8	2.07

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Males

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO	NEUTRO	% LYMPHO	LYMPHO
1	1	9.9	9.51	47	50	1.0	20.8	16.4	10	1.7	87	14.4
	2	9.7	8.77	48	54	1.1	20.4	13.2	10	1.3	89	11.7
	3	9.8	9.17	48	53	1.1	20.3	13.4	7	1.0	90	12.1
	4	10.2	9.78	50	51	1.0	20.6	19.5	6	1.2	92	17.9
	5	8.9	8.68	44	51	1.0	20.1	12.5	8	1.0	90	11.2
	6	10.3	10.05	50	50	1.0	20.4	16.7	11	1.8	87	14.5
	7	9.9	9.40	47	50	1.1	21.0	12.7	11	1.3	86	10.9
	8	10.5	9.28	51	55	1.1	20.4	14.4	5	0.7	93	13.3
	9	10.4	9.07	49	54	1.1	21.1	12.1	6	0.7	91	11.0
	10	10.3	9.74	51	53	1.1	20.2	14.6	7	1.1	87	12.8
2	21	d	d	d	d	d	d	d	d	d	d	d
	22	9.5	8.95	46	52	1.1	20.5	10.1	7	0.8	92	9.3
	23	10.1	9.19	48	53	1.1	20.8	13.9	9	1.2	88	12.2
	24	10.7	9.81	52	53	1.1	20.5	17.1	11	1.9	85	14.6
	25	9.9	9.35	49	52	1.1	20.2	14.1	8	1.1	88	12.4
	26	9.9	9.77	49	50	1.0	20.1	12.8	7	0.9	92	11.7
	27	9.7	9.42	47	50	1.0	20.5	13.8	12	1.7	83	11.5
	28	9.1	8.31	44	53	1.1	20.6	23.7	6	1.4	92	21.7
	29	10.1	9.29	49	53	1.1	20.6	14.1	6	0.9	91	12.8
	30	10.3	9.56	48	50	1.1	21.3	8.6	7	0.6	90	7.7
	31	10.6	9.19	51	55	1.2	21.0	18.3	7	1.3	89	16.2
3	41	9.5	8.32	46	55	1.1	20.6	14.2	7	1.0	90	12.8
	42	9.5	9.58	47	49	1.0	20.0	17.8	10	1.8	88	15.6
	43	9.4	8.53	46	54	1.1	20.4	8.8	8	0.7	88	7.8
	44	d	d	d	d	d	d	d	d	d	d	d
	45	9.9	9.46	49	51	1.0	20.3	11.0	8	0.9	87	9.6
	46	10.1	9.20	50	54	1.1	20.4	13.0	6	0.8	92	12.0
	47	11.3	10.54	54	52	1.1	20.8	13.9	10	1.4	84	11.7
	48	9.2	9.00	45	50	1.0	20.4	11.4	5	0.6	94	10.7
	49	10.0	9.25	48	52	1.1	20.7	21.8	7	1.6	89	19.4
	50	9.8	9.31	48	52	1.1	20.4	18.8	6	1.0	93	17.5

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Males

GROUP	ANIMAL		Hb	RBC	HT	MCV	MCH	MCHC	WBC	%		%	
	NO									NEUTRO	NEUTRO	LYMPHO	LYMPHO
4	61		9.2	8.52	46	53	1.1	20.3	9.1	8	0.8	91	8.2
	62		10.0	9.50	49	51	1.1	20.5	13.5	10	1.3	87	11.8
	63		9.8	9.02	47	52	1.1	20.8	13.9	10	1.4	88	12.2
	64		10.1	9.42	50	53	1.1	20.3	21.6	10	2.1	88	18.9
	65		10.0	9.79	49	50	1.0	20.5	17.5	8	1.4	91	15.9
	66		10.7	10.61	52	49	1.0	20.6	15.3	9	1.4	86	13.1
	67	b	d	d	d	d	d	d	d	d	d	d	d
	68		9.5	9.45	47	50	1.0	20.3	13.2	6	0.8	91	12.1
	69		d	d	d	d	d	d	d	d	d	d	d
	70		10.2	9.27	50	53	1.1	20.7	17.4	5	0.8	93	16.1

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

b/d = dead during blood sampling

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Males

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
1	1	1	0.2	0	0	1	0.2	619	15.7	14.4	3.24
	2	0	0.1	0	0	0	0.0	595	15.7	14.6	2.92
	3	1	0.1	0	0	2	0.3	489	18.0	15.8	3.25
	4	0	0.0	0	0	2	0.4	539	17.0	15.3	3.77
	5	1	0.1	0	0	2	0.2	614	20.2	16.1	3.91
	6	1	0.1	0	0	2	0.3	600	11.2	13.7	3.65
	7	3	0.4	0	0	1	0.1	1028	15.7	13.7	2.65
	8	1	0.1	0	0	2	0.2	525	19.5	14.4	3.18
	9	1	0.1	0	0	3	0.3	495	21.0	15.0	3.50
	10	2	0.3	0	0	3	0.4	583	18.5	14.9	3.73
2	21	d	d	d	d	d	d	d	d	d	d
	22	0	0.0	0	0	1	0.1	527	17.5	14.6	3.23
	23	1	0.1	0	0	3	0.4	602	.	14.3	3.44
	24	0	0.0	0	0	4	0.7	501	18.0	15.0	3.72
	25	1	0.1	0	0	3	0.4	474	24.2	14.9	3.11
	26	1	0.1	0	0	1	0.1	606	19.2	14.3	3.11
	27	3	0.4	0	0	2	0.3	389	16.2	14.1	3.40
	28	1	0.2	0	0	2	0.4	776	24.7	13.8	5.02
	29	1	0.2	0	0	2	0.2	527	19.7	15.0	2.97
	30	2	0.1	0	0	2	0.1	601	16.7	15.0	3.04
	31	1	0.2	0	0	3	0.6	524	19.5	15.6	3.79
3	41	1	0.1	0	0	2	0.3	598	17.5	14.3	3.09
	42	0	0.1	0	0	2	0.3	515	21.5	15.0	3.14
	43	1	0.1	0	0	3	0.2	481	25.5	15.0	3.18
	44	d	d	d	d	d	d	d	d	d	d
	45	1	0.1	0	0	4	0.5	596	15.9	15.3	3.20
	46	1	0.1	0	0	1	0.1	371	13.9	13.8	3.51
	47	3	0.4	0	0	3	0.4	439	18.5	14.4	3.48
	48	1	0.1	0	0	0	0.0	592	14.4	14.4	3.94
	49	1	0.2	0	0	3	0.5	659	16.2	15.0	3.27
	50	1	0.1	0	0	1	0.2	552	21.5	15.4	3.33

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

. = measuring error or not possible to measure

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Males

GROUP	ANIMAL NO	% EOS	% EOS	% BASO	% BASO	% MONO	% MONO	Plt	APTT	Pt	Fib
4	61	1	0.1	0	0	1	0.1	576	20.5	15.8	3.24
	62	0	0.1	0	0	3	0.4	525	17.2	14.7	3.27
	63	0	0.1	0	0	2	0.3	501	14.4	14.7	3.05
	64	1	0.1	0	0	2	0.5	573	30.2	15.2	3.54
	65	1	0.1	0	0	1	0.2	529	18.5	14.4	3.56
	66	2	0.3	0	0	3	0.5	310	25.2	15.3	1.60
	67	b	d	d	d	d	d	d	36.0	14.4	3.54
	68	1	0.2	0	0	2	0.2	625	12.9	14.4	3.02
	69	d	d	d	d	d	d	d	d	d	d
	70	1	0.1	0	0	2	0.3	564	15.7	14.9	3.22

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

b/d = dead during blood sampling

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Females

GROUP	ANIMAL								% NEUTRO		% LYMPHO		
	NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	NEUTRO	NEUTRO	LYMPHO	LYMPHO	
1	11	9.1	8.17	44	54	1.1	20.5	14.4	10	1.4	89	12.7	
	12	9.2	8.25	45	54	1.1	20.6	12.4	11	1.4	87	10.8	
	13	9.4	7.95	45	57	1.2	20.8	13.3	9	1.2	88	11.7	
	14	9.5	8.69	47	54	1.1	20.4	13.6	13	1.7	86	11.7	
	15	9.5	8.34	45	54	1.1	20.9	13.6	8	1.1	90	12.2	
	16	9.4	8.68	45	52	1.1	20.8	11.3	8	0.9	88	9.9	
	17	9.6	8.57	46	54	1.1	20.9	12.5	9	1.1	89	11.1	
	18	9.8	8.95	47	52	1.1	21.0	11.6	6	0.7	91	10.5	
	19	9.9	9.00	47	52	1.1	21.0	14.3	3	0.5	95	13.6	
	20	10.0	9.01	49	54	1.1	20.6	12.2	5	0.7	90	11.0	
2	32	9.1	8.20	45	54	1.1	20.4	12.6	13	1.6	85	10.7	
	33	9.0	8.37	44	52	1.1	20.5	12.0	9	1.1	90	10.8	
	34	9.5	8.43	46	54	1.1	20.7	8.3	10	0.8	87	7.2	
	35	9.2	8.29	43	52	1.1	21.2	11.2	7	0.8	91	10.1	
	36	8.8	7.89	42	54	1.1	20.8	9.2	5	0.5	94	8.6	
	37	9.2	8.27	44	54	1.1	20.8	14.7	9	1.3	88	12.9	
	38	9.3	8.17	45	55	1.1	20.6	10.9	13	1.4	82	8.9	
	39	10.0	8.63	47	55	1.2	21.1	18.3	4	0.7	95	17.4	
	40	10.0	9.04	48	53	1.1	20.9	17.5	5	0.9	92	16.0	
	101	1	9.5	8.70	47	54	1.1	20.1	14.5	12	1.7	87	12.6
	102	1	9.6	8.34	47	56	1.2	20.6	13.1	9	1.2	89	11.6
	3	51	9.0	7.90	43	55	1.1	20.7	12.0	15	1.8	82	9.9
52		9.4	8.25	45	55	1.1	20.7	17.4	9	1.5	90	15.6	
53		d	d	d	d	d	d	d	d	d	d	d	
54		8.5	8.36	43	52	1.0	19.6	10.6	4	0.4	96	10.2	
55		8.7	8.20	42	51	1.1	20.7	15.6	7	1.0	92	14.4	
56		9.3	8.23	44	53	1.1	21.2	8.9	6	0.5	91	8.0	
57		9.9	8.71	48	55	1.1	20.7	18.7	8	1.5	90	16.7	
58		10.1	8.95	49	55	1.1	20.7	20.1	6	1.2	92	18.6	
59		d	d	d	d	d	d	d	d	d	d	d	
60		9.5	8.43	46	55	1.1	20.5	21.6	8	1.6	90	19.5	

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Females

GROUP	ANIMAL NO	Hb	RBC	HT	MCV	MCH	MCHC	WBC	% NEUTRO		% LYMPHO	
4	71	8.8	8.16	43	52	1.1	20.8	10.2	6	0.6	93	9.5
	72	9.4	8.68	45	52	1.1	20.8	13.3	12	1.5	87	11.5
	73	8.8	7.87	43	54	1.1	20.5	16.3	9	1.5	89	14.5
	74	9.5	8.47	46	54	1.1	20.6	14.9	9	1.3	90	13.3
	75	9.2	8.13	45	55	1.1	20.6	12.2	6	0.8	92	11.2
	76	9.0	8.21	43	52	1.1	20.8	8.5	7	0.6	91	7.7
	77	8.9	8.09	42	52	1.1	21.1	9.0	8	0.7	89	8.0
	78	9.2	8.78	45	51	1.0	20.5	12.4	6	0.7	90	11.2
	79	9.6	8.65	47	54	1.1	20.6	11.2	6	0.7	92	10.3
	80	9.8	8.89	47	53	1.1	20.9	11.2	6	0.7	93	10.4

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Females

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
1	11	1	0.2	0	0	1	0.1	577	15.7	14.6	2.29
	12	1	0.1	0	0	1	0.1	557	18.5	15.3	2.57
	13	1	0.1	0	0	2	0.3	618	15.7	15.4	2.61
	14	1	0.1	0	0	1	0.1	516	16.5	15.2	2.89
	15	1	0.1	0	0	1	0.1	559	16.2	15.0	2.53
	16	3	0.4	0	0	1	0.1	627	20.0	14.1	2.41
	17	1	0.2	0	0	1	0.1	708	18.0	13.8	2.24
	18	2	0.3	0	0	1	0.1	671	17.0	14.1	2.65
	19	1	0.1	0	0	1	0.1	606	17.0	13.9	2.21
	20	3	0.4	0	0	1	0.2	497	17.5	14.9	2.53
2	32	1	0.1	0	0	2	0.3	507	17.2	14.9	2.43
	33	1	0.1	0	0	1	0.1	539	17.0	15.0	2.10
	34	2	0.1	0	0	1	0.1	562	14.9	14.7	2.68
	35	2	0.2	0	0	0	0.0	515	15.4	14.1	2.60
	36	1	0.1	0	0	0	0.0	551	11.9	14.7	2.55
	37	1	0.2	0	0	2	0.3	592	16.7	13.9	2.16
	38	4	0.4	0	0	2	0.2	621	18.2	14.3	2.70
	39	1	0.1	0	0	1	0.1	551	17.7	13.9	2.74
	40	2	0.3	0	0	1	0.2	752	18.0	14.3	2.71
	101	1	0.1	0	0	0	0.1	592	15.7	14.9	2.71
3	102	1	0.3	0	0	1	0.1	484	17.0	14.6	2.17
	51	1	0.2	0	0	2	0.2	594	14.9	15.3	2.66
	52	1	0.2	0	0	1	0.1	582	20.0	15.4	2.52
	53	d	d	d	d	d	d	d	d	d	d
	54	0	0.0	0	0	0	0.0	549	13.4	13.7	2.51
	55	1	0.1	0	0	0	0.1	544	11.9	14.7	2.62
	56	3	0.2	0	0	1	0.1	610	17.7	14.1	2.57
	57	1	0.2	0	0	2	0.3	453	16.5	14.1	2.13
	58	1	0.1	0	0	1	0.2	556	18.0	14.4	2.58
	59	d	d	d	d	d	d	d	d	d	d
	60	2	0.3	0	0	1	0.2	511	40.2	14.7	2.86

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Haematology

Individual values - Before termination of treatment

Females

GROUP	ANIMAL NO	% EOS	EOS	% BASO	BASO	% MONO	MONO	Plt	APTT	Pt	Fib
4	71	0	0.0	0	0	1	0.1	581	16.5	14.9	2.29
	72	1	0.1	0	0	1	0.1	560	14.7	15.8	3.00
	73	1	0.1	0	0	1	0.2	555	15.4	15.2	2.21
	74	1	0.1	0	0	1	0.2	521	11.7	14.6	2.38
	75	1	0.1	0	0	1	0.1	590	13.2	15.0	2.33
	76	2	0.1	0	0	1	0.1	738	15.4	13.5	2.05
	77	2	0.2	0	0	1	0.1	530	17.7	14.4	2.17
	78	4	0.5	0	0	1	0.1	772	17.2	14.1	2.30
	79	1	0.1	0	0	1	0.1	618	17.0	13.9	2.36
	80	1	0.1	0	0	1	0.1	556	29.0	14.1	2.59

