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TEST REPORT

STUDY REPORT NO: MB-**AOT**-106-07

Study Completion Date: 10 May 2007

Title : ACUTE ORAL TOXICITY

VITEX

Study Sponsor :	**Testing Facility :**
Vitex Industries Sdn Bhd E2-2, Jalan Selaman ½, Dataran Palma, 68000 Ampang, Selangor Darul Ehsan.	**Makmal Bioserasi** Institut Biologi Sistem (INBIOSIS), Universiti Kebangsaan Malaysia, Bangi, Selangor Darul Ehsan.

Veterinary Toxicologist : Assoc. Prof. Dr. Md Anuar Osman

Study Director : Dr. Saadiah Sulaiman

Quality Assurance : Arniza Binti A. Rashid

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- It contains 16 pages
- This test report concerns only the product tested.

ACUTE ORAL TOXICITY STUDY

(Animal Study)

Study Director (1)	**Signatures**
Assoc. Prof. Dr Md. Anuar Osman *DVM (Pak), M. Sc (W.Aust),* *PhD (Murdoch).*	 **Date:** 10/5/2007
Study Director (2)	
Dr Saadiah Sulaiman *MBBCh (Dub), MMED (UKM)*	 **Date:** 10/5/07
Sponsor	
VITEX INDUSTRIES SDN. BHD.	**Date:**

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TEST REPORT - Acute Oral Toxicity Study (Limit Test)

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SUMMARY

Acute Oral Toxicity Study of Vitex (LIMIT TEST)

Protocol Reference	: Protocol AL-AOT
Study Completion Date	: 10/5/07
Study Reference Number	: AL-AOT-275-07
Study Report Number	: MB-AOT-106-07
Test Material	: Vitex
Conditions of Use	: Neat
File	: AOT-07

1. OBJECTIVE

To evaluate the toxic potential of a test material by determining the adverse effects occurring within a short time following an oral administration in rats.

2. EXPERIMENTAL PROCEDURE

Animals : Fifteen Sprague Dawley albino rats, (5 for negative control), male/ female
Weight: 68.54 g – 80.25 g

Start of acclimatization	6 April 2007
Date of treatment	13 April 2007
Observation period	13 April 2007 – 26 April 2007
Date of completion	27 April 2007

Treatment

Following 7 days of acclimatization in the laboratory, two groups of animals were treated with a single dose of 2000 mg/kg of the test material by intubation using a plastic gavage tube attached to a 2cc syringe.

3. OBSERVATIONS

The rats were observed for mortality, signs of gross toxicity, behavioral changes and respiratory effects, tremors, convulsion, diarrhea and other effects such as walking backwards. Changes on the fur, and eyes were also observed for.

Clinical Observation

Animals were observed for morbidity and mortality at 1 hour and 3 hours after dose administration on the first day and once daily thereafter for 14 days.

Body weight

Body weights were obtained and recorded prior to initiation, once weekly and at termination (day 14).
Upon termination, all rats were euthanized with chloroform. The major organ systems of the cranial, thoracic and abdominal cavities were grossly examined.

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Gross Necropsy
All animals in the study were subjected to gross necropsy which includes careful examination of the external surface of the body, all orifices and the cranial, thoracic and abdominal cavities and their contents. The kidneys, spleen, brain, lungs, heart and pancreas of all animals were trimmed of any adherent tissue as appropriate, and individually weighed.

4. RESULT

Mortality
There was no death observed during the study.

Clinical Observation
All animals appeared normal throughout the period of study.

Body Weight
There was no remarkable change or difference in body weight.

Gross Necropsy
All necropsied organs, including lungs, kidneys, brain, spleen, heart and pancreas appeared normal on gross necropsy and there was no remarkable weight difference of the individual organ.

5. CONCLUSION

There was no death or remarkable body weight changes during the study. The single dose acute oral LD50 of Vitex is greater than 2000mg/kg of body weight when administrated once orally via gastric intubation to male and female albino rats.

