

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 |
|---|---|

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: 20-21September, 25-29 September, 02-03October-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

26 October 2006

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 (Mydriacyl, 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™/ACL™ (*) | sec. |
| Prothrombin time (Pt) | IL Test™/ACL™(*) | sec. |
| Fibrinogen (Fib) | IL Test™/ACL™(*) | 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.

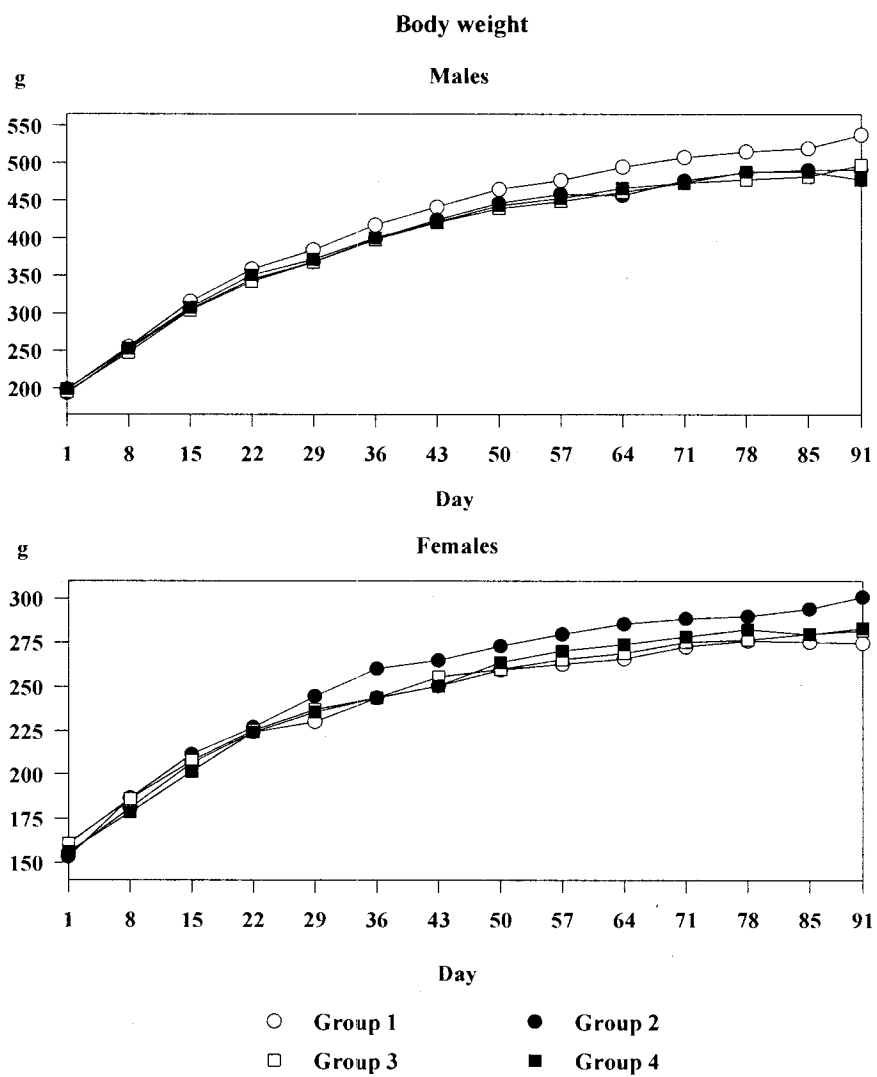
CONCLUSION

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



ACYLTRANSFERASE 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

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 | 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

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 | 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

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 | 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

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

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

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 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

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 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

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 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

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 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

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

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

ACYLTRANFERASE 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

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

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

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

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

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 | 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

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 | 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

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 | 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

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 | 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

ACYLTRANFERASE 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 | PUPIL REFLEX | TOE PINCH REACT. | GRASP RESPONSE | GRIP STRENGTH | EYELID REFLEX | STARTLE RESPONSE | HEAD SHAKE RESPONSE | RIGHTING REFLEX TABLE | RIGHTING REFLEX HAND | PLACING REFLEX | NEGA- TIVE GEOTAXIS |
|-------|--------------|-----------------|------------------------|-------------------|------------------|------------------|---------------------|---------------------------|-----------------------------|----------------------------|-------------------|---------------------------|
| | | | | | | | | | | | | |
| 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]