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical chemistry

Individual values - Before termination of treatment

Males												
ANIMAL												
GROUP	NO	ALAT	ASAT	ALKPH	BILI	GGT	CHOL	TRIG	UREA	CREAT	GLUC	
1	1		1.59	1.40	3.15	<LOD	<LOD	2.8	2.48	6.51	26	6.6
	2		1.44	1.38	2.73	1.6	<LOD	2.4	2.58	6.63	23	6.9
	3		1.48	1.25	3.20	<LOD	<LOD	2.7	5.27	6.63	26	6.9
	4		1.41	1.51	3.07	<LOD	<LOD	2.6	2.07	7.27	23	9.6
	5		1.63	1.38	3.88	<LOD	<LOD	3.4	1.99	6.57	27	7.2
	6		1.53	1.44	2.85	<LOD	<LOD	4.2	3.56	6.82	24	6.1
	7		1.67	1.36	3.01	<LOD	<LOD	3.3	2.13	7.02	24	7.2
	8		1.67	1.62	3.02	2.0	<LOD	2.5	2.61	6.75	22	7.6
	9		1.86	1.97	2.96	<LOD	<LOD	2.9	1.60	6.79	25	6.2
	10		1.53	1.71	3.47	<LOD	<LOD	3.6	2.74	7.24	29	5.7
2	21	d	1.97	5.10	2.68	<LOD	<LOD	5.2	0.87	12.17	54	29.7
	22		1.35	1.33	2.65	<LOD	<LOD	3.1	1.57	7.83	25	8.3
	23		2.44	2.02	3.09	1.5	<LOD	3.6	1.98	8.64	26	6.2
	24		1.71	1.42	3.15	<LOD	<LOD	2.9	3.17	8.14	26	5.4
	25		1.69	1.66	3.12	<LOD	<LOD	2.8	3.70	8.49	27	6.4
	26		1.52	1.29	3.13	<LOD	<LOD	3.1	2.36	6.86	26	6.5
	27		1.48	1.51	3.06	<LOD	<LOD	3.0	1.53	5.54	25	5.7
	28		1.43	1.43	2.61	<LOD	<LOD	3.2	3.53	7.28	32	7.8
	29		1.40	1.23	4.84	<LOD	<LOD	2.8	2.88	5.88	28	6.0
	30		1.70	1.72	2.03	<LOD	<LOD	2.7	1.98	6.15	28	6.6
	31		1.53	1.78	3.22	1.7	<LOD	3.2	1.63	8.23	26	6.6
3	41		3.31	3.20	3.25	<LOD	<LOD	2.9	1.80	7.57	24	6.3
	42		1.41	1.41	3.17	<LOD	<LOD	2.0	1.83	5.78	24	6.6
	43		1.41	1.33	2.82	<LOD	<LOD	2.4	1.89	6.27	27	7.0
	44		d	d	d	d	d	d	d	d	d	d
	45		2.04	1.98	2.97	<LOD	<LOD	3.4	2.91	8.05	30	6.3
	46		1.47	1.68	4.23	<LOD	<LOD	2.3	1.75	8.43	26	7.3
	47		1.32	1.30	3.74	<LOD	<LOD	3.3	1.46	5.57	26	7.2
	48		1.45	1.47	4.53	<LOD	<LOD	2.9	2.13	6.68	30	6.6
	49		1.68	1.64	3.92	1.4	<LOD	3.0	1.82	5.59	24	6.8
	50		1.60	1.55	3.74	<LOD	<LOD	2.8	1.94	5.75	24	7.0

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI = 1.3

Limit of detection for GGT = 0.04

d = dead before termination of treatment, results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Clinical chemistry

Individual values - Before termination of treatment

Males

GROUP	ANIMAL NO	ALAT	ASAT	ALKPH	BILI	GGT	CHOL	TRIG	UREA	CREAT	GLUC
4	61	1.47	1.23	2.23	<LOD	<LOD	2.4	2.33	7.20	26	6.9
	62	1.70	1.36	2.74	<LOD	<LOD	3.3	1.93	6.81	26	6.6
	63	1.53	1.36	2.87	<LOD	<LOD	3.0	2.18	7.61	32	6.5
	64	1.55	1.51	2.24	1.6	<LOD	3.0	3.19	6.66	24	6.7
	65	1.66	1.79	3.20	<LOD	<LOD	3.1	2.67	6.98	26	6.6
	66	1.55	1.24	4.09	1.8	<LOD	2.7	1.75	7.46	25	6.5
	67	1.35	1.37	2.62	<LOD	<LOD	2.9	1.88	6.54	27	5.8
	68	2.31	2.86	3.75	<LOD	<LOD	4.4	2.33	8.07	26	6.4
	69	d	d	d	d	d	d	d	d	d	d
	70	2.61	2.74	3.13	<LOD	<LOD	2.8	1.80	7.86	27	8.3

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI = 1.3

Limit of detection for GGT = 0.04

d = dead before termination of treatment, results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Males												
ANIMAL												
GROUP	NO		Na	K	Ca	Mg	P	Cl	PROTEIN	ALB	GLOBULIN	ALB/G Ratio
1	1		144.8	6.73	2.83	1.08	3.13	100.4	69.9	44	25.9	1.70
	2		148.7	6.80	3.01	1.04	2.76	100.1	68.9	44	24.9	1.77
	3		152.4	7.17	2.96	1.20	3.47	100.9	70.7	45	25.7	1.75
	4		150.7	6.64	2.95	1.21	3.34	103.2	76.5	49	27.5	1.78
	5		146.7	7.13	2.87	1.07	2.55	100.0	73.7	44	29.7	1.48
	6		148.1	7.17	3.02	1.09	2.62	99.5	79.9	45	34.9	1.29
	7		152.0	6.40	3.11	1.09	3.42	103.8	73.5	44	29.5	1.49
	8		149.6	7.21	3.00	1.01	2.35	100.4	74.5	46	28.5	1.61
	9		150.9	7.37	3.06	1.12	3.03	100.6	75.1	46	29.1	1.58
	10		147.5	6.80	2.94	0.94	2.33	101.0	72.6	45	27.6	1.63
2	21	d	142.0	7.37	3.09	2.11	6.73	90.2	69.7	38	31.7	1.20
	22		151.0	5.78	2.95	1.10	2.95	101.2	68.4	44	24.4	1.80
	23		149.6	6.89	2.94	1.03	2.79	98.6	71.1	44	27.1	1.62
	24		151.3	7.01	2.90	1.13	2.82	99.7	71.9	45	26.9	1.67
	25		152.7	6.79	3.09	1.17	2.30	100.4	78.4	49	29.4	1.67
	26		150.4	6.81	3.12	0.99	2.62	100.6	76.4	47	29.4	1.60
	27		148.3	6.51	2.93	0.94	2.91	101.6	71.2	44	27.2	1.62
	28		147.0	7.42	3.06	1.31	2.80	99.5	70.8	39	31.8	1.23
	29		149.9	6.76	2.98	1.07	2.70	99.3	73.9	46	27.9	1.65
	30		145.6	6.37	2.90	1.03	2.76	101.1	75.2	46	29.2	1.58
	31		147.9	6.83	2.92	0.96	2.53	100.7	72.6	43	29.6	1.45
3	41		149.1	6.83	2.87	0.96	2.54	101.1	69.0	43	26.0	1.65
	42		145.8	6.17	2.82	0.97	2.70	97.5	68.0	44	24.0	1.83
	43		147.9	6.74	2.76	1.04	2.66	100.2	68.3	43	25.3	1.70
	44		d	d	d	d	d	d	d	d	d	d
	45		151.7	6.53	2.99	1.16	2.56	101.8	75.0	47	28.0	1.68
	46		148.2	6.78	2.91	1.04	2.70	100.3	71.0	44	27.0	1.63
	47		144.6	6.98	2.91	0.94	3.13	101.5	71.8	42	29.8	1.41
	48		150.1	6.87	2.93	1.05	2.65	100.3	73.9	46	27.9	1.65
	49		149.2	6.12	2.94	0.95	2.33	100.8	73.7	47	26.7	1.76
	50		148.9	6.48	3.04	0.96	2.63	99.5	75.9	46	29.9	1.54

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment, results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Males

GROUP	ANIMAL NO	Na	K	Ca	Mg	P	Cl	PROTEIN	ALB	GLOBULIN	ALB/G Ratio
4	61	152.5	5.78	2.80	0.93	2.51	102.0	66.8	41	25.8	1.59
	62	150.0	6.56	2.90	0.94	2.61	100.8	69.7	44	25.7	1.71
	63	151.5	6.90	2.84	1.01	2.53	101.2	72.3	44	28.3	1.55
	64	150.3	6.42	3.00	0.97	2.92	101.5	72.6	45	27.6	1.63
	65	150.8	6.97	2.96	1.15	2.70	100.1	72.7	45	27.7	1.62
	66	149.4	6.31	3.03	1.04	2.85	101.2	78.8	47	31.8	1.48
	67	151.4	6.79	2.97	0.94	2.39	103.9	75.0	46	29.0	1.59
	68	151.5	6.51	2.98	0.94	2.73	103.7	73.0	48	25.0	1.92
	69	d	d	d	d	d	d	d	d	d	d
	70	149.4	6.43	3.02	1.09	2.88	103.1	74.3	47	27.3	1.72

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment, results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Females

GROUP	ANIMAL		ALAT	ASAT	ALKPH	BILI	GGT	CHOL	TRIG	UREA	CREAT	GLUC
	NO											
1	11		1.08	1.37	1.83	<LOD	<LOD	2.8	0.79	5.70	25	7.0
	12		1.43	1.65	2.77	<LOD	<LOD	2.6	0.81	6.15	26	8.4
	13		1.16	1.34	2.48	2.0	<LOD	3.0	1.23	8.27	30	6.7
	14		1.31	1.38	2.09	1.4	<LOD	3.4	1.48	9.10	30	7.3
	15		1.59	1.41	2.85	<LOD	<LOD	3.0	1.86	8.70	25	5.9
	16		1.50	1.96	2.52	<LOD	<LOD	2.8	0.51	7.64	26	6.4
	17		0.95	1.31	2.78	2.3	<LOD	3.2	0.81	5.93	25	5.5
	18		1.28	2.29	2.30	1.7	<LOD	2.4	1.01	6.71	29	6.6
	19		1.01	1.38	1.85	2.2	<LOD	2.4	0.74	4.92	23	6.9
	20		1.42	1.69	2.12	1.7	<LOD	2.7	0.65	5.54	27	6.7
2	32		1.26	1.20	2.37	<LOD	<LOD	3.3	3.05	6.11	28	7.0
	33		1.39	1.36	2.73	<LOD	<LOD	2.5	1.50	7.44	26	7.1
	34		1.27	1.38	1.82	<LOD	<LOD	2.7	1.37	6.47	30	7.4
	35		1.46	1.61	2.98	<LOD	<LOD	2.6	1.90	7.65	28	6.0
	36		1.25	1.47	2.83	1.5	<LOD	1.9	0.86	8.11	29	6.5
	37		1.65	1.71	2.01	2.2	<LOD	3.1	0.80	7.41	29	6.0
	38		1.50	1.37	1.95	1.6	<LOD	2.7	1.28	7.43	27	9.8
	39		1.59	1.60	2.64	2.7	<LOD	3.6	0.74	7.73	29	5.8
	40		1.35	1.85	3.48	1.5	<LOD	3.5	0.69	6.55	30	6.9
	101	1	1.41	1.52	2.17	<LOD	<LOD	2.7	2.10	6.46	20	6.3
	102	1	1.35	1.63	3.31	2.2	<LOD	3.3	1.04	6.84	27	7.5
3	51		1.40	1.48	1.71	<LOD	<LOD	2.5	0.82	6.11	27	6.8
	52		1.53	1.38	2.31	1.8	<LOD	2.7	0.96	6.61	29	7.1
	53		d	d	d	d	d	d	d	d	d	d
	54		1.76	1.59	2.18	1.9	<LOD	2.8	1.12	7.11	27	7.1
	55		0.84	1.55	1.87	2.2	<LOD	3.3	1.17	6.91	33	7.1
	56		1.03	1.84	2.46	1.6	<LOD	2.3	0.50	6.04	25	7.0
	57		1.90	1.71	3.77	<LOD	<LOD	2.4	1.25	5.30	25	6.2
	58		1.53	1.81	2.63	1.9	<LOD	2.7	1.22	6.36	27	5.8
	59		d	d	d	d	d	d	d	d	d	d
	60		1.74	1.93	2.83	2.5	<LOD	2.7	1.10	5.69	27	5.8

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI = 1.3

Limit of detection for GGT = 0.04

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Females

GROUP	ANIMAL NO	ALAT	ASAT	ALKPH	BILI	GGT	CHOL	TRIG	UREA	CREAT	GLUC
4	71	1.21	1.07	1.59	<LOD	<LOD	2.6	0.84	5.77	26	7.5
	72	1.16	1.53	2.43	1.7	<LOD	2.4	1.22	6.49	26	6.9
	73	1.18	1.58	2.54	1.4	<LOD	2.2	1.20	5.63	24	7.1
	74	1.33	1.58	2.27	<LOD	<LOD	2.2	1.45	6.46	26	6.4
	75	1.27	1.58	2.71	<LOD	<LOD	2.3	1.12	7.45	28	7.2
	76	1.41	1.53	2.52	1.4	<LOD	2.8	1.22	4.98	30	6.9
	77	1.30	1.62	2.65	<LOD	<LOD	2.5	0.92	6.07	27	7.0
	78	2.18	3.64	3.01	2.3	<LOD	2.8	0.98	5.49	24	7.4
	79	1.78	1.65	1.81	1.8	<LOD	3.2	0.73	9.30	28	7.7
	80	0.87	1.27	2.17	1.6	<LOD	2.7	0.69	7.28	31	6.8

Abbreviations and units are explained in subsection 'Clinical pathology'

Limit of detection for BILI = 1.3

Limit of detection for GGT = 0.04

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML7B0-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Females

