



Propiconazole/Fenpropidin

Propiconazole/Fenpropidin EC (A9050B) - Acute Dermal Toxicity Study in Rats

Final Report

DATA REQUIREMENT(S): OECD 402 (1987)
EPA OPPTS 870.1200 (1998)
EC 440/2008 (2008)

AUTHOR(S): Viktória Zelenák, M.Sc.

STUDY COMPLETION DATE: 06 April 2011

PERFORMING LABORATORY: LAB Research Ltd.
H-8200 Veszprém, Szabadságpuszta
Hungary

LABORATORY PROJECT ID: Report Number: 10/290-002P
Study Number: 10/290-002P
Task Number: TK0037019

SPONSOR(S): Syngenta Ltd.
Jealott's Hill International Research Centre
Bracknell, Berkshire, RG42 6EY, United Kingdom

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study has been performed in accordance with the Principles of Good Laboratory Practice (Hungarian GLP Regulations: 9/2001. (III. 30.) EüM-FVM joint decree of the Minister of Health and the Minister of Agriculture and Regional Development which corresponds to the OECD GLP, ENV/MC/CHEM (98) 17.).

I, the undersigned, declare that this report constitutes a true record of the actions undertaken and the results obtained in the course of this study.

Viktória Zelenák

Viktória Zelenák, M.Sc.
Study Director

06 April 2011

Date

Performing Laboratory: LAB Research Ltd.
H-8200 Veszprém, Szabadságpuszta
Hungary

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FLAGGING STATEMENT

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QUALITY ASSURANCE STATEMENT

Study Code: 10/290-002P

Study title: Propiconazole/Fenpropidin EC (A9050B) - Acute Dermal Toxicity Study in Rats

Test item: Propiconazole/Fenpropidin EC (A9050B)

This study has been inspected, and this report audited by the Quality Assurance Unit in compliance with the Principles of Good Laboratory Practice. As far as it can be reasonably established the methods described and the results incorporated in this report accurately reflect the raw data produced during this study.

All inspections, data reviews and the report audit were reported in written form to the study director and to management. The dates of such inspections and of the report audit are given below:

| Date of Inspection | Phase(s) Inspected/Audited | Date of report to | |
|--------------------|----------------------------|-------------------|------------------|
| | | Management | Study Director |
| 25 November 2010 | Study Plan | 25 November 2010 | 25 November 2010 |
| 08 December 2010 | Treatment | 08 December 2010 | 08 December 2010 |
| 17 February 2011 | Clinical observation | 17 February 2011 | 17 February 2011 |
| 17 March 2011 | Draft Report | 17 March 2011 | 17 March 2011 |
| 05 April 2011 | Final Report | 05 April 2011 | 05 April 2011 |

Signature: Ciucuzay Diana
Diana Ciucuzay, M.Sc.

Date: 06 April 2011

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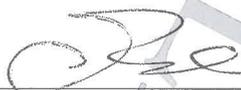
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STATEMENT OF THE MANAGEMENT

According to the conditions of the research and development agreement between Syngenta Ltd. (as Sponsor) and LAB Research Ltd. the study titled "Propiconazole/Fenpropidin EC (A9050B) - Acute Dermal Toxicity Study in Rats" was performed, in compliance with the Principles of Good Laboratory Practice.

Signature: _____



Christopher Banks, DABT
Managing Director

Date: _____

06 April 2011

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GENERAL INFORMATION

Contributors

The following contributed to this report in the capacities indicated:

| Name | Function |
|-------------------------|--|
| Viktória Zelenák, M.Sc. | Study Director |
| Judit Tavaszi, M.Sc. | Assistant Scientist |
| István Pásztor, DVM | Veterinary Control |
| Peter Maslej, DVM, PhD | Head of Pathology |
| Tamás Mészáros, PhD | Technical Team Leader of Central Dispensary Unit |
| Eric Yau | Syngenta Study Manager |

Study dates

5000mg/kg bw (males and females)

| | |
|--------------------------------|------------------|
| Study initiation date: | 02 December 2010 |
| Experimental start date: | 08 December 2010 |
| Experimental termination date: | 22 December 2010 |

2000mg/kg bw (females)

| | |
|--------------------------------|------------------|
| Study initiation date: | 07 February 2011 |
| Experimental start date: | 16 February 2011 |
| Experimental termination date: | 02 March 2011 |

Retention of samples

See in other below

Performing laboratory test substance reference number

100101

Other

The study documents:

- study plan and amendment,
- all raw data,
- sample of the test item,
- original study report and any amendments,
- correspondence

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will be archived according to the Hungarian GLP regulations and to applicable SOP's in the archives of LAB Research Ltd. 8200 Veszprém, Szabadságpuszta, Hungary. This is for a period of 15 years.

After the retention time of 15 years has elapsed all the archived materials listed above will be returned to the Sponsor or retained for a further period if agreed by a contract. Otherwise the materials will be discarded.

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1.0 EXECUTIVE SUMMARY

1.1 Study Design

Two groups of 5 female RjHan:(WI) Wistar rats were treated with either 5000 and 2000 mg/kg bodyweight (bw) with a single dermal application of Propiconazole/Fenpropidin EC (A9050B). Additionally, one group of 5 male RjHan:(WI) Wistar rats was treated with 5000 mg/kg bw. The application period was 24 hours, followed by a 14 day observation period. The test item was applied undiluted as supplied by the Sponsor.