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 | |
|-------|-----------|------------|----------------------|-------|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-----------|---------|--|
| 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 | 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 | | | |
| 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 | 231 | 225 | 232 | 242 | 247 | 245 | 254 | 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 | 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 |
| 3 | 46 1 | 98.0 | 67.5 | 85.5 | . | 82.5 | 64.0 | 96.0 | 67.0 | 82.5 | 70.5 | 65.0 | . | 92.0 |
| | 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 |
| 4 | 30 | | | | | | | | | | | | | |
| | 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 |
| 4 | 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 | % | | % | | % | | Plt | APTT | Pt | Fib |
|-------|--------------|-----|-----|------|------|------|------|-----|------|------|------|
| | | EOS | EOS | BASO | BASO | MONO | MONO | | | | |
| 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 | % | | % | | % | | Plt | APTT | Pt | Fib |
|-------|--------------|-----|-----|------|------|------|------|-----|------|------|------|
| | | EOS | EOS | BASO | BASO | MONO | MONO | | | | |
| 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 |
| 4 | 61 | 9.3 | 8.47 | 46 | 54 | 1.1 | 20.3 | 10.8 | 6 | 0.7 | 92 |
| | 62 | 9.4 | 9.09 | 47 | 52 | 1.0 | 20.1 | 11.1 | 6 | 0.7 | 93 |
| | 63 | 9.7 | 9.04 | 48 | 53 | 1.1 | 20.1 | 13.6 | 6 | 0.8 | 93 |
| | 64 | 10.0 | 9.16 | 50 | 54 | 1.1 | 20.1 | 22.1 | 6 | 1.4 | 93 |
| | 65 | 9.4 | 9.19 | 47 | 51 | 1.0 | 19.9 | 17.2 | 6 | 1.0 | 93 |
| | 66 | 10.0 | 9.64 | 50 | 51 | 1.0 | 20.1 | 17.3 | 7 | 1.3 | 91 |
| | 67 | 9.5 | 8.76 | 47 | 53 | 1.1 | 20.3 | 18.5 | 6 | 1.1 | 93 |
| | 68 | 9.3 | 8.97 | 46 | 51 | 1.0 | 20.3 | 13.0 | 6 | 0.8 | 93 |
| | 69 | 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 |

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 | | % BASO | | % MONO | | Plt | APTT | Pt | Fib |
|-------|--------------|----------|-----|-----------|------|-----------|------|-----|------|------|------|
| | | EOS | EOS | BASO | BASO | MONO | MONO | | | | |
| 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'

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 | % 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 | % EOS | EOS | % BASO | BASO | % MONO | MONO | Plt | APTT | Pt | Fib |
|-------|--------------|----------|-----|-----------|------|-----------|------|-----|------|------|------|
| 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

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 | % 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 | | Hb | RBC | HT | MCV | MCH | MCHC | WBC | % NEUTRO | | % LYMPHO | |
|-------|--------|----|------|------|------|-----|-----|------|------|-------------|-----|-------------|------|
| | NO | | | | | | | | | | | | |
| 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 |
| 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'

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

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 | | | | | | | | | | | | |
|-------|--------|---|------|------|-------|------|------|------|------|-------|-------|------|
| GROUP | ANIMAL | | ALAT | ASAT | ALKPH | BILI | GGT | CHOL | TRIG | UREA | CREAT | GLUC |
| | NO | | | | | | | | | | | |
| 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 |
| 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

ACYLTRANFERASE 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

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 | 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 | | LEUCO- | | | NITRITE | BLOOD | GLUCOSE | KETONES | BILI- UROBILI- | |
|-------|-----------|----------|-----|--------|---------|-------|---------|-------|---------|---------|----------------|-------|
| | | GRAVITY | pH | COLOUR | 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

ACYLTRANFERASE 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 | SPECIFIC | | | LEUCO- | | | | BLOOD | GLUCOSE | KETONES | BILI- | UROBILI- |
|-------|--------|----------|-------|--------|---------|-------|---------|-------|-------|---------|---------|-------|----------|
| | NO | GRAVITY | pH | COLOUR | PROTEIN | CYTES | NITRITE | 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 |
| | 102 | 1 | 1.020 | 7.0 | y | 0.3 | - | - | - | - | - | - | 3.2 |
| | 3 | 51 | 1.025 | 6.5 | y | Trace | - | + | - | - | - | - | - |
| 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