ANIMAL											ALB/G	
GROUP	NO	Na	K	Ca	Mg	P	Cl	PROTEIN	ALB	GLOBULIN	Ratio	
1	11	148.7	6.12	2.94	1.08	2.81	104.3	67.5	46	21.5	2.14	
	12	150.5	5.99	3.01	1.06	2.82	101.8	64.8	43	21.8	1.97	
	13	149.3	6.48	3.06	1.15	2.52	101.5	74.5	51	23.5	2.17	
	14	153.0	7.03	3.25	1.31	2.87	103.3	77.6	51	26.6	1.92	
	15	151.5	6.43	3.09	1.19	2.81	102.9	73.8	51	22.8	2.24	
	16	147.7	6.84	2.87	1.22	2.11	102.0	73.7	48	25.7	1.87	
	17	147.7	6.25	2.95	1.18	3.14	101.6	72.2	49	23.2	2.11	
	18	144.0	6.66	2.94	1.06	2.88	102.5	68.9	46	22.9	2.01	
	19	144.2	6.21	2.97	1.13	2.48	98.2	74.0	50	24.0	2.08	
	20	141.5	6.06	2.98	1.07	2.44	97.0	73.7	49	24.7	1.98	
2	32	150.4	6.09	3.15	1.10	2.60	99.8	78.8	53	25.8	2.05	
	33	151.6	6.50	2.98	1.07	2.74	103.8	70.5	48	22.5	2.13	
	34	154.2	5.48	3.25	1.27	3.49	102.7	75.1	52	23.1	2.25	
	35	150.5	7.12	2.94	1.16	2.40	103.1	70.6	49	21.6	2.27	
	36	154.8	6.45	2.96	1.14	2.54	107.7	68.9	48	20.9	2.30	
	37	143.6	6.58	2.91	1.09	3.19	100.0	66.4	44	22.4	1.96	
	38	144.0	6.93	3.29	1.44	3.11	99.2	74.8	46	28.8	1.60	
	39	145.6	6.54	2.98	1.09	2.75	99.4	71.4	47	24.4	1.93	
	40	145.2	5.92	2.88	1.10	1.79	101.6	77.1	50	27.1	1.85	
	101	1	144.2	6.24	2.87	1.07	1.95	99.0	74.0	51	23.0	2.22
	102	1	147.0	6.31	2.96	1.12	2.20	99.9	74.2	53	21.2	2.50
	3	51	152.3	6.54	2.92	1.16	2.82	103.8	65.0	44	21.0	2.10
52		148.8	6.11	3.06	1.08	2.84	101.0	71.5	48	23.5	2.04	
53		d	d	d	d	d	d	d	d	d	d	
54		152.0	6.71	3.06	1.19	2.89	101.5	69.3	45	24.3	1.85	
55		153.0	6.50	3.07	1.24	3.38	105.5	72.6	49	23.6	2.08	
56		147.3	6.16	3.02	1.16	2.60	102.4	74.9	50	24.9	2.01	
57		147.9	6.47	2.91	1.09	2.61	97.7	74.8	50	24.8	2.02	
58		146.1	6.08	3.00	1.18	2.84	99.2	77.3	51	26.3	1.94	
59		d	d	d	d	d	d	d	d	d	d	
60		143.4	5.82	3.00	1.11	2.65	97.5	73.7	50	23.7	2.11	

Abbreviations and units are explained in subsection 'Clinical pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats
Clinical chemistry

Individual values - Before termination of treatment

Females

GROUP	ANIMAL NO	Na	K	Ca	Mg	P	Cl	PROTEIN	ALB	GLOBULIN	ALB/G Ratio
4	71	155.2	5.63	3.01	1.02	2.58	104.3	69.0	46	23.0	2.00
	72	150.3	5.93	3.09	1.13	2.97	103.1	74.4	51	23.4	2.18
	73	149.4	6.26	2.84	1.06	2.50	102.3	65.9	47	18.9	2.49
	74	150.1	6.15	2.94	1.15	2.63	101.5	68.7	49	19.7	2.49
	75	148.2	5.43	2.93	1.00	2.90	100.6	63.8	45	18.8	2.39
	76	145.8	5.69	2.91	1.10	2.26	101.6	68.8	48	20.8	2.31
	77	146.4	6.68	2.83	1.05	2.53	102.4	71.3	48	23.3	2.06
	78	144.1	6.93	2.83	1.06	3.09	102.3	71.3	48	23.3	2.06
	79	145.3	6.24	2.91	1.16	3.09	99.9	70.3	45	25.3	1.78
	80	141.1	6.36	2.86	1.15	1.80	97.8	75.0	49	26.0	1.88

Abbreviations and units are explained in subsection 'Clinical pathology'

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Males

GROUP	ANIMAL NO	VOLUME	Na	K	Cl
1	1	10	109	154.3	91
	2	12	75	119.9	62
	3	15	84	116.5	78
	4	10	101	123.8	91
	5	18	65	106.7	91
	6	15	80	148.0	106
	7	26	42	65.1	54
	8	15	72	113.6	85
	9	12	82	110.7	75
	10	13	81	120.0	74
2	21	d	d	d	d
	22	13	90	120.9	104
	23	8	52	139.6	85
	24	16	58	78.0	71
	25	18	78	97.6	74
	26	17	47	118.7	61
	27	13	84	103.6	80
	28	13	68	121.1	98
	29	18	86	113.6	103
	30	8	85	125.1	105
	31	12	94	157.7	96
3	41	14	70	133.9	98
	42	12	93	87.6	79
	43	17	22	66.7	46
	44	d	d	d	d
	45	23	44	75.0	61
	46	13	70	162.1	103
	47	18	66	118.5	80
	48	12	86	122.2	100
	49	7	87	160.2	86
	50	19	57	85.8	66

Abbreviations and units are explained in subsection 'Clinical Pathology'

d = dead before termination of treatment

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Males

GROUP	ANIMAL	VOLUME	Na	K	Cl
	NO				
4	61	17	42	134.7	78
	62	21	51	82.9	60
	63	15	48	131.5	80
	64	8	34	162.5	81
	65	10	97	116.3	122
	66	14	65	123.4	82
	67	14	54	117.9	61
	68	12	70	125.2	81
	69	d	d	d	d
	70	16	66	100.8	69

Abbreviations and units are explained in subsection 'Clinical Pathology'

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Males

GROUP	ANIMAL NO	SPECIFIC		COLOUR	LEUCO-		NITRITE	BLOOD	GLUCOSE	KETONES	BILI- UROBILI-	
		GRAVITY	pH		PROTEIN	CYTES					RUBIN	NOGEN
1	1	1.025	7.0	y	1.0	70	-	-	-	Trace	-	3.2
	2	1.020	7.5	y	0.3	70	-	-	-	1.5	-	3.2
	3	1.010	8.5	y	0.3	15	-	-	-	1.5	-	3.2
	4	1.015	8.5	y	1.0	70	-	-	-	1.5	-	3.2
	5	1.020	7.5	ly	1.0	125	-	-	-	Trace	-	3.2
	6	1.020	7.5	y	1.0	125	-	-	-	Trace	-	3.2
	7	1.020	7.5	ly	1.0	500	+	-	-	Trace	-	3.2
	8	1.020	7.0	y	0.3	70	+	-	-	1.5	-	3.2
	9	1.015	7.5	y	0.3	70	-	-	-	Trace	-	3.2
	10	1.025	7.5	y	≥3.0	500	-	-	-	1.5	-	3.2
2	21	d	d									
	22	1.015	8.5	y	0.3	70	-	-	-	1.5	-	3.2
	23	≥1.030	6.5	y	1.0	125	-	-	-	1.5	-	3.2
	24	1.015	7.5	ly	0.3	70	+	-	-	1.5	-	3.2
	25	1.015	8.0	y	1.0	70	-	-	-	1.5	-	3.2
	26	1.015	8.0	ly	0.3	70	-	-	-	Trace	-	3.2
	27	1.020	7.0	ly	0.3	70	-	-	-	Trace	-	3.2
	28	1.020	8.0	ly	≥3.0	500	-	-	-	Trace	-	3.2
	29	1.020	7.5	ly	0.3	70	-	-	-	Trace	-	3.2
	30	1.020	7.5	y	1.0	70	+	-	-	Trace	-	3.2
	31	≥1.030	7.0	y	≥3.0	500	-	-	-	Trace	-	3.2
3	41	1.025	7.0	y	≥3.0	125	-	-	-	1.5	-	3.2
	42	1.015	8.0	y	0.3	70	-	-	-	Trace	-	3.2
	43	1.015	7.5	ly	0.3	70	+	-	-	-	-	3.2
	44	d	d									
	45	1.015	7.5	ly	0.3	70	-	-	-	Trace	-	3.2
	46	1.025	7.0	ly	1.0	500	-	-	-	1.5	-	3.2
	47	1.015	7.5	ly	0.3	70	-	-	-	1.5	-	3.2
	48	1.020	7.5	ly	0.3	70	+	-	-	1.5	-	3.2
	49	1.020	7.5	y	1.0	70	-	-	-	1.5	-	3.2
	50	1.015	7.5	ly	0.3	70	-	-	-	Trace	-	3.2

ly = light yellow y = yellow

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Males

GROUP	ANIMAL	SPECIFIC			LEUCO-				BILI- UROBILI-			
	NO	GRAVITY	pH	COLOUR	PROTEIN	CYTES	NITRITE	BLOOD	GLUCOSE	KETONES	RUBIN	NOGEN
4	61	1.020	7.5	y	0.3	70	-	-	-	Trace	-	3.2
	62	1.015	7.5	ly	0.3	70	-	-	-	Trace	-	3.2
	63	1.020	7.5	y	1.0	125	-	-	-	1.5	-	3.2
	64	1.020	7.0	y	1.0	70	-	-	-	1.5	-	3.2
	65	1.025	7.0	y	≥3.0	70	-	-	-	1.5	-	3.2
	66	1.015	8.0	y	0.3	70	-	-	-	Trace	-	3.2
	67	1.015	8.5	y	0.3	70	-	-	-	Trace	-	3.2
	68	1.020	7.5	y	≥3.0	125	-	-	-	1.5	-	3.2
	69	d	d									
	70	1.015	8.0	y	0.3	15	-	-	-	1.5	-	3.2

ly = light yellow y = yellow

d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Females

GROUP	ANIMAL NO	VOLUME	Na	K	Cl
1	11	15	70	79.5	78
	12	8	91	120.5	96
	13	8	78	93.9	100
	14	10	71	79.3	88
	15	17	81	112.9	89
	16	7	68	51.9	67
	17	6	104	97.4	114
	18	8	56	106.2	63
	19	24	35	47.7	47
	20	4	77	179.6	96
2	32	11	72	97.1	79
	33	13	69	94.6	85
	34	10	86	111.9	94
	35	13	50	59.0	65
	36	9	84	117.5	101
	37	10	62	97.8	84
	38	23	46	69.9	64
	39	13	61	78.9	56
	40	9	71	121.1	80
	101	1	8	59	84.2
	102	1	6	82	121.2
					101
3	51	10	37	90.1	58
	52	11	58	85.1	68
	53	d	d	d	d
	54	11	83	88.8	81
	55	10	65	89.8	76
	56	9	61	90.7	87
	57	14	80	111.6	98
	58	13	68	68.0	74
	59	d	d	d	d
	60	8	97	84.2	98

Abbreviations and units are explained in subsection 'Clinical Pathology'

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Females

GROUP	ANIMAL NO	VOLUME	Na	K	Cl
4	71	8	66	128.5	77
	72	8	57	98.2	94
	73	8	103	149.0	125
	74	12	81	79.8	85
	75	8	43	126.3	57
	76	13	58	76.6	61
	77	11	63	102.0	68
	78	8	74	111.4	66
	79	8	84	90.5	94
	80	5	117	188.3	99

Abbreviations and units are explained in subsection 'Clinical Pathology'

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Females

GROUP	ANIMAL NO	SPECIFIC		COLOUR	LEUCO-		NITRITE	BLOOD	GLUCOSE	KETONES	BILI- UROBILI-	
		GRAVITY	pH		PROTEIN	CYTES					RUBIN	NOGEN
1	11	1.020	7.0	y	Trace	-	-	-	-	-	-	3.2
	12	≥1.030	6.5	y	1.0	70	-	-	-	-	-	3.2
	13	1.025	7.0	y	Trace	15	-	-	-	-	-	3.2
	14	1.025	6.0	y	Trace	-	-	-	-	-	-	3.2
	15	1.025	7.0	y	Trace	15	-	-	-	-	-	3.2
	16	1.015	7.0	ly	-	15	-	-	-	-	-	3.2
	17	1.025	6.5	y	0.3	-	-	-	-	-	-	3.2
	18	1.020	7.0	y	1.0	70	-	-	-	-	-	3.2
	19	1.010	7.0	ly	-	15	-	-	-	-	-	3.2
	20	≥1.030	6.5	y	1.0	-	-	-	-	Trace	-	16
2	32	1.025	7.0	y	1.0	70	-	-	-	-	-	3.2
	33	1.020	7.0	y	Trace	15	-	-	-	-	-	3.2
	34	1.020	7.0	y	0.3	15	-	-	-	-	-	3.2
	35	1.015	7.0	ly	Trace	-	-	-	-	-	-	3.2
	36	1.025	6.5	y	1.0	70	-	-	-	-	-	3.2
	37	1.025	6.5	y	Trace	-	-	-	-	-	-	3.2
	38	1.015	7.0	ly	-	15	-	-	-	-	-	3.2
	39	1.020	7.0	ly	1.0	125	-	-	-	-	-	3.2
	40	1.025	7.0	y	1.0	70	-	-	-	-	-	3.2
	101 1	1.020	7.0	y	Trace	-	-	-	-	-	-	3.2
3	102 1	1.020	7.0	y	0.3	-	-	-	-	-	-	3.2
	51	1.025	6.5	y	Trace	-	+	-	-	-	-	3.2
	52	1.025	6.5	y	Trace	15	-	-	-	-	-	3.2
	53	d	d									
	54	1.020	7.0	y	Trace	15	-	-	-	-	-	3.2
	55	1.020	7.0	ly	Trace	-	-	-	-	-	-	3.2
	56	≥1.030	6.0	y	Trace	-	-	-	-	-	-	3.2
	57	1.020	7.0	y	Trace	-	-	-	-	-	-	3.2
	58	1.015	7.5	y	-	-	-	-	-	-	-	3.2
	59	d	d									
	60	1.025	6.5	y	Trace	-	-	-	-	-	-	3.2

ly = light yellow y = yellow

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis

Individual values

Females

GROUP	ANIMAL NO	SPECIFIC			LEUCO-					BILI- UROBILI-		
		GRAVITY	pH	COLOUR	PROTEIN	CYTES	NITRITE	BLOOD	GLUCOSE	KETONES	RUBIN	NOGEN
4	71	1.025	7.0	y	Trace	-	-	-	-	-	-	3.2
	72	≥1.030	6.0	y	1.0	15	-	-	-	-	-	3.2
	73	1.025	7.0	y	1.0	70	-	-	-	-	-	3.2
	74	1.020	7.0	y	Trace	-	-	-	-	-	-	3.2
	75	1.025	6.5	y	0.3	15	-	-	-	-	-	3.2
	76	1.020	7.0	y	Trace	15	-	-	-	-	-	3.2
	77	1.015	7.5	y	0.3	15	-	-	-	-	-	3.2
	78	1.020	7.0	y	0.3	15	-	-	-	-	-	3.2
	79	1.025	6.5	y	0.3	15	-	-	-	-	-	3.2
	80	≥1.030	6.5	y	1.0	70	-	-	-	-	-	16

y = yellow

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Individual values

Males

GROUP	ANIMAL NO	ERYTHRO-CYTES	LEUCO-CYTES	EPITHELIAL CELLS	CRYSTALS	URATES	HYALINE CASTS	GRANULAR CASTS	BACTERIA
1	1	+	-	(+)	+++	+	-	-	+++
	2	(+)	-	(+)	+++	+	-	-	+++
	3	-	-	(+)	++	(+)	-	-	+++
	4	(+)	-	(+)	+++	+	-	-	+++
	5	(+)	-	(+)	++	+	-	-	+++
	6	(+)	(+)	+	++	(+)	-	-	+++
	7	(+)	-	-	++	(+)	-	-	+++
	8	+	-	+	++	++	-	-	+++
	9	+	-	(+)	+++	-	-	-	+++
	10	+	-	+	++	+	-	-	+++
2	21	d							
	22	-	-	(+)	++	+	-	-	+++
	23	+	-	+	++	(+)	-	-	+++
	24	+	-	+	++	+	-	-	+++
	25	(+)	-	(+)	++	+	-	-	+++
	26	(+)	(+)	(+)	+	-	-	-	+++
	27	(+)	-	-	++	+	-	-	+++
	28	(+)	-	(+)	+++	+	-	-	+++
	29	-	-	-	++	+	-	-	+++
	30	(+)	-	(+)	+++	+	-	-	+++
	31	+	-	+	++	(+)	-	-	+++
3	41	(+)	-	(+)	++	(+)	-	-	+++
	42	-	-	-	++	++	-	-	+++
	43	(+)	-	-	+++	+	-	-	+++
	44	d							
	45	(+)	-	(+)	++	-	-	-	+++
	46	(+)	-	-	++	+	-	-	+++
	47	-	-	-	++	(+)	-	-	+++
	48	(+)	(+)	+	++	-	-	-	+++
	49	(+)	-	-	+++	+	-	-	+++
	50	(+)	-	(+)	++	-	-	-	+++