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3.3 Project staff

3.3.1 Study director (1)
Assoc. Prof. Dr Md. Anuar Osman
DVM (Pak), M. Sc (W. Aust), PhD (Murdoch)

3.3.2 Study director (2)
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3.5 Study Timetable

3.5.1	Start of acclimatization period	6 April 2007
	Date of treatment	13 April 2007
	Observation period	13 April 2007 – 27 April 2007
	Date of completion	27 April 2007

3.6 Environment and Husbandry

3.6.1 Species and strain
Sprague Dawley albino rat.

3.6.2 Supplier
Animal Laboratory UKM.

3.6.3 Number of animal and sex.
Fifteen Sprague Dawley albino rats, (5 for negative control), male/ female

3.6.4 Body weight at initiation of treatment.
From: 68.54 g – 80.25 g.

3.6.5 Housing: Animals were housed in a plastic caging with saw dust bedding.
Size of cage: Plastic cage internal dimension: 22cmX 15cmX 37cm. Two to three animals were placed in one cage.

3.6.5.1 Animal Room Temperature: 23^0c to 25^0c

3.6.5.2 Period : 12 hour light/dark cycle

3.6.5.3 Acclimatization period : 7 days

3.6.6 Diet
Mouse pellet

3.6.7 Water
Filtered tap water *ad libitum* continuously supplied through water dispensing bottles.

3.6.8 Contaminant: There were no known contaminants reasonably expected to be found in the food or water at levels which would interfere with the results of the study.

3.7 Pre-Treatment Procedures

3.7.1 Check for ill health
On arrival and just before the beginning of treatment to ensure only healthy animals were used in the study.

3.7.2 Body weight
All animals were weighed on the day just before treatment, once weekly and at termination of study (day 14).

3.7.3 Acclimatization period
At least 5 days between arrival of animals and start of treatment

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3.7.4 Selection and allocation of animal
Rats were selected randomly at the start of the acclimatization period.

3.7.5 Identification

Animals	: Individually numbered (permanent marker pen) on the tail.
Cages	: Labelled with animal number, sex of animal and study reference number
Animal	: Each rat was marked with a color code (permanent marker pen) on the tail and given a sequential animal number assigned to study reference number, which constitutes a unique identification system.

4. TEST METHODS INCLUDING THE SCORING METHOD

4.1 Name of test: Acute Oral Toxicity Study of Vitex (Limit Test)

4.2 Objective
The objective of this study is to determine the potential of the test material to induce acute oral toxicity when administered as a single dose to albino rats.

4.3 Significance and Use
In the assessment and evaluation of the toxic characteristics of a chemical, the determination of acute oral toxicity is usually an initial step. It provides information on health hazards likely to arise from a short-term exposure by the oral route. Data from an acute study serve as a basis for classification and labeling. It is an initial step in establishing a dosage regimen in subchronic and other studies and could provide initial information on the mode of toxic action of a substance.

4.4 Material
4.4.1 Animal model
Fifteen Sprague Dawley albino rats, (5 for negative control), male/ female

4.4.2 Miscellaneous
A 5ml syringe and a plastic tube attached to the syringe.

4.5 Preparation of test material
4.5.1 Dose levels are as listed in the table below:

Test material (mg)	Animal weight (g)
2.0	100
1.2	60
1.0	50

4.5.2 Test Material for oral administration
Test material was given orally in a suspension form through a plastic gavage.

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4.5.3 Route and Rationale of Test Material Administration
The route of test material administration was by oral gastric intubation. This is the route of exposure in human and is the accepted technique for assessment of acute oral toxicity.

4.5.4 Method of Test Material Administration:
Individual doses of the test material were calculated based on body weights obtained just prior to dosing giving a dose level of 2000 mg/kg.

The test material was administered orally via gastric intubation by using a plastic gavage tube attached to an appropriate syringe.

4.5.5 Dose Level/Group/Treatment Regimen:
Two groups of 5 rats were administered with a single dose of 2000mg/kg test material per animal.

4.6 Procedure
4.6.1 Preparation and Selection of Animals

4.6.1.1 On the day before initiation, animals were weighed and the skin, fur and eyes were examined for any abnormalities. The test procedure was conducted following a minimum of 5 day acclimatization period. The animals were fasted for at least 24 hours by removing feed from their cages while continuing with non-stop water supply. Each animal was fed with 2000mg/kg of test material using a plastic gavage. After oral administration, each animal was returned to its cage and feeding was resumed after 3 hours of dosing.

4.6.1.2 Treatment and Observation Period

Rats were observed for mortality, signs of gross toxicity and behavioral changes. Changes on the fur, and eyes were observed. Respiratory effects, tremors, convulsion, diarrhea and other effects such as walking backwards were also observed for.