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 |
|-------|--------------|-------------------|-----------------|---------------------|----------|--------|------------------|-------------------|----------|
| 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

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 |
|-------|--------------|-------------------|-----------------|---------------------|----------|--------|------------------|-------------------|----------|
| 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

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- | | | | | | |
|-------|--------|---|----------|-------|---------|-------|---------|-------|--------|--------|--------|
| | 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 | 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

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

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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

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(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

ACYLTRANFERASE 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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| | 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 |
| ----- | | | |

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PATHOLOGY REPORT

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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

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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| 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. | PathData#System | V6.2a2 |

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

| | DOSE GROUP: | 1 | | 2 | | 3 | | 4 | |
|-----------------------|-------------|---|---|---|---|---|---|---|---|
| | SEX: | M | F | M | F | M | F | M | F |
| ORGAN/FINDING | 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 | - | - | - | - | - | - |

PATHOLOGY REPORT
SUMMARY TABLES

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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

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 | - | - | - |

PATHOLOGY REPORT

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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.

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 |
| 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 | - |

PATHOLOGY REPORT
SUMMARY TABLES

PAGE : 5/ 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

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 | | |
| KIDNEYS : | 10 | 10 | 10 | 10 | | |
| - Tubular baso/dilat. : | 8 | 1 | 6 | 3 | | |
| Grade 1: | 5 | 1 | 5 | 3 | | |
| Grade 2: | 3 | - | 1 | - | | |
| - Mineralization focal: | - | 3 | - | 4 | | |
| Grade 1: | - | 3 | - | 4 | | |
| - Tubular casts, focal: | 6 | 1 | 3 | 4 | | |
| Grade 1: | 4 | 1 | 2 | 4 | | |
| Grade 2: | 2 | - | 1 | - | | |
| - Hyperplasia urothel.: | 1 | 3 | 2 | - | | |
| Grade 1: | 1 | 3 | 2 | - | | |
| - Glomerulosclerosis : | - | - | 1 | - | | |
| Grade 1: | - | - | 1 | - | | |
| - Mononucl cells focal: | 5 | 1 | 1 | 4 | | |
| Grade 1: | 5 | 1 | 1 | 4 | | |
| - Pelvic dilatation : | - | 1 | - | - | | |
| Grade 1: | - | 1 | - | - | | |
| URINARY BLADDER : | 9 | 10 | 10 | 9 | | |
| - Mononucl cells focal: | 1 | - | 2 | 2 | | |
| Grade 1: | 1 | - | 2 | 2 | | |
| TESTES : | 10 | - | 10 | - | | |
| - Tubular atrophy foc.: | 1 | - | - | - | | |
| Grade 1: | 1 | - | - | - | | |
| EPIDIDYMIDES : | 10 | - | 10 | - | | |
| - Mononucl cells focal: | 3 | - | 2 | - | | |
| Grade 1: | 3 | - | 2 | - | | |
| PROSTATE GLAND : | 10 | - | 10 | - | | |
| - Mononucl cells focal: | 6 | - | 6 | - | | |
| Grade 1: | 5 | - | 6 | - | | |
| Grade 2: | 1 | - | - | - | | |
| PITUITARY GLAND : | 10 | 10 | 10 | 10 | | |
| - Cyst(s), focal : | 5 | 2 | 2 | - | | |

PATHOLOGY REPORT
SUMMARY TABLES

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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

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

THYROID GLAND

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

[illegible]

RECTUM

[illegible]

STERNUM

RECTUM

[illegible]

MESENT. LYMPH NODE

STERNUM

| | | | | |
|------------------------|---------|---|-----|----|
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| 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 |

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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 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 :

| | 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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|------------------------|---------|---|-----|----|
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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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| 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 |
|------------------------|-----|-----|------|-----|-----|-----|-----|-----|------|-----|
| | 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. | . | . | . | . | . | . | . |

PATHOLOGY REPORT
INDIVIDUAL ANIMAL DATA

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PROJECT : :

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 | |

ILEUM

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 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 | - | - |

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|------------------------|---------|---|-----|----|
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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 : 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

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|------------------------|---------|-----------------------------|-----------------|-------------|
| 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 STATE OF | FINAL 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 |

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|------------------------|---------|-----------------------------|------------------------|-------------|
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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 | |

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
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* NECROPSY FINDINGS

NO NECROPSY OBSERVATIONS NOTED.