Abbreviations and units are explained in subsection 'Clinical pathology'

- = no trace (+) = traces + = slight ++ = moderate +++ = marked
d = dead before termination of treatment

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Individual values

Males

GROUP	ANIMAL NO	ERYTHRO- CYTES	LEUCO- CYTES	EPITHELIAL CELLS	CRYSTALS	URATES	HYALINE CASTS	GRANULAR CASTS	BACTERIA
4	61	(+)	-	(+)	++	+	-	-	+++
	62	(+)	-	-	++	-	-	-	+++
	63	(+)	-	(+)	+++	(+)	-	-	++
	64	(+)	-	(+)	+++	(+)	-	-	+++
	65	(+)	-	(+)	++	++	-	-	+++
	66	-	-	(+)	+++	(+)	-	-	+++
	67	-	-	-	++	(+)	-	-	+++
	68	(+)	(+)	-	+++	+	-	-	+++
	69	d							
	70	(+)	-	(+)	+++	++	-	-	+++

Abbreviations and units are explained in subsection 'Clinical pathology'

- = no trace (+) = traces + = slight ++ = moderate +++ = marked
d = dead before termination of treatment

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Individual values

Females

GROUP	ANIMAL NO	ERYTHRO-CYTES	LEUCO-CYTES	EPITHELIAL CELLS	CRYSTALS	URATES	HYALINE CASTS	GRANULAR CASTS	BACTERIA
1	11	(+)	-	-	++	(+)	-	-	+++
	12	-	-	(+)	++	(+)	-	-	+++
	13	-	-	(+)	++	-	-	-	+++
	14	(+)	-	-	+	-	-	-	++
	15	-	-	(+)	+++	+	-	-	+++
	16	-	-	(+)	++	-	-	-	+++
	17	-	-	(+)	++	+	-	-	++
	18	(+)	(+)	(+)	+++	+	-	-	+++
	19	-	-	(+)	+	-	-	-	+++
	20	-	-	-	++	-	-	-	++
2	32	-	-	+	+++	(+)	-	-	+++
	33	-	-	(+)	++	+	-	-	+++
	34	(+)	-	-	+++	(+)	-	-	+++
	35	(+)	-	(+)	+	+	-	-	+++
	36	(+)	(+)	(+)	++	+	-	-	+++
	37	-	-	(+)	++	+	-	-	++
	38	-	-	-	+	(+)	-	-	++
	39	(+)	-	+	++	++	-	-	+++
	40	-	-	(+)	++	-	-	-	++
	101	1	-	(+)	++	+	-	-	++
	102	1	(+)	(+)	+	(+)	-	-	++
3	51	(+)	(+)	(+)	+	-	-	-	+++
	52	-	-	(+)	++	-	-	-	+++
	53	d	-	-	-	-	-	-	-
	54	-	-	(+)	+++	+	-	-	+++
	55	(+)	-	(+)	+++	+	-	-	++
	56	-	-	-	+	(+)	-	-	++
	57	(+)	-	(+)	+++	+	-	-	+++
	58	-	-	-	++	(+)	-	-	+++
	59	d	-	-	-	-	-	-	-
	60	-	-	-	++	+	-	-	+++

Abbreviations and units are explained in subsection 'Clinical pathology'

- = no trace (+) = traces + = slight ++ = moderate +++ = marked

d = dead before termination of treatment

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Urinalysis - Microscopy

Individual values

Females

GROUP	ANIMAL NO	ERYTHRO- CYTES	LEUCO- CYTES	EPITHELIAL CELLS	CRYSTALS	URATES	HYALINE CASTS	GRANULAR CASTS	BACTERIA
4	71	-	-	(+)	++	-	-	-	+++
	72	-	-	(+)	+	(+)	-	-	++
	73	(+)	(+)	(+)	++	(+)	-	-	+++
	74	-	-	(+)	++	-	-	-	+++
	75	(+)	-	(+)	++	-	-	-	+++
	76	(+)	-	(+)	++	(+)	-	-	+++
	77	(+)	-	-	+++	-	-	-	+++
	78	-	-	(+)	+++	+	-	-	+++
	79	-	-	-	++	+	-	-	+++
	80	(+)	-	-	++	-	-	-	++

Abbreviations and units are explained in subsection 'Clinical pathology'

- = no trace (+) = traces + = slight ++ = moderate +++ = marked

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Organ weight (mg)

Individual values

Males

GROUP	ANIMAL		ADRENALS	BRAIN	EPIDI-						
	NO				DYMIDES	HEART	KIDNEYS	LIVER	SPLEEN	TESTES	THYMUS
1	1		50	2309	1586	1604	3199	18552	1124	3868	347
	2		65	2172	1339	1489	3127	17105	902	3894	346
	3		71	2342	1544	1844	3926	22142	1191	3937	552
	4		61	2101	1520	1517	3505	14838	1043	3560	472
	5		47	2357	1558	1696	3496	19230	1030	3885	510
	6		47	2404	1308	1846	3911	23632	1171	3882	615
	7		45	2166	1271	1566	3125	17842	796	3451	310
	8		55	2451	1362	1753	3727	18311	1100	4550	383
	9		73	2419	1474	1597	3199	17232	913	3965	358
	10		37	2370	1518	1985	3152	17389	975	3689	336
2	21	d	63	2306	1536	2229	3366	15142	1090	3516	926
	22		53	2350	1527	1617	3151	18240	939	3775	548
	23		78	2417	1596	1696	3466	20103	959	4554	345
	24		38	2187	1349	1551	3006	14900	830	3844	409
	25		35	2239	1550	1586	3760	19706	920	3570	376
	26		42	2161	1411	1801	3433	19742	815	3834	294
	27		55	2387	1356	1751	3488	17084	1099	3926	466
	28		51	2185	731	1862	3479	19059	1185	2208	502
	29		56	2328	1729	1567	2967	17655	1159	4164	503
	30		39	2262	1274	1704	2839	14343	785	3230	572
	31		55	2438	1325	1809	3442	17151	1113	3944	531
3	41		51	2420	1683	1867	3625	19701	1247	4158	647
	42		55	2098	1459	1571	3139	15086	1218	3358	434
	43		44	2193	1279	1426	2931	14314	735	3028	447
	44	d	76	2275	1427	2094	3944	17965	1167	3279	631
	45		48	2272	1514	1795	3077	19860	878	4527	353
	46		50	2432	1276	1798	3568	18536	1051	3734	393
	47		68	2325	1357	1938	3764	20109	1125	3922	413
	48		44	2281	1531	1558	3028	15760	959	3753	404
	49		44	2226	1899	1481	2994	13869	873	4175	396
	50		54	2320	1378	1711	3296	18971	1225	3982	437

d = dead before termination of treatment - result excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Organ weight (mg)

Individual values

Males

GROUP	ANIMAL	ADRENALS	BRAIN	EPIDI -	HEART	KIDNEYS	LIVER	SPLEEN	TESTES	THYMUS	
	NO			DYMIDES							
4	61	56	2219	1600	1644	3570	21876	999	3814	758	
	62	57	2159	1259	1610	3302	17380	935	3597	373	
	63	64	2339	1421	1725	3494	21103	1097	3960	312	
	64	46	2138	1266	1540	3172	18215	960	3970	651	
	65	55	2165	1198	1569	2749	16359	965	4002	362	
	66	57	2321	1406	1656	3266	15914	1079	3861	475	
	67	55	2303	1462	1634	3146	16707	894	4193	405	
	68	40	2177	1450	1631	3311	18449	1018	3776	203	
	69	d	56	2323	1208	1769	3228	16525	1050	3404	756
	70	62	2494	1495	1602	3143	17311	959	4088	412	

d = dead before termination of treatment - result excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Relative (% of body wt) organ weight

Individual values

Males

GROUP	ANIMAL NO	BODY WT, g	ADRENALS	BRAIN	EPIDI- DYMIDES	HEART	KIDNEYS	LIVER	SPLEEN	TESTES	THYMUS
1	1	506	0.0099	0.456	0.313	0.317	0.632	3.67	0.222	0.76	0.069
	2	449	0.0145	0.484	0.298	0.332	0.696	3.81	0.201	0.87	0.077
	3	576	0.0123	0.407	0.268	0.320	0.682	3.84	0.207	0.68	0.096
	4	432	0.0141	0.486	0.352	0.351	0.811	3.43	0.241	0.82	0.109
	5	553	0.0085	0.426	0.282	0.307	0.632	3.48	0.186	0.70	0.092
	6	606	0.0078	0.397	0.216	0.305	0.645	3.90	0.193	0.64	0.101
	7	483	0.0093	0.448	0.263	0.324	0.647	3.69	0.165	0.71	0.064
	8	522	0.0105	0.470	0.261	0.336	0.714	3.51	0.211	0.87	0.073
	9	536	0.0136	0.451	0.275	0.298	0.597	3.21	0.170	0.74	0.067
	10	540	0.0069	0.439	0.281	0.368	0.584	3.22	0.181	0.68	0.062
2	21	d 493	0.0128	0.468	0.312	0.452	0.683	3.07	0.221	0.71	0.188
	22	509	0.0104	0.462	0.300	0.318	0.619	3.58	0.184	0.74	0.108
	23	528	0.0148	0.458	0.302	0.321	0.656	3.81	0.182	0.86	0.065
	24	429	0.0089	0.510	0.314	0.362	0.701	3.47	0.193	0.90	0.095
	25	507	0.0069	0.442	0.306	0.313	0.742	3.89	0.181	0.70	0.074
	26	521	0.0081	0.415	0.271	0.346	0.659	3.79	0.156	0.74	0.056
	27	511	0.0108	0.467	0.265	0.343	0.683	3.34	0.215	0.77	0.091
	28	459	0.0111	0.476	0.159	0.406	0.758	4.15	0.258	0.48	0.109
	29	498	0.0112	0.467	0.347	0.315	0.596	3.55	0.233	0.84	0.101
	30	441	0.0088	0.513	0.289	0.386	0.644	3.25	0.178	0.73	0.130
	31	516	0.0107	0.472	0.257	0.351	0.667	3.32	0.216	0.76	0.103
3	41	529	0.0096	0.457	0.318	0.353	0.685	3.72	0.236	0.79	0.122
	42	428	0.0129	0.490	0.341	0.367	0.733	3.52	0.285	0.78	0.101
	43	423	0.0104	0.518	0.302	0.337	0.693	3.38	0.174	0.72	0.106
	44	d 480	0.0158	0.474	0.297	0.436	0.822	3.74	0.243	0.68	0.131
	45	507	0.0095	0.448	0.299	0.354	0.607	3.92	0.173	0.89	0.070
	46	525	0.0095	0.463	0.243	0.342	0.680	3.53	0.200	0.71	0.075
	47	535	0.0127	0.435	0.254	0.362	0.704	3.76	0.210	0.73	0.077
	48	483	0.0091	0.472	0.317	0.323	0.627	3.26	0.199	0.78	0.084
	49	436	0.0101	0.511	0.436	0.340	0.687	3.18	0.200	0.96	0.091
	50	508	0.0106	0.457	0.271	0.337	0.649	3.73	0.241	0.78	0.086

d = dead before termination of treatment - result excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Relative (% of body wt) organ weight

Individual values

Males

GROUP	ANIMAL NO	BODY WT, g	EPIDI-								
			ADRENALS	BRAIN	DYMIDES	HEART	KIDNEYS	LIVER	SPLEEN	TESTES	THYMUS
4	61	548	0.0102	0.405	0.292	0.300	0.651	3.99	0.182	0.70	0.138
	62	470	0.0121	0.459	0.268	0.343	0.703	3.70	0.199	0.77	0.079
	63	533	0.0120	0.439	0.267	0.324	0.656	3.96	0.206	0.74	0.059
	64	494	0.0093	0.433	0.256	0.312	0.642	3.69	0.194	0.80	0.132
	65	462	0.0119	0.469	0.259	0.340	0.595	3.54	0.209	0.87	0.078
	66	459	0.0124	0.506	0.306	0.361	0.712	3.47	0.235	0.84	0.103
	67	475	0.0116	0.485	0.308	0.344	0.662	3.52	0.188	0.88	0.085
	68	460	0.0087	0.473	0.315	0.355	0.720	4.01	0.221	0.82	0.044
	69	d 388	0.0144	0.599	0.311	0.456	0.832	4.26	0.271	0.88	0.195
	70	516	0.0120	0.483	0.290	0.310	0.609	3.35	0.186	0.79	0.080

d = dead before termination of treatment - result excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Organ weight (mg)