Clinical Observation
Animals were observed for morbidity and mortality at 1 hour and 3 hours post dosing on the first day, and once daily thereafter for 14 days

Body weight
Body weights were obtained and recorded prior to initiation once, weekly and at termination (day 14).

Gross Necropsy
All animals in the study were subjected to a full, detailed gross necropsy which includes careful examination of the external surfaces of the body, all orifices, and the cranial, thoracic and abdominal cavities and their contents. The kidneys, spleen, brain, lungs, heart and pancreas were trimmed of any adherent tissue, as appropriate and individually weighed.

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4.7 Scoring system

Acute Oral Toxicity Study of Vitex in rats

4.7.1 Table 1a: The observed features are presented as below:

Fur Changes	A
Eyes Changes	B
Respiratory Effect - Increased respiratory depth-slow, labored respiratory - Decreased respiratory depth-slow, rapid respiratory	C a b
Motor activity - Increased motor activity- speed of movement increased - Decreased motor activity- lethartic, does not respond to external stimuli	D a b
Convulsion - Tonic convulsion-sustained spasm with head arched backward - Clonic convulsion- short choppy spasm with head arched toward stomach - Mixed convulsions-combination of clonic and tonic	E a b c
Walking backwards and/or Ataxia-inability to coordinate bodily movement (gross wobbling)	F
Diarrhea	G
Death-self-explantory	H

Table 1b: Severity Score of Observed Changes

Changes	**Score**
Normal/No changes	0
Mild	1
Moderate	2
Severe	3

4.8 Interpretation of Results

The rats were visually assessed for signs of toxicity within 1 hour, 3 hours after feeding and once daily thereafter for 14 days. Any sign of abnormalities are recorded and tabulated.

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5. QUALITY ASSURANCE

The final report was audited in agreement with the raw data records and for compliance with the protocol of Makmal Bioserasi Standard Operating Procedures. Dates of inspections and audits performed during the study and the dates of reporting of the inspection and audit findings to the Study Director and Facility Management were presented in the Quality Assurance Statement.

6. DEVIATIONS FROM APPROVED PROTOCOL

None

7. RECORDS TO BE MAINTAINED

A copy of this signed report, together with the protocol and all raw data generated at the laboratory is retained in the Makmal Bioserasi ARCHIVE-Section 2A.

8. DATES OF INITIATION

Start of acclimatization	6 April 2007
Date of treatment	13 April 2007
Observation period	13 April 2007 – 27 April 2007
Date of completion	27 April 2007

9. SUMMARY OF RESULTS

9.1 Treatment

Test Material: Vitex

Study reference no: AOT-275-07

9.2 Morbidity / Mortality

Animals were examined daily. These observations were recorded in the study raw data documentation and reported. There was no mortality.

9.3 Clinical Observation (Table 2)

All animals appeared normal throughout the study.

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Table 2: Observed Changes during Treatment and Observation Period

Group	Animal		Reading (Day														
	No	Sex	1hr	3hrs	2	3	4	5	6	7	8	9	10	11	12	13	14
			A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H	A-H
1	T1	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T2	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T3	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T4	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T5	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	T6	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T7	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T8	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T9	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	T10	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	C1	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	C2	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	C3	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	C4	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	C5	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

9.4 Body Weight

Individual bodyweights of animals were recorded prior to initiation, and again on the day after completion. There were no remarkable changes and differences observed in body weight between the male and female treatment group at the end of the test period.

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Table 3: Individual Body Weight and Doses- Group Treated with Vitex and Group Treated with Normal Saline

GROUP	ANIMAL NO.	SEX	BODYWEIGHT (g) Initial – Day 0	BODYWEIGHT (g) Initial Day 14	DOSE (g)
(Test Animal)	T1	M	75.65	126.76	1.5
	T2	M	80.25	115.80	1.6
	T3	M	76.06	130.24	1.5
	T4	M	79.32	124.13	1.6
	T5	M	70.18	115.60	1.4
	T6	F	69.49	100.25	1.4
	T7	F	75.31	109.69	1.5
	T8	F	75.32	96.64	1.5
	T9	F	69.72	106.76	1.4
	T10	F	79.64	108.24	1.6
Mean			**75.094**	**113.41**	
Control (Normal Saline)	C1	F	73.36	127.45	1.5
	C2	F	68.54	110.13	1.4
	C3	F	79.24	136.90	1.6
	C4	M	69.46	145.33	1.4
	C5	M	71.26	166.48	1.4
Mean			**72.37**	**137.26**	

9.5 Gross Necropsy

9.5.1 All necropsied organs including, brain, spleen, liver, heart, pancreas, lungs, kidneys and stomach appear normal in gross necropsy.