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|--|---------|-----------------------------|----------------|-------------|
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| 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.

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|------------------------|---------|-----------------------------|-----------------|-------------|
| 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.

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|------------------------|---|-----------------------------|-----------------|----------|-----------|
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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 | |

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.

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|------------------------|---------|-----------------------------|-----------------|-------------|
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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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| TEXT OF GROSS AND MICROSCOPIC FINDINGS | |
| DOSE GROUP | : 1, 0 mg/kg |
| | MALE |

| | |
|-------------------------|------------------|
| * STATE AT NECROPSY: K0 | |
| DAYS ON TEST | : 92 |
| | * ANIMAL NO. : 7 |

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* 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.

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|------------------------|---------|---|-----|----|
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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 |

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|--|--------------|
| 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.

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|------------------------|---------|-----------------------------|------------------------|
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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 |

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.

| | | | |
|------------------------|---------|-----------------------------|------------------------|
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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 |

TEXT OF GROSS AND MICROSCOPIC FINDINGS

| | | | |
|------------|---|------------|------|
| DOSE GROUP | : | 1, 0 mg/kg | MALE |
|------------|---|------------|------|

| | | | |
|-------------------------|---|----|-------------------|
| * STATE AT NECROPSY: K0 | | | |
| DAYS ON TEST | : | 92 | * ANIMAL NO. : 10 |

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* 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.

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|------------------------|---------|-----------------------------|------------------------|
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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 |

TEXT OF GROSS AND MICROSCOPIC FINDINGS

| | | | |
|------------|---|------------|--------|
| DOSE GROUP | : | 1, 0 mg/kg | FEMALE |
|------------|---|------------|--------|

* STATE AT NECROPSY: K0

| | | | | |
|--------------|---|----|----------------|----|
| DAYS ON TEST | : | 91 | * ANIMAL NO. : | 11 |
|--------------|---|----|----------------|----|

.....

* 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.

| | | |
|--|-----------------|-------------|
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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 |
| ----- | | |
| 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

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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

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.

| | | | |
|--|---------|-----------------------------|------------------------|
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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 |
| ----- | | | |
| 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

| | | | |
|--|---------|-----------------------------|------------------------|
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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 |
| ----- | | | |
| 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.

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|--|---------|-----------------------------|------------------------|
| 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. | PathData7System 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. | PathData7System | 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. | PathDataSystem | 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: | K0 | | |
| 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. 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. : 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

* STATE AT NECROPSY: K0
DAYS ON TEST : 92 * ANIMAL NO. : 46
.....

* 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.

[illegible]

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. | PathData7System | 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 |
|--------------|---|----|----------------|----|

.....

* 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 |

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|------------------------|---------|---|-----|----|
| 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.



Genencor International®

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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 |

A Danisco Company

| | |
|----------------------------|----------------|
| 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 |

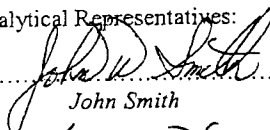
Refrigerator (4C): Undiluted Material

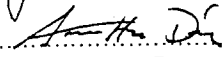
| Sample ID | Dilution | T=0 | T = 7 days | % of T = 0 |
|-----------|----------|------|------------|------------|
| 20068010 | straight | 1094 | 851 | 77.8 |
| 20068010 | 1/2 | 542 | 441 | 81.3 |
| 20068010 | 1/4 | 274 | 220 | 80.2 |

Frozen (-20°C) : Undiluted Material

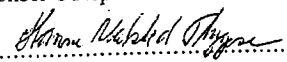
| Sample ID | Dilution | T = 0 | T = 30 days | % of T = 0 | T = 60 days | % of T = 0 | T = 90 days | % of T = 0 |
|-----------|----------|-------|-------------|------------|-------------|------------|-------------|------------|
| 20068010 | straight | 1094 | 1097 | 100.3 | 1120 | 102.4 | 1106 | 101.1 |
| 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:

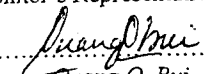
 Date: 7/31/06
John Smith

 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 |