Individual values

Females

GROUP	ANIMAL NO	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	OVARIES	SPLEEN	THYMUS	UTERUS
1	11	68	2080	1168	2052	9152	103	603	446	575
	12	69	1896	1027	1888	8966	103	689	303	557
	13	60	2035	957	1688	8200	91	576	338	699
	14	62	2215	1114	2021	10062	101	733	418	594
	15	70	2145	1154	2056	9597	94	677	280	602
	16	76	2149	1107	1892	9734	113	591	288	690
	17	78	2012	1182	1829	8342	78	565	322	733
	18	64	2080	1115	1895	9847	112	635	306	517
	19	75	2211	1337	1970	9126	99	655	291	1100
	20	67	2120	1081	2165	9055	103	703	422	560
2	32	57	2090	1006	2240	10839	104	630	361	1406
	33	74	2211	1056	1955	10802	90	740	361	526
	34	78	2260	1280	2002	9414	94	645	222	655
	35	59	2015	1218	1865	9857	86	579	245	604
	36	72	2181	1068	2025	10306	108	787	493	702
	37	58	2039	1226	1967	10386	80	722	282	497
	38	75	2278	1369	2194	12171	154	861	419	463
	39	61	2022	1144	1717	9524	101	684	332	574
	40	68	2047	1092	1904	8985	85	689	309	703
	101	1	72	2030	1027	1730	128	539	223	899
	102	1	78	2208	1258	1819	102	609	274	847
3	51	80	2114	1066	2043	10790	109	835	434	522
	52	72	2104	1145	1991	11110	103	659	336	609
	53	d	101	2103	1316	2286	13750	98	698	732
	54		76	2138	929	2052	9943	96	655	391
	55		63	2085	1111	1768	9092	105	648	337
	56		66	2183	1113	2099	8734	112	560	324
	57		62	2023	1128	2032	9895	84	607	343
	58		81	2190	1260	1807	9473	100	635	274
	59	d	70	1998	1070	1538	9775	56	523	510
	60		63	2018	835	1804	8045	75	625	294

d = dead before termination of treatment - result excluded from statistical analysis

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Organ weight (mg)

Individual values

Females

GROUP	ANIMAL	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	OVARIES	SPLEEN	THYMUS	UTERUS
	NO									
4	71	80	2182	967	2112	9214	124	725	351	968
	72	74	2053	971	1744	8452	109	640	215	788
	73	48	1956	962	2044	9795	99	621	429	687
	74	79	2062	1090	1893	9416	99	639	330	612
	75	68	2119	1126	1926	9805	145	875	350	564
	76	67	2144	1038	1846	9816	84	655	260	758
	77	68	2338	1205	2087	10469	117	667	275	712
	78	64	2077	996	2120	9814	114	514	307	669
	79	75	2174	1222	2177	10732	92	767	256	613
	80	80	1968	1139	2046	9193	90	546	267	581

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3⁺ CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Relative (% of body wt) organ weight

Individual values

Females

GROUP	ANIMAL NO	BODY WT, g	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	OVARIES	SPLEEN	THYMUS	UTERUS
1	11	273	0.0249	0.762	0.428	0.752	3.35	0.0377	0.221	0.163	0.211
	12	275	0.0251	0.689	0.373	0.687	3.26	0.0375	0.251	0.110	0.203
	13	257	0.0233	0.792	0.372	0.657	3.19	0.0354	0.224	0.132	0.272
	14	292	0.0212	0.759	0.382	0.692	3.45	0.0346	0.251	0.143	0.203
	15	288	0.0243	0.745	0.401	0.714	3.33	0.0326	0.235	0.097	0.209
	16	263	0.0289	0.817	0.421	0.719	3.70	0.0430	0.225	0.110	0.262
	17	275	0.0284	0.732	0.430	0.665	3.03	0.0284	0.205	0.117	0.267
	18	288	0.0222	0.722	0.387	0.658	3.42	0.0389	0.220	0.106	0.180
	19	271	0.0277	0.816	0.493	0.727	3.37	0.0365	0.242	0.107	0.406
	20	276	0.0243	0.768	0.392	0.784	3.28	0.0373	0.255	0.153	0.203
2	32	320	0.0178	0.653	0.314	0.700	3.39	0.0325	0.197	0.113	0.439
	33	293	0.0253	0.755	0.360	0.667	3.69	0.0307	0.253	0.123	0.180
	34	298	0.0262	0.758	0.430	0.672	3.16	0.0315	0.216	0.074	0.220
	35	283	0.0208	0.712	0.430	0.659	3.48	0.0304	0.205	0.087	0.213
	36	295	0.0244	0.739	0.362	0.686	3.49	0.0366	0.267	0.167	0.238
	37	305	0.0190	0.669	0.402	0.645	3.41	0.0262	0.237	0.092	0.163
	38	352	0.0213	0.647	0.389	0.623	3.46	0.0438	0.245	0.119	0.132
	39	274	0.0223	0.738	0.418	0.627	3.48	0.0369	0.250	0.121	0.209
	40	272	0.0250	0.753	0.401	0.700	3.30	0.0313	0.253	0.114	0.258
	101	1 243	0.0296	0.835	0.423	0.712	3.79	0.0527	0.222	0.092	0.370
	102	1 252	0.0310	0.876	0.499	0.722	3.49	0.0405	0.242	0.109	0.336
3	51	285	0.0281	0.742	0.374	0.717	3.79	0.0382	0.293	0.152	0.183
	52	279	0.0258	0.754	0.410	0.714	3.98	0.0369	0.236	0.120	0.218
	53	d 269	0.0375	0.782	0.489	0.850	5.11	0.0364	0.259	0.272	0.141
	54	283	0.0269	0.755	0.328	0.725	3.51	0.0339	0.231	0.138	0.278
	55	288	0.0219	0.724	0.386	0.614	3.16	0.0365	0.225	0.117	0.311
	56	279	0.0237	0.782	0.399	0.752	3.13	0.0401	0.201	0.116	0.213
	57	311	0.0199	0.650	0.363	0.653	3.18	0.0270	0.195	0.110	0.255
	58	284	0.0285	0.771	0.444	0.636	3.34	0.0352	0.224	0.096	0.236
	59	d 188	0.0372	1.063	0.569	0.818	5.20	0.0298	0.278	0.271	0.228
	60	253	0.0249	0.798	0.330	0.713	3.18	0.0296	0.247	0.116	0.199

d = dead before termination of treatment - result excluded from statistical analysis

1 = data collected 14 days after other animals - results excluded from statistical analysis

ACYLTRANSFERASE BL1
(Bacillus licheniformis strain BML780-KLM3' CAP50)(GICC 3265)

A 13-Week Oral (Gavage) Toxicity Study in Rats

Relative (% of body wt) organ weight

Individual values

Females

GROUP	ANIMAL NO	BODY									
		WT, g	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	OVARIES	SPLEEN	THYMUS	UTERUS
4	71	270	0.0296	0.808	0.358	0.782	3.41	0.0459	0.269	0.130	0.359
	72	272	0.0272	0.755	0.357	0.641	3.11	0.0401	0.235	0.079	0.290
	73	294	0.0163	0.665	0.327	0.695	3.33	0.0337	0.211	0.146	0.234
	74	269	0.0294	0.767	0.405	0.704	3.50	0.0368	0.238	0.123	0.228
	75	254	0.0268	0.834	0.443	0.758	3.86	0.0571	0.344	0.138	0.222
	76	260	0.0258	0.825	0.399	0.710	3.78	0.0323	0.252	0.100	0.292
	77	306	0.0222	0.764	0.394	0.682	3.42	0.0382	0.218	0.090	0.233
	78	269	0.0238	0.772	0.370	0.788	3.65	0.0424	0.191	0.114	0.249
	79	294	0.0255	0.739	0.416	0.740	3.65	0.0313	0.261	0.087	0.209
	80	287	0.0279	0.686	0.397	0.713	3.20	0.0314	0.190	0.093	0.202

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TEST ITEM : Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR : Genencor International Inc.	PathData\System V6.2a2

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EXPLANATION OF CODES AND SYMBOLS

CODES AND SYMBOLS USED AT ANIMAL LEVEL:

M = Male animal
F = Female animal
K0 = Terminal sacrifice group
+ = Intercurrent death/sacrificed moribund
+1 = Found dead
+2 = Sacrificed moribund

CODES AND SYMBOLS USED AT ORGAN LEVEL:

G = Gross observation checked off histologically
! = Gross observat.not checked off histologically
* = Comment in text of individual animal data
0 = Tissue not present for histologic examination
' = Histologic examination not required
+ = Organ examined, findings present
- = Organ examined, no pathologic findings noted (AOFT only)
? = Re-examination required
(= Only one of paired organs examined/present

CODES AND SYMBOLS USED AT FINDING LEVEL:

GRADE 1 = Minimal / very few / very small
GRADE 2 = Slight / few / small
GRADE 3 = Moderate / moderate number / moderate size
P = Finding present, severity not scored
(= Finding unilateral in paired organs

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TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

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NUMBER OF ANIMALS WITH NECROPSY FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

ORGAN/FINDING	DOSE GROUP:		1		2		3		4	
	SEX:		M	F	M	F	M	F	M	F
	ANIM.EXAM.:		-	1	2	-	1	2	1	-
LUNG	:									
- discoloration, red.	:		-	-	-	-	-	1	-	-
SMALL INTESTINE	:									
- reddened.	:		-	-	-	-	-	1	-	-
TESTES	:									
- diminished in size.	:		-	-	1	-	-	-	-	-
EPIDIDYMIDES	:									
- diminished in size.	:		-	-	1	-	-	-	-	-
THYMUS	:									
- hemorrhage.	:		-	-	1	-	-	-	-	-
EYES	:									
- perforation.	:		-	1	-	-	-	-	-	-

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TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
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NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

	DOSE GROUP:		1	4
SEX :	M	F	M	F
NO.ANIMALS:	10	10	10	10
BRAIN :	10	10	10	10
- Mononucl cells focal:	-	-	1	-
Grade 1:	-	-	1	-
HEART :	10	10	10	10
- Pericarditis, focal :	1	-	1	-
Grade 1:	1	-	1	-
- Fibrosis, focal :	-	1	-	-
Grade 1:	-	1	-	-
- Mononucl cells focal:	1	-	2	-
Grade 1:	1	-	2	-
LUNG :	10	10	10	10
- Alveolitis, focal :	5	5	4	8
Grade 1:	5	5	3	8
Grade 2:	-	-	1	-
- Alv macrophages/foam:	1	-	1	-
Grade 1:	1	-	1	-
- Osseous metaplasia :	1	-	-	-
ESOPHAGUS :	10	10	10	10
- Mononucl cells focal:	-	-	1	-
Grade 1:	-	-	1	-
STOMACH NONGLANDULAR :	10	10	10	10
- Inflam cells focal :	1	-	-	-
Grade 1:	1	-	-	-
STOMACH GLANDULAR :	10	10	10	10
- Mononucl cells focal:	1	-	-	-
Grade 1:	1	-	-	-
- Glandular dilatation:	3	4	2	2
Grade 1:	3	4	2	2
DUODENUM :	10	10	10	10
- Mononucl cells focal:	1	-	-	-
Grade 1:	1	-	-	-

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SUMMARY TABLES

PROJECT : :

TEST ITEM : Acyltransferase BL1

PATHOL. NO.: 62129 GN

TEST SYSTEM : RAT, 13 WEEK, ORAL

DATE : 17-OCT-06

SPONSOR : Genencor International Inc.

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NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX

STATUS AT NECROPSY: K0, INCL. DEATHS

	DOSE GROUP:		1	4
SEX :	M	F	M	F
NO.ANIMALS:	10	10	10	10
RECTUM :	10	10	10	10
- Mononucl cells focal:	-	-	-	1
Grade 1:	-	-	-	1
LIVER :	10	10	10	10
- Mononucl cells/EMH :	3	3	-	3
Grade 1:	3	3	-	3
- Peri-/arteritis foc.:	1	-	1	-
Grade 2:	1	-	-	-
Grade 3:	-	-	1	-
- Single cell necrosis:	1	-	-	-
Grade 1:	1	-	-	-
- Vacuolation, focal :	2	-	2	-
Grade 1:	2	-	2	-
PANCREAS :	10	10	10	9
- Mononucl cells focal:	-	1	-	-
Grade 1:	-	1	-	-
- Exocrine atrophy foc:	1	-	1	-
Grade 1:	1	-	1	-

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TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
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NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

	DOSE GROUP:		1		4	
SEX :	M	F	M	F	M	F
NO. ANIMALS:	10	10	10	10	10	10
KIDNEYS :	10	10	10	10	10	10
- Tubular baso/dilat. :	8	1	6	3	8	1
Grade 1:	5	1	5	3	5	1
Grade 2:	3	-	1	-	3	-
- Mineralization focal:	-	3	-	4	-	4
Grade 1:	-	3	-	4	-	4
- Tubular casts, focal:	6	1	3	4	6	1
Grade 1:	4	1	2	4	4	1
Grade 2:	2	-	1	-	2	-
- Hyperplasia urothel.:	1	3	2	-	1	3
Grade 1:	1	3	2	-	1	3
- Glomerulosclerosis :	-	-	1	-	-	-
Grade 1:	-	-	1	-	-	-
- Mononucl cells focal:	5	1	1	4	5	1
Grade 1:	5	1	1	4	5	1
- Pelvic dilatation :	-	1	-	-	-	1
Grade 1:	-	1	-	-	-	1
URINARY BLADDER :	9	10	10	9	9	10
- Mononucl cells focal:	1	-	2	2	1	-
Grade 1:	1	-	2	2	1	-
TESTES :	10	-	10	-	10	-
- Tubular atrophy foc.:	1	-	-	-	1	-
Grade 1:	1	-	-	-	1	-
EPIDIDYMIDES :	10	-	10	-	10	-
- Mononucl cells focal:	3	-	2	-	3	-
Grade 1:	3	-	2	-	3	-
PROSTATE GLAND :	10	-	10	-	10	-
- Mononucl cells focal:	6	-	6	-	6	-
Grade 1:	5	-	6	-	5	-
Grade 2:	1	-	-	-	1	-
PITUITARY GLAND :	10	10	10	10	10	10
- Cyst(s), focal :	5	2	2	-	5	2

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TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData#System V6.2a2

NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

	DOSE GROUP: 1		4	
SEX :	M	F	M	F
NO.ANIMALS:	10	10	10	10
ADRENAL GLANDS :	10	10	10	10
- Vacuolation, cortex :	1	-	2	-
Grade 1:	1	-	2	-
THYMUS :	10	10	10	10
- Hemorrhage, focal :	4	4	4	4
Grade 1:	4	4	4	4
SKIN/SUBCUTIS :	10	10	10	10
- Mononucl cells focal:	-	-	1	-
Grade 1:	-	-	1	-

THYROID GLAND

STERNUM

RECTUM

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
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[illegible]

STERNUM

RECTUM

[illegible]