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9.5.2 Organ Weight Data

Table 4a: Weight of animal and weight of organ (gram) upon necropsy-Test animal

Group	Animal No.	Sex	Weight (g)							
			Brain	Spleen	Liver	Heart	Pancreas	Lungs	Kidneys	Stomach
1	T1	M	1.16	0.32	6.76	0.73	0.26	0.86	1.20	1.42
	T2	M	1.40	0.48	5.72	0.53	0.26	0.73	1.31	1.18
	T3	M	1.22	0.97	6.98	0.50	0.32	0.64	1.60	1.40
	T4	M	1.49	0.43	6.42	0.60	0.52	0.72	1.55	1.63
	T5	M	1.30	0.45	6.09	0.63	0.40	0.84	1.09	1.37
2	T6	F	1.26	0.21	3.84	0.37	0.23	0.72	0.84	0.95
	T7	F	1.25	0.28	4.93	0.56	0.27	0.48	1.20	0.98
	T8	F	1.26	0.19	4.35	0.32	0.26	0.56	0.84	1.08
	T9	F	1.23	0.16	4.47	0.43	0.37	0.73	1.04	1.01
	T10	F	1.28	0.18	5.90	0.56	0.44	0.89	0.98	1.13
Mean			**1.285**	**0.367**	**5.546**	**0.523**	**0.333**	**0.717**	**1.165**	**1.215**

Table 4b: Weight of animal and weight of organ (gram) upon necropsy- Control animal

Group	Animal No.	Sex	Weight (g)							
			Brain	Spleen	Liver	Heart	Pancreas	Lungs	Kidneys	Stomach
Control	C1	F	1.28	0.38	6.36	0.58	0.31	0.82	1.26	1.32
	C2	F	1.37	0.26	5.07	0.52	0.45	0.75	1.19	0.82
	C3	F	1.64	0.46	8.27	0.53	0.48	0.99	1.44	1.52
	C4	M	1.34	0.29	7.26	0.63	0.42	0.96	1.73	1.05
	C5	M	1.49	0.68	9.50	0.71	0.73	1.32	1.92	1.53
Mean			**1.424**	**0.414**	**7.292**	**0.594**	**0.478**	**0.968**	**1.508**	**1.248**

10. ANALYSIS, INTERPRETATION OF RESULTS AND CONCLUSION

10.1 Analysis and interpretation of results

There was no adverse reaction observe following the administration of test material.

10.2 Conclusion

There was no death or remarkable body weight changes during the study. The single dose acute oral LD50 of Vitex is greater than 2000mg/kg of body weight when administrated once orally via gastric intubation to male and female albino rats.

11. REFERENCE

OECD Guideline for Testing of Chemicals, Acute Oral Toxicity. 401.1987

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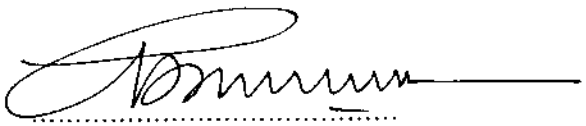
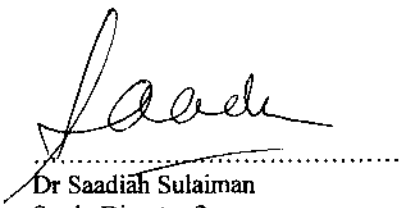
12. VERIFICATION

We the undersigned declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study,



Assoc. Prof. Dr Md. Anuar Osman
Study Director 1

10/5/2007
Date



Dr Saadiah Sulaiman
Study Director 2

10/5/07
Date

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13 QUALITY ASSURANCE INSPECTIONS STATEMENT

The Quality Assurance Unit randomly selects intervals for QA inspections prior to study initiation. Records of the findings of these inspections are kept on file. The summary below provides verification of statements made in the final report section that addresses QA audits.

Inspections were made of:

DATE	PROCEDURE INSPECTED
6/4/07	Animal Care
9/5/07	Raw data
4/5/07	Draft report
10/5/07	Final report

Findings reported to:

Study Director 10/5/07

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Armiza A. Rashid
Quality Assurance Officer.

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