MESENT. LYMPH NODE

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TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)
DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	41	42	43	44	45	46	47	48	49	50
	MKO	MKO	MKO	MKO+	MKO	MKO	MKO	MKO	MKO	MKO
GENERAL OBSERVATIONS				*						
BRAIN				-						
SPINAL CORD, CERVIC.				-						
SPINAL CORD, THORAC.				-						
SPINAL CORD, LUMBAR				-						
SCIATIC NERVE, RIGHT				-						
HEART				-						
AORTA				-						
TRACHEA				+						
- Mononucle cells focal				1.						
LUNG				+						
- Alveolitis, focal				2.						
- Alv macrophages/foam				3.						
- Alveolar hemorrhage				2.						
- Foreign material				P.						
ESOPHAGUS				-						
STOMACH NONGLANDULAR				-						
STOMACH GLANDULAR				-						
DUODENUM				-						
JEJUNUM				-						
ILEUM				-						
CECUM				-						

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TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData#System V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)

DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	41	42	43	44	45	46	47	48	49	50
	MKO	MKO	MKO	MKO+	MKO	MKO	MKO	MKO	MKO	MKO
COLON				-						
RECTUM				-						
LIVER				-						
PANCREAS				-						
KIDNEYS				+						
- Tubular baso/dilat.				1.						
URINARY BLADDER				-						
TESTES				-						
EPIDIDYIMIDES				-						
PROSTATE GLAND				-						
SEMIN.VESICLE				-						
PITUITARY GLAND				-						
THYROID GLAND				-						
PARATHYROID GLANDS				-						
ADRENAL GLANDS				-						
SPLEEN				-						
BONE MARROW SMEAR				OG						
THYMUS				+						
- Hemorrhage, focal				2.						
MESENT. LYMPH NODE				-						
MANDIBULAR LN RIGHT				-						

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TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData7System	V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)
DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	41	42	43	44	45	46	47	48	49	50
	MKO	MKO	MKO	MKO+	MKO	MKO	MKO	MKO	MKO	MKO
SUBLING. GLAND, RIGHT				-						
SUBMANDIB. GLD. RIGHT				-						
MAMMARY GLAND				-						
SKIN/SUBCUTIS				-						
SKELETAL MUSCLE				-						
EYES				-	(
OPTIC NERVES				-						
STERNUM				-						

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TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)

DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	51	52	53	54	55	56	57	58	59	60
	FKO	FKO	FKO+	FKO	FKO	FKO	FKO	FKO	FKO+	FKO
GENERAL OBSERVATIONS	.	.	+	+	.
BRAIN	.	.	-	-	.
SPINAL CORD, CERVIC.	.	.	-	-	.
SPINAL CORD, THORAC.	.	.	-	-	.
SPINAL CORD, LUMBAR	.	.	-	-	.
SCIATIC NERVE, RIGHT	.	.	-	-	.
HEART	.	.	-	-	.
AORTA	.	.	-	-	.
TRACHEA	.	.	-	-	.
LUNG	.	.	+G	+	.
- Alveolitis, focal	.	.	1.	1.	.
- Pleuritis, multifoc.	.	.	1.
- Alv macrophages/foam	1.	.
- Alveolar hemorrhage	.	.	1.
- Foreign material	P.	.
ESOPHAGUS	.	.	-	-	.
STOMACH NONGLANDULAR	.	.	-	-	.
STOMACH GLANDULAR	.	.	+	-	.
- Glandular dilatation	.	.	1.
SMALL INTESTINE	.	.	-G
DUODENUM	.	.	+	-	.
- Congestion	.	.	P.
JEJUNUM	.	.	+	-	.
- Hemorrhage	.	.	P.

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INDIVIDUAL ANIMAL DATA

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TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData7System V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)

DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	51	52	53	54	55	56	57	58	59	60
	FKO	FKO	FKO+	FKO	FKO	FKO	FKO	FKO	FKO+	FKO
ILEUM			-						-	
CECUM			-						-	
COLON			-						-	
RECTUM			-						-	
LIVER			+						-	
- Vacuolation, focal			1.						.	
PANCREAS			-						-	
KIDNEYS			+						-	
- Tubular baso/dilat.			1.						.	
URINARY BLADDER			-						-	
OVARIES			-						-	
UTERUS			-*						-	
CERVIX			-						-	
VAGINA			-						-	
PITUITARY GLAND			-						-	
THYROID GLAND			-						-	
PARATHYROID GLANDS			-						0	
ADRENAL GLANDS			+						-	
- Vacuolation, cortex			1.						.	
SPLEEN			+						-	
- Increased EMH focal			1.						.	
BONE MARROW SMEAR			OG						OG	

PATHOLOGY REPORT	PAGE	:	21/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)

DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER :

	51	52	53	54	55	56	57	58	59	60
	FK0	FK0	FK0+	FK0	FK0	FK0	FK0	FK0	FK0+	FK0
THYMUS	'	'	-	'	'	'	'	'	-	'
MESENT. LYMPH NODE	'	'	-	'	'	'	'	'	-	'
MANDIBULAR LN RIGHT	'	'	-	'	'	'	'	'	-	'
SUBLING.GLAND, RIGHT	'	'	-	'	'	'	'	'	-	'
SUBMANDIB.GLD. RIGHT	'	'	-	'	'	'	'	'	-	'
MAMMARY GLAND	'	'	-	'	'	'	'	'	-	'
SKIN/SUBCUTIS	'	'	-	'	'	'	'	'	-	'
SKELETAL MUSCLE	'	'	-	'	'	'	'	'	-	'
EYES	'	'	-	'	'	'	'	'	-	'
OPTIC NERVES	'	'	-	'	'	'	'	'	-	'
STERNUM	'	'	-	'	'	'	'	'	-	'

ILEUM

PATHOLOGY REPORT PAGE : 23/ 91
 INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
 TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
 SPONSOR : Genencor International Inc. PathData#System V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)

DOSE GROUP : 4, 41.00 mg/kg

ANIMAL NUMBER :

	61	62	63	64	65	66	67	68	69	70
	MKO	MKO	MKO	MKO	MKO	MKO	MKO	MKO	MKO+	MKO
CECUM	-	-	-	-	-	-	-	-	-	-
COLON	-	-	-	-	-	-	-	-	-	-
RECTUM	-	-	-	-	-	-	-	-	-	-
LIVER	+	+	-	-	+	-	-	-	-	-
- Peri-/arteritis foc.	3.
- Vacuolation, focal	1.	1.
PANCREAS	-	-	-	+	-	-	-	-	-	-
- Exocrine atrophy foc	.	.	.	1.
KIDNEYS	+	-	+	-	+	+	+	+	-	-
- Tubular baso/dilat.	1.	.	1.	.	1.	(1.	1.	2.	.	.
- Tubular casts, focal	1.	(1.	.	2.	.	.
- Hyperplasia urothel.	(1.	(1.	.	.
- Glomerulosclerosis	.	.	(1.
- Mononucl cells focal	(1.	.	.
URINARY BLADDER	-	-	-	+	-	+	-	-	-	-
- Mononucl cells focal	.	.	.	1.	.	1.
TESTES	-	-	-	-	-	-	-	-	-	-
EPIDIDYMIDES	-	+	-	+	-	-	-	-	-	-
- Mononucl cells focal	.	(1.	.	1.
PROSTATE GLAND	-	+	+	+	-	-	+	+	-	+
- Mononucl cells focal	.	1.	1.	1.	.	.	1.	1.	.	1.
SEMIN.VESICLE	-	-	-	-	-	-	-	-	-	-
PITUITARY GLAND	-	-	-	-	-	-	-	-	+	+
- Cyst(s), focal	P.	P.
THYROID GLAND	-	-	0	-	-	(-	-	-	-	-
PARATHYROID GLANDS	-	-	0	-	-	0	-	0	-	-

[illegible]

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 25/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (AOFT)
DOSE GROUP : 4, 41.00 mg/kg

ANIMAL NUMBER :

	71	72	73	74	75	76	77	78	79	80
	FKO	FKO	FKO	FKO	FKO	FKO	FKO	FKO	FKO	FKO
BRAIN	-	-	-	-	-	-	-	-	-	-
SPINAL CORD, CERVIC.	-	-	-	-	-	-	-	-	-	-
SPINAL CORD, THORAC.	-	-	-	-	-	-	-	-	-	-
SPINAL CORD, LUMBAR	-	-	-	-	-	-	-	-	-	-
SCIATIC NERVE, RIGHT	-	-	-	-	-	-	-	-	-	-
HEART	-	-	-	-	-	-	-	-	-	-
AORTA	-	-	-	-	-	-	-	-	-	-
TRACHEA	-	-	-	-	-	-	-	-	-	-
LUNG	-	-	+	+	+	+	+	+	+	+
- Alveolitis, focal	.	.	1.	1.	1.	1.	1.	1.	1.	1.
ESOPHAGUS	-	-	-	-	-	-	-	-	-	-
STOMACH NONGLANDULAR	-	-	-	-	-	-	-	-	-	-
STOMACH GLANDULAR	+	-	-	-	+	-	-	-	-	-
- Glandular dilatation	1.	.	.	.	1.
DUODENUM	-	-	-	-	-	-	-	-	-	-
JEJUNUM	-	-	-	-	-	-	-	-	-	-
ILEUM	-	-	-	-	-	-	-	-	-	-
CECUM	-	-	-	-	-	-	-	-	-	-
COLON	-	-	-	-	-	-	-	-	-	-
RECTUM	-	-	-	-	+	-	-	-	-	-
- Mononucl cells focal	1.

[illegible]

STERNUM

PATHOLOGY REPORT	PAGE	:	28/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

ANIMAL HEADING DATA

DOSE GROUP : 1, 0 mg/kg

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY	TEST DAYS	FIRST AND LAST DAY UNDER TEST	DATE OF NECROPSY
1	M	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
2	M	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
3	M	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
4	M	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
5	M	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
6	M	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
7	M	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
8	M	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
9	M	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
10	M	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
11	F	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
12	F	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
13	F	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
14	F	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
15	F	K0	K0	91	25-APR-06 24-JUL-06 24-JUL-06
16	F	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
17	F	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
18	F	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
19	F	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06
20	F	K0	K0	92	25-APR-06 25-JUL-06 25-JUL-06

PATHOLOGY REPORT		PAGE	:	29/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN		
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06		
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2		

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 1
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

HEART:

-Pericarditis, focal, chronic, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular casts, focal, at corticomedullary junction, unilateral,
grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

ADRENAL GLANDS:

-Vacuolation, cortex, zona fasciculata, diffuse, macrovesc.,
bilateral, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 2
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	:	30/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	1, 0 mg/kg		MALE

CONT./FF. ANIMAL NO. : 2

* MICROSCOPIC FINDINGS

LUNG:

- Alveolitis, focal, mainly perivascular/-arterial, grade 1
- Osseous metaplasia

STOMACH NONGLANDULAR PART:

- Inflammatory cells, mixed, focal, at limiting ridge, grade 1

KIDNEYS:

- Tubular basophilia/dilatation, focal, bilateral, grade 1

URINARY BLADDER:

Tissue not present for histologic examination

THYMUS:

- Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 3

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

- Alveolar macrophages/foam cells, focal, grade 1

PANCREAS:

- Exocrine pancreatic cell atrophy, focal, grade 1

KIDNEYS:

- Tubular basophilia/dilatation, focal, unilateral, grade 1

PATHOLOGY REPORT	PAGE	:	31/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

CONT./FF. ANIMAL NO. : 3

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 4

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:
-Glandular dilatation, focal, grade 1
LIVER:
-Periarteritis/arteritis, focal, chronic, grade 2
KIDNEYS:
-Tubular basophilia/dilatation, focal, unilateral, grade 1
-Tubular casts, focal, at corticomedullary junction, unilateral,
grade 1
-Hyperplasia, urothelial, focal, unilateral, grade 1
PROSTATE GLAND:
-Mononuclear cells, focal, in the interstitium, grade 1
PITUITARY GLAND:
-Cyst(s), focal, pars distalis
THYMUS:
-Hemorrhage, focal, grade 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	32/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 5
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

STOMACH GLANDULAR PART:

-Mononuclear cells, focal, in submucosa, grade 1

LIVER:

-Single cell necrosis, focal, grade 1

-Vacuolation, focal, macrovesicular, in single lobe, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 2

-Tubular casts, focal, at corticomedullary junction, bilateral,
grade 2

-Mononuclear cells, focal, unilateral, grade 1

TESTES:

-Tubular atrophy, focal, unilateral, grade 1

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT		PAGE	:	33/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 92 * ANIMAL NO. : 6

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

-Tubular casts, focal, at corticomedullary junction, bilateral,
grade 1

-Mononuclear cells, focal, related to basophilic tubules,
bilateral, grade 1

EPIDIDYMIDES:

-Mononuclear cells, focal, in the interstitium, bilateral,
grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 2

PITUITARY GLAND:

-Cyst(s), focal, pars distalis

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 34/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS

DOSE GROUP : 1, 0 mg/kg

MALE

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 7

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 2

-Tubular casts, focal, at corticomedullary junction, bilateral,
grade 1

-Mononuclear cells, focal, related to basophilic tubules,
bilateral, grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

PITUITARY GLAND:

-Cyst(s), focal, pars distalis

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	35/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS

DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 8

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

DUODENUM:

-Mononuclear cells, focal, in lamina propria, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

-Mononuclear cells, focal, related to basophilic tubules,
bilateral, grade 1

URINARY BLADDER:

-Mononuclear cells, focal, in submucosa, grade 1

EPIDIDYMIDES:

-Mononuclear cells, focal, in the interstitium, unilateral,
grade 1

PITUITARY GLAND:

-Cyst(s), focal, pars distalis

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	36/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 9

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

HEART:

-Mononuclear cells, focal, grade 1

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Mononuclear cells, focal, subcapsular, unilateral, grade 1

EPIDIDYMIDES:

-Mononuclear cells, focal, in the interstitium, bilateral,
grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

PITUITARY GLAND:

-Cyst(s), focal, pars intermedius

THYROID GLAND (BOTH LOBES):

Only one of paired organs examined/present

PARATHYROID GLANDS:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	37/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 1, 0 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 10

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

LIVER:

-Vacuolation, focal, macrovesicular, in single lobe, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 2

-Tubular casts, focal, at corticomedullary junction, bilateral,
grade 2

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

ADRENAL GLANDS:

Only one of paired organs examined/present

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	38/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS

DOSE GROUP	:	1, 0 mg/kg	FEMALE
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* STATE AT NECROPSY: K0

DAYS ON TEST	:	91	* ANIMAL NO. :	11
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* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Hyperplasia, urothelial, focal, unilateral, grade 1
-Pelvic dilatation, bilateral, grade 1

UTERUS:

diestrus

THYMUS:

-Hemorrhage, focal, grade 1

MAMMARY GLAND:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST	:	91	* ANIMAL NO. :	12
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* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	: 39/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	: :

TEST ITEM : Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR : Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS		
DOSE GROUP : 1, 0 mg/kg		FEMALE

CONT./FF. ANIMAL NO. : 12

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, unilateral, grade 1

-Mineralization, focal, bilateral, grade 1

-Hyperplasia, urothelial, focal, unilateral, grade 1

UTERUS:

proestrus

MANDIBULAR LYMPH NODE, RIGHT:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 13

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

KIDNEYS:

-Mineralization, focal, bilateral, grade 1

PATHOLOGY REPORT	PAGE	:	40/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	1, 0 mg/kg	FEMALE

CONT./FF. ANIMAL NO. : 13

UTERUS:

estrus

PARATHYROID GLANDS:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 14

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

CECUM:

Tissue not present for histologic examination

UTERUS:

estrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	41/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	1, 0 mg/kg	FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 15
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:
-Alveolitis, focal, mainly perivascular/-arterial, grade 1
PANCREAS:
-Mononuclear cells, focal, perivascular/interstitial, grade 1
UTERUS:
proestrus
SUBLINGUAL GLAND (RIGHT):
Tissue not present for histologic examination
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 16
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:
-Alveolitis, focal, mainly perivascular/-arterial, grade 1
KIDNEYS:
-Mineralization, focal, bilateral, grade 1
-Tubular casts, focal, unilateral, grade 1

PATHOLOGY REPORT	PAGE	:	42/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	1, 0 mg/kg		FEMALE

CONT./FF. ANIMAL NO. : 16

.....

-Mononuclear cells, focal, related to glomerulus, unilateral,
grade 1

UTERUS:

proestrus

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 17

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

UTERUS:

estrus

PITUITARY GLAND:

-Cyst(s), focal, pars intermedius

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	43/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	1, 0 mg/kg	FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 18
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:
-Alveolitis, focal, mainly perivascular/-arterial, grade 1
UTERUS:
diestrus
PITUITARY GLAND:
-Cyst(s), focal, pars intermedius
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 19
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

SPINAL CORD (CERVICAL SEGMENT):
Tissue not present for histologic examination
SPINAL CORD (THORACIC SEGMENT):
Tissue not present for histologic examination
SPINAL CORD (LUMBAR SEGMENT):
Tissue not present for histologic examination

PATHOLOGY REPORT		PAGE	:	44/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	1, 0 mg/kg			FEMALE

CONT./FF. ANIMAL NO. : 19

HEART:

-Fibrosis, focal, subendocardial, grade 1

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

UTERUS:

proestrus going towards estrus

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 20

* NECROPSY FINDINGS

EYES:

01: Left: Perforation.

NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Hyperplasia, urothelial, focal, unilateral, grade 1

UTERUS:

proestrus

PATHOLOGY REPORT	PAGE	:	45/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\$System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS	
DOSE GROUP	: 1, 0 mg/kg FEMALE

CONT./FF. ANIMAL NO. : 20

EYES:

No microscopic finding corresponding to necropsy observation no. 01.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	46/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

ANIMAL HEADING DATA
DOSE GROUP : 2, 4.56 mg/kg

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY	TEST DAYS	FIRST AND LAST DAY UNDER TEST	DATE OF NECROPSY	
21	M	K0	+2	74	25-APR-06 07-JUL-06	07-JUL-06
22	M	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
23	M	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
24	M	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
25	M	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
26	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
27	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
28	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
29	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
30	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
31	M	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
32	F	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
33	F	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
34	F	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
35	F	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
36	F	K0	K0	91	25-APR-06 24-JUL-06	24-JUL-06
37	F	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
38	F	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
39	F	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
40	F	K0	K0	92	25-APR-06 25-JUL-06	25-JUL-06
101	F	K0	K0	93	09-MAY-06 08-AUG-06	08-AUG-06
102	F	K0	K0	93	09-MAY-06 08-AUG-06	08-AUG-06

PATHOLOGY REPORT	PAGE	:	47/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg MALE

* STATE AT NECROPSY: K0/+2
DAYS ON TEST : 74 * ANIMAL NO. : 21

* NECROPSY FINDINGS

THYMUS:
01: Hemorrhage.
NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

LUNG:
-Alveolitis, focal, mainly perivascular/-arterial, grade 1
ESOPHAGUS:
Tissue not present for histologic examination
STOMACH GLANDULAR PART:
-Glandular dilatation, focal, grade 1
COLON:
Tissue not present for histologic examination
LIVER:
-Bile duct/oval cell hyperplasia, focal, grade 1
-Pericholangitis, focal, grade 1
-Vacuolation, focal, macrovesicular, mainly centrilobular,
grade 1
KIDNEYS:
-Tubular basophilia/dilatation, focal, bilateral, grade 1
-Tubular dilatation, multifocal, with flattened epithelium,
bilateral, grade 3
-Inflammation, focal, suburothelial, unilateral, grade 1
-Hyperplasia, urothelial, focal, above inflammation, unilateral,
grade 1
PROSTATE GLAND:
-Mononuclear cells, focal, in the interstitium, grade 1
THYROID GLAND (BOTH LOBES):
Tissue not present for histologic examination
PARATHYROID GLANDS:
Tissue not present for histologic examination

PATHOLOGY REPORT	PAGE	:	48/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg MALE

CONT./FF. ANIMAL NO. : 21

THYMUS:

-Hemorrhage, focal, grade 3

This finding corresponds to necropsy observation no: 01.

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 22

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 23

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT PAGE : 49/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg MALE

CONT./FF. ANIMAL NO. : 23
.....

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 24
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 25
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT PAGE : 50/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData*System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg MALE

CONT./FF. ANIMAL NO. : 25

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92 * ANIMAL NO. : 26

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92 * ANIMAL NO. : 27

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	:	51/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	2, 4.56 mg/kg		MALE

CONT./FF. ANIMAL NO. : 27

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 28

* NECROPSY FINDINGS

TESTES:

01: Right: Diminished in size.

EPIDIDYMIDES:

01: Right: Diminished in size.

NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 52/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg

MALE

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 29

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 30

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT PAGE : 53/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathDataSystem V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 92 * ANIMAL NO. : 31
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	54/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 32
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 33
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT PAGE : 55/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 34

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 35

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT PAGE : 56/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 36

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 37

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	57/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\$System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 2, 4.56 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 38

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 39

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	58/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS

DOSE GROUP	:	2, 4.56 mg/kg	FEMALE
------------	---	---------------	--------

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 40
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 106 * ANIMAL NO. : 101
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	59/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS	
DOSE GROUP	: 2, 4.56 mg/kg
	FEMALE

* STATE AT NECROPSY: K0	
DAYS ON TEST	: 106
	* ANIMAL NO. : 102

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 60/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

ANIMAL HEADING DATA

DOSE GROUP : 3, 13.68 mg/kg

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY	TEST DAYS	FIRST AND LAST DAY UNDER TEST	DATE OF NECROPSY
41	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
42	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
43	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
44	M	K0 +1	73	25-APR-06 06-JUL-06	06-JUL-06
45	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
46	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
47	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
48	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
49	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
50	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
51	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
52	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
53	F	K0 +1	29	25-APR-06 23-MAY-06	23-MAY-06
54	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
55	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
56	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
57	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
58	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
59	F	K0 +1	12	25-APR-06 06-MAY-06	06-MAY-06
60	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06

PATHOLOGY REPORT	PAGE	:	61/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData/System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 91 * ANIMAL NO. : 41

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: KO
DAYS ON TEST : 91 * ANIMAL NO. : 42

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	62/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	3, 13.68 mg/kg		MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 43
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0/+1
DAYS ON TEST : 73 * ANIMAL NO. : 44
.....

* NECROPSY FINDINGS

BONE MARROW SMEAR:
01: Tissue not preserved.
NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

GENERAL OBSERVATIONS:
Autolytic changes present in a proportion of tissues
examined.
TRACHEA:
-Mononuclear cells, focal, in submucosa, grade 1
LUNG:
-Alveolitis, focal, mainly perivascular/-arterial, grade 2
-Alveolar macrophages/foam cells, diffuse, grade 3
-Alveolar hemorrhage, diffuse, grade 2
-Foreign material, diffuse, in the alveoles and bronchi

PATHOLOGY REPORT	PAGE	:	63/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	3, 13.68 mg/kg		MALE

CONT./FF. ANIMAL NO. : 44

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

BONE MARROW SMEAR:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

THYMUS:

-Hemorrhage, focal, grade 2

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 45

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

EYES:

Only one of paired organs examined/present

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	64/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS

DOSE GROUP	:	3, 13.68 mg/kg	MALE
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* STATE AT NECROPSY: K0

DAYS ON TEST	:	92	* ANIMAL NO. :	46
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* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0				
DAYS ON TEST	:	92	* ANIMAL NO. :	47

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	65/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS	
DOSE GROUP	: 3, 13.68 mg/kg
	MALE

* STATE AT NECROPSY: K0	
DAYS ON TEST	: 92
	* ANIMAL NO. : 48

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0	
DAYS ON TEST	: 92
	* ANIMAL NO. : 49

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	66/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:		:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathDataSystem	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	3, 13.68 mg/kg		MALE

* STATE AT NECROPSY:	K0			
DAYS ON TEST	:	92	* ANIMAL NO. :	50

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 67/ 91
PROJECT :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg

FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91

* ANIMAL NO. : 51

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91

* ANIMAL NO. : 52

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	68/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg FEMALE

* STATE AT NECROPSY: K0/+1
DAYS ON TEST : 29 * ANIMAL NO. : 53

* NECROPSY FINDINGS

LUNG:

01: All lobes: discoloration, red.

SMALL INTESTINE:

01: Peyer's patches: Reddened, Many.

BONE MARROW SMEAR:

01: Tissue not preserved.

NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

GENERAL OBSERVATIONS:

Autolytic changes present in a proportion of tissues examined.

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

-Pleuritis, multifocal, grade 1

-Alveolar hemorrhage, diffuse, grade 1

This finding corresponds to necropsy observation no: 01.

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

DUODENUM:

-Congestion

JEJUNUM:

-Hemorrhage

This finding corresponds to necropsy observation no.: 01
in the SMALL INTESTINE.

LIVER:

-Vacuolation, diffuse, macrovescicular, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

UTERUS:

proestrus

PATHOLOGY REPORT	PAGE	:	69/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	3, 13.68 mg/kg		FEMALE

CONT./FF. ANIMAL NO. : 53

ADRENAL GLANDS:

-Vacuolation, cortex, zona fasciculata, diffuse, macrovesc.,
bilateral, grade 1

SPLEEN:

-Increased extramedullary haematopoiesis, focal, grade 1

BONE MARROW SMEAR:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 54

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 70/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 55

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 56

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

PAGE : 71/ 91
PROJECT : :

TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.

PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 57

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 58

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT	PAGE	:	72/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData7System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS	
DOSE GROUP : 3, 13.68 mg/kg	FEMALE

* STATE AT NECROPSY: K0/+1

DAYS ON TEST	:	12	* ANIMAL NO. :	59
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* NECROPSY FINDINGS

BONE MARROW SMEAR:

01: Tissue not preserved.

NO OTHER NECROPSY OBSERVATIONS NOTED

* MICROSCOPIC FINDINGS

GENERAL OBSERVATIONS:

Autolytic changes present in a proportion of tissues examined.

LUNG:

- Alveolitis, focal, mainly perivascular/-arterial, grade 1
- Alveolar macrophages/foam cells, focal, grade 1
- Foreign material, diffuse, in the alveoles

PARATHYROID GLANDS:

Tissue not present for histologic examination

BONE MARROW SMEAR:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT PAGE : 73/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 3, 13.68 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 60
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

NO EXAMINATION REQUIRED.

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATAPAGE : 74/ 91
PROJECT : :TEST ITEM : Acyltransferase BL1
TEST SYSTEM : RAT, 13 WEEK, ORAL
SPONSOR : Genencor International Inc.PATHOL. NO.: 62129 GN
DATE : 17-OCT-06
PathData\System V6.2a2

ANIMAL HEADING DATA

DOSE GROUP : 4, 41.00 mg/kg

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY	TEST DAYS	FIRST AND LAST DAY UNDER TEST	DATE OF NECROPSY
61	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
62	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
63	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
64	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
65	M	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
66	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
67	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
68	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
69	M	K0 +1	37	25-APR-06 31-MAY-06	31-MAY-06
70	M	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
71	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
72	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
73	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
74	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
75	F	K0 K0	91	25-APR-06 24-JUL-06	24-JUL-06
76	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
77	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
78	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
79	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06
80	F	K0 K0	92	25-APR-06 25-JUL-06	25-JUL-06

PATHOLOGY REPORT	PAGE	:	75/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 61
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

ESOPHAGUS:

-Mononuclear cells, focal, in tunica muscularis, grade 1

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

LIVER:

-Vacuolation, focal, macrovesicular, in single lobe, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

-Hyperplasia, urothelial, focal, unilateral, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 62
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	:	76/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS				
DOSE GROUP	:	4, 41.00 mg/kg		MALE

CONT./FF. ANIMAL NO. : 62

* MICROSCOPIC FINDINGS

BRAIN:

-Mononuclear cells, focal, subependymal, grade 1

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

-Alveolar macrophages/foam cells, focal, grade 1

LIVER:

-Vacuolation, focal, macrovesicular, in single lobe, grade 1

EPIDIDYMIDES:

-Mononuclear cells, focal, in the interstitium, unilateral,
grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

ADRENAL GLANDS:

-Vacuolation, cortex, zona fasciculata, diffuse, microvesc.,
bilateral, grade 1

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 63

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	:	77/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg MALE

CONT./FF. ANIMAL NO. : 63

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

-Glomerulosclerosis, focal, single glomerulus, unilateral, grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

THYROID GLAND (BOTH LOBES):

Tissue not present for histologic examination

PARATHYROID GLANDS:

Tissue not present for histologic examination

ADRENAL GLANDS:

Only one of paired organs examined/present

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 64

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

HEART:

-Mononuclear cells, focal, grade 1

PANCREAS:

-Exocrine pancreatic cell atrophy, focal, grade 1

PATHOLOGY REPORT		PAGE	:	78/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	4, 41.00 mg/kg			MALE

CONT./FF. ANIMAL NO. : 64

URINARY BLADDER:

-Mononuclear cells, focal, in submucosa, grade 1

EPIDIDYMIDES:

-Mononuclear cells, focal, in the interstitium, bilateral,
grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

SKIN/SUBCUTIS:

-Mononuclear cells, focal, subepidermal/dermal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 91

* ANIMAL NO. : 65

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

LIVER:

-Periarteritis/arteritis, focal, chronic, grade 3

KIDNEYS:

-Tubular basophilia/dilatation, focal, bilateral, grade 1

-Tubular casts, focal, bilateral, grade 1

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	79/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 66

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

KIDNEYS:

- Tubular basophilia/dilatation, focal, unilateral, grade 1
- Tubular casts, focal, unilateral, grade 1

URINARY BLADDER:

- Mononuclear cells, focal, in submucosa, grade 1

THYROID GLAND (BOTH LOBES):

Only one of paired organs examined/present

PARATHYROID GLANDS:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 67

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT		PAGE	:	80/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	4, 41.00 mg/kg			MALE

CONT./FF. ANIMAL NO. : 67

* MICROSCOPIC FINDINGS

HEART:

- Pericarditis, focal, chronic, grade 1
- Mononuclear cells, focal, grade 1

LUNG:

- Alveolitis, focal, subacute, mainly perivascular/-arterial, grade 2

KIDNEYS:

- Tubular basophilia/dilatation, focal, bilateral, grade 1

PROSTATE GLAND:

- Mononuclear cells, focal, in the interstitium, grade 1

ADRENAL GLANDS:

- Vacuolation, cortex, zona fasciculata, diffuse, macrovesc., bilateral, grade 1

THYMUS:

- Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 68

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT	PAGE	:	81/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg MALE

CONT./FF. ANIMAL NO. : 68

* MICROSCOPIC FINDINGS

KIDNEYS:

- Tubular basophilia/dilatation, focal, bilateral, grade 2
- Tubular casts, multifocal, bilateral, grade 2
- Hyperplasia, urothelial, focal, unilateral, grade 1
- Mononuclear cells, focal, unilateral, grade 1

PROSTATE GLAND:

- Mononuclear cells, focal, in the interstitium, grade 1

PARATHYROID GLANDS:

Tissue not present for histologic examination

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0/+1

DAYS ON TEST : 37

* ANIMAL NO. : 69

* NECROPSY FINDINGS

BONE MARROW SMEAR:

01: Tissue not preserved.

EYES:

01: Tissue not preserved.

OPTIC NERVES:

01: Tissue not preserved.

NO OTHER NECROPSY OBSERVATIONS NOTED

PATHOLOGY REPORT	PAGE	:	82/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	4, 41.00 mg/kg	MALE

CONT./FF. ANIMAL NO. : 69

* MICROSCOPIC FINDINGS

GENERAL OBSERVATIONS:

Autolytic changes present in a proportion of tissues examined.

PITUITARY GLAND:

-Cyst(s), focal, pars distalis

BONE MARROW SMEAR:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

EYES:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

OPTIC NERVES:

Tissue not present for histologic examination

No microscopic finding corresponding to necropsy observation no. 01.

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 70

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, incl. single cyst, grade 1

PROSTATE GLAND:

-Mononuclear cells, focal, in the interstitium, grade 1

PATHOLOGY REPORT PAGE : 83/ 91
INDIVIDUAL ANIMAL DATA PROJECT : :

TEST ITEM : Acyltransferase BL1 PATHOL. NO.: 62129 GN
TEST SYSTEM : RAT, 13 WEEK, ORAL DATE : 17-OCT-06
SPONSOR : Genencor International Inc. PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg MALE

CONT./FF. ANIMAL NO. : 70
.....

PITUITARY GLAND:

-Cyst(s), focal, pars distalis

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	84/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	4, 41.00 mg/kg	FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 71
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

STOMACH GLANDULAR PART:
-Glandular dilatation, focal, grade 1
KIDNEYS:
-Mineralization, focal, bilateral, grade 1
UTERUS:
estrus
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 72
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

KIDNEYS:
-Tubular casts, focal, in single tubule, unilateral, grade 1
UTERUS:
estrus
THYMUS:
-Hemorrhage, focal, grade 1

PATHOLOGY REPORT		PAGE	:	85/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	4, 41.00 mg/kg			FEMALE

CONT./FF. ANIMAL NO. : 72

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0		
DAYS ON TEST	:	91
		* ANIMAL NO. : 73

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular casts, focal, unilateral, grade 1

URINARY BLADDER:

-Mononuclear cells, focal, in submucosa, grade 1

UTERUS:

proestrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	86/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 74
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Mineralization, focal, unilateral, grade 1

-Mononuclear cells, focal, suburothelial, unilateral, grade 1

URINARY BLADDER:

Tissue not present for histologic examination

UTERUS:

Diestrus going towards proestrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 91 * ANIMAL NO. : 75
.....

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT		PAGE	:	87/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData#System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	4, 41.00 mg/kg			FEMALE

CONT./FF. ANIMAL NO. : 75

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

STOMACH GLANDULAR PART:

-Glandular dilatation, focal, grade 1

RECTUM:

-Mononuclear cells, focal, in submucosa, grade 1

PANCREAS:

Tissue not present for histologic examination

URINARY BLADDER:

-Mononuclear cells, focal, in submucosa, grade 1

UTERUS:

proestrus

PARATHYROID GLANDS:

Tissue not present for histologic examination

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 76

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

PATHOLOGY REPORT		PAGE	:	88/	91
INDIVIDUAL ANIMAL DATA		PROJECT	:		

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN	
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	:	17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2	

TEXT OF GROSS AND MICROSCOPIC FINDINGS					
DOSE GROUP	:	4, 41.00 mg/kg			FEMALE

CONT./FF. ANIMAL NO. : 76

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Mineralization, focal, bilateral, grade 1

-Mononuclear cells, focal, suburothelial, unilateral, grade 1

UTERUS:

proestrus going towards estrus

THYROID GLAND (BOTH LOBES):

Tissue not present for histologic examination

PARATHYROID GLANDS:

Tissue not present for histologic examination

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 77

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Tubular casts, focal, unilateral, grade 1

-Mononuclear cells, focal, unilateral, grade 1

PATHOLOGY REPORT	PAGE	:	89/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS			
DOSE GROUP	:	4, 41.00 mg/kg	FEMALE

CONT./FF. ANIMAL NO. : 77

UTERUS:

proestrus

THYMUS:

-Hemorrhage, focal, grade 1

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0

DAYS ON TEST : 92

* ANIMAL NO. : 78

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

LIVER:

-Mononuclear cells/extramedullary haematopoiesis, focal,
grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, unilateral, grade 1

UTERUS:

diestrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

PATHOLOGY REPORT	PAGE	:	90/ 91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.: 62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE : 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 4, 41.00 mg/kg FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 79

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, unilateral, grade 1

UTERUS:

proestrus going towards estrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 80

* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

* MICROSCOPIC FINDINGS

LUNG:

-Alveolitis, focal, mainly perivascular/-arterial, grade 1

KIDNEYS:

-Tubular basophilia/dilatation, focal, unilateral, grade 1

-Mineralization, focal, bilateral, grade 1

-Tubular casts, multifocal, bilateral, grade 1

-Mononuclear cells, focal, related to basophilic tubules,

PATHOLOGY REPORT	PAGE	:	91/	91
INDIVIDUAL ANIMAL DATA	PROJECT	:	:	:

TEST ITEM	:	Acyltransferase BL1	PATHOL. NO.:	62129 GN
TEST SYSTEM	:	RAT, 13 WEEK, ORAL	DATE	: 17-OCT-06
SPONSOR	:	Genencor International Inc.	PathData\System	V6.2a2

TEXT OF GROSS AND MICROSCOPIC FINDINGS	
DOSE GROUP	: 4, 41.00 mg/kg FEMALE

CONT./FF. ANIMAL NO. : 80

unilateral, grade 1

UTERUS:

estrus

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS.



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To: Quang Bui

From: Christine Rechichi, Kelly Altman

Date: September 12, 2006

Subject: Analytical Determination of Dosing Preparations

Study: No. 62129

Test Material: Acyltransferase BL 1 (*Bacillus licheniformis* strain BML780-KLM3'
CAP50)(GICC 3265)

Samples collected: Weeks 1, 6 and 13

Purpose

Scantox collected samples during the Acyltransferase BL 1 tox study to be analyzed for dose verification. The samples were sent to the Genencor BioAnalytical group for dose verification by total protein analysis.

Total Protein Results by SOP #R-SOP-AL-070-01

The Total Protein results below are reported in mg/ml. Total protein is determined by nitrogen analysis using a conversion of 6.25g protein /g nitrogen.

Dose concentration	21/4-2006	26/5-06	21/7-06
0 mg/ml	<0.60	<0.59	<0.64
0.91 mg/ml	1.51	1.27	0.99
2.74 mg/ml	3.03	2.71	2.89
8.20 mg/ml	7.56	7.95	8.16

BioAnalytical Chemist:

Christine Rechichi Date: 9/18/06
Christine Rechichi

Site QA Representative:

Kelly A. Altman Date: 9/18/06
Kelly Altman

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CERTIFICATE OF ANALYSIS

Name of Test Article: ACYLTRANSFERASE BL1

Production/Strain Name: *Bacillus licheniformis* BML780-KLM3' CAP50.

Production Site: Rochester, USA

Genencor International Culture Collection Number: GICC 3265

Designation of Lot Tested: 20068010

Description: Clear brown liquid

Expiration Date: Stable for at least 1 year from date of issuance when stored frozen

All of the analytical studies listed below were conducted in accordance with GLP regulations and ISO 9002 standards.

RESULTS:

1. Activity: 1156 U/ml
2. Total and TCA Protein
The samples were measured for TCA and total protein by nitrogen analysis (with a KLM3' conversion factor of 5.96 g protein/g nitrogen).

Total Proteins: 30.40 mg/ml
TCA Proteins: 14.13 mg/ml
% Total Organic Solids: 8.67%
(100% – moisture% – ash%)
3. Specific gravity: 1.021 g/ml
4. pH: 6.30
5. Inorganic materials
% Ash: 1.05%
% moisture: 90.28%
6. Microbial analysis: Microbial analysis conducted by GCOR, Rochester, NY

Analysis	Results
Total viable count	< 1CFU/ml
Coliform	< 1CFU/ml

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E. Coli	negative/25 ml
Salmonella	negative/25 ml
Staphylococcus aureus	< 1 CFU/ml
Production strain	negative
Anaerobic sulfite reducers	negative
Antibiotic activity assay	negative

7. Mycotoxin analysis: Not applicable
 8. Heavy metals analysis (conducted at Siliker Laboratories)

Analysis	Results
Heavy metals as Pb	< 30 ppm
Arsenic	< 3 ppm
Lead	< 0.5 ppm
Mercury	< 0.5 ppm
Cadmium	< 5 ppm

9. Stability Data :

Room Temperature (all activity units are reported in U/ml)

Sample ID	Dilution	T = 0	T = 5 hours	% of T = 0
20068010	straight	1094	1088	99.5
20068010	1/2	542	554	102.2
20068010	1/4	274	270	98.5

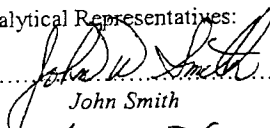
Refrigerator (4C): Undiluted Material

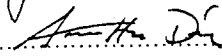
Sample ID	Dilution	T=0	T = 7 days	% of T = 0
20068010	straight	1094	851	77.8
20068010	1/2	542	441	81.3
20068010	1/4	274	220	80.2

Frozen (-20°C) : Undiluted Material

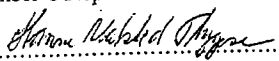
Sample ID	Dilution	T = 0	T = 30 days	% of T = 0	T = 60 days	% of T = 0	T = 90 days	% of T = 0
20068010	straight	1094	1097	100.3	1120	102.4	1106	101.1
20068010	1/2	542	557	102.8	551	101.7	529	97.6
20068010	1/4	274	271	98.9	277	101.1	229	83.6

Bio-Analytical Representatives:

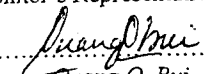
 Date: 7/31/06
John Smith

 Date: 7/31/06
Annette Diaz

Study Sponsor's Representative

 Date: 25 Aug. 2006
Hanne Valsted Thygesen

Study Monitor's Representative:

 Date: 08/02/2006
Quang Q. Bui

LAB SCANTOX HISTORICAL DATA

Rat toxicity studies

Clinical chemistry

breed=Mol:Sprd-SPF

13 weeks studies

SEX	PARAMETER	Number of studies	MEAN	MIN	MAX	95% CONFIDENCE	INTERVALS
						LOWER LIMIT	UPPER LIMIT
male	ALAT	16	2.22	1.70	3.02	1.14	3.29
female	ALAT	16	1.75	1.31	2.15	0.92	2.57
male	ASAT	16	2.15	1.47	2.98	1.01	3.29
female	ASAT	16	1.83	1.23	2.38	0.81	2.85
male	ALKPH	16	3.53	2.22	11.69	1.70	5.36
female	ALKPH	16	2.46	1.70	7.30	1.15	3.78
male	BILI	16	1.15	0.62	1.81	0.17	2.13
female	BILI	16	1.04	0.63	1.52	0.00	2.17
male	GGT	16	0.00	0.00	0.01	0.00	0.01
female	GGT	16	0.01	0.00	0.02	0.00	0.03
male	CHOL	16	2.75	2.24	3.12	1.74	3.75
female	CHOL	16	3.01	1.99	3.51	2.08	3.94
male	TRIG	16	1.93	1.45	2.39	0.99	2.87
female	TRIG	16	1.47	0.83	2.06	0.46	2.47
male	UREA	16	7.56	3.91	8.66	5.91	9.21
female	UREA	16	7.24	4.55	8.20	5.52	8.96
male	CREAT	16	41.45	23.90	56.50	31.88	51.01
female	CREAT	16	42.79	24.10	55.50	31.37	54.20
male	GLUC	16	6.97	5.51	8.99	4.06	9.89
female	GLUC	16	7.05	5.48	8.76	3.90	10.19

LAB SCANTOX HISTORICAL DATA

Rat toxicity studies

Clinical chemistry

breed=Mol:Sprd-SPF

13 weeks studies

SEX	PARAMETER	Number of studies	MEAN	MIN	MAX	95% CONFIDENCE	INTERVALS
						LOWER LIMIT	UPPER LIMIT
male	Na	16	145.13	138.11	150.16	140.37	149.90
female	Na	16	144.03	136.80	149.03	139.45	148.61
male	K	16	6.00	5.51	6.66	4.97	7.04
female	K	16	5.66	4.91	6.65	4.63	6.68
male	Ca	16	2.83	2.59	2.96	2.51	3.16
female	Ca	16	2.89	2.74	3.11	2.69	3.10
male	Mg	16	1.13	0.97	1.35	0.89	1.37
female	Mg	16	1.10	0.87	1.25	0.92	1.29
male	P	16	3.04	2.73	3.38	2.37	3.71
female	P	16	2.61	2.28	3.04	1.92	3.30
male	Cl	16	103.93	101.32	106.63	99.75	108.11
female	Cl	16	104.51	100.43	107.69	99.74	109.27
male	PROTEIN	16	68.28	60.02	71.70	62.51	74.05
female	PROTEIN	16	68.29	59.59	72.68	61.73	74.84
male	ALB	16	39.91	34.54	45.07	35.79	44.03
female	ALB	16	43.08	36.47	47.40	37.89	48.27
male	GLOBULIN	12	27.59	24.53	33.13	23.21	31.98
female	GLOBULIN	12	24.15	21.13	27.86	20.53	27.77
male	ALB/G Ratio	16	1.44	0.97	1.79	1.18	1.70
female	ALB/G Ratio	16	1.75	1.36	2.18	1.41	2.09