Clinical observations of surviving animals were performed at 1 and 5 hours after dosing and daily for 14 days thereafter. Body weight was measured prior to dosing on Day 0 and on Days 7 and 14. Rats were euthanized and subjected to a gross macroscopic examination at the end of the 2-week observation period (Day 14).

1.2 Results

Propiconazole/Fenpropidin EC (A9050B) caused mortalities at 5000 mg/kg bw (4/5) in females and (1/5) in males. No mortality occurred following a dermal application at 2000 mg/kg bw in female rats.

Clinical signs were noted in all animals. Activity decreased, hunched back, piloerection were observed in the animals. Local signs were noted in all animals. These included erythema, oedema, fur loss, wound, scab, tough and thickening of the treated skin.

Two males treated at 5000 mg/kg bw were observed with slight bodyweight loss during the first week of the observation period. Additionally, one female treated at 5000 mg/kg bw and three female at 2000 mg/kg bw was observed with slight bodyweight loss during the first week of the observation period.

Treatment-related thickening of the treated skin or missing fur/scab at the dorsal/right thoracic/flank area were found in 3/5 premature deceased female rats. In surviving animals treatment-related missing/thin fur and/or scab at the dorsal/right thoracic and/or lumbar area were noted at dose levels of 2000 and 5000 mg/kg.

1.3 Conclusion

The median lethal dose of Propiconazole/Fenpropidin EC (A9050B) after a single dermal administration was found to be greater than 5000 mg/kg bw in male RjHan:(WI) Wistar rats and between 2000 mg/kg bw and 5000 mg/kg bw in female RjHan:(WI) Wistar rats.

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2.0 INTRODUCTION

2.1 Purpose

The purpose of the study was to assess the acute dermal toxicity of Propiconazole/Fenpropidin EC (A9050B) when administered to male and female rats by a single semi-occlusive dermal application at 5000 mg/kg bw and 2000 mg/kg bw (female rats only) followed by an observation period of 14 days.

This study was designed to provide a rational basis for hazard classification.

2.2 Guidelines

The study was performed according to the following guidelines:

OECD Guidelines for Testing of Chemicals, Section 4, Number 402 "Acute Dermal Toxicity", adopted February 24, 1987.

United States Environmental Protection Agency Health Effects Division Test Guidelines, OPPTS 870.1200 Acute Dermal Toxicity EPA 712-C-98-192, August 1998

Commission Regulation (EC) No 440/2008, B.3 (L 142, 30 May 2008)

2.3 Test Facility

This study was performed in an AAALAC-accredited laboratory. The Institutional Animal Care and Use Committee (IACUC) of LAB Research Ltd. reviewed the study plan and authorized the conduct of the study.

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3.0 MATERIALS AND METHODS

3.1 Test Substance

Data as supplied by the Sponsor.

The certificate of analysis is attached in Appendix 1.

Name: Propiconazole/Fenpropidin EC (A9050B)
Batch number: SMO0G120
Purity: Propiconazole – 129 g/L corresponding to 13.6 % w/w
Fenpropidin – 278 g/L corresponding to 29.2 % w/w
Product code: A9050B
Appearance: Brown liquid
Density: 952 kg/m³
Reanalysis date: End of September 2015
Storage conditions: Room temperature (<30 °C)
Safety Precautions: Routine safety precautions (lab coat, gloves, goggles, face mask) for unknown materials were applied to assure personnel health and safety

3.1.1 Identification and receipt of the test substance

Test item's name as it appears in the report: Propiconazole/Fenpropidin EC (A9050B)

The test item of a suitable chemical purity was provided by the Sponsor. All precautions required in the handling and disposal of the test item were outlined by the Sponsor. The test item was identified by the Central Dispensary of LAB Research Ltd. on the basis of the information supplied by the Sponsor.

3.1.2 Formulation

The test item was administered as a single dose, as supplied by the Sponsor.

3.1.3 Other materials

For euthanasia:

Name: Euthasol[®] 40 %
Lot No.: 10C25 7
Expiry Date: February 2013
Produced by: AST Beheer B.V. Oudewater Netherlands

3.2 Experimental Design

3.2.1 Doses

Justification of the doses:

The limit test at 5000 mg/kg bw was adequate for males. For females the test substance was toxic at 5000 mg/kg bw in the first part of the study. A further dose level at 2000 mg/kg was conducted in females only according to OECD 402, Commission Regulation (EC) No 440/2008 B.3 and OPPTS 870.1200

3.2.2 Experimental design

| Dose Group | Number of cages | Number of animals |
|-------------------------------|-----------------|-------------------|
| Male group 5000 mg/kg bw | Cages 1-5 | 5 |
| Female group 5000 mg/kg bw | Cages 6-10 | 5 |
| Female group 2000 mg/kg bw | Cages 11-15 | 5 |

A single administration was performed by the dermal route and was followed by a fourteen-day observation period. The test item was applied undiluted as delivered by the Sponsor.

The application volume was 5.25 mL/kg bw ($\times 952 \text{ mg/mL} = 5000 \text{ mg/kg}$) at 5000 mg/kg bw and 2.10 mL/kg bw ($\times 952 \text{ mg/mL} = 2000 \text{ mg/kg}$) at 2000mg/kg/bw.

3.2.3 Procedure

The backs of the animals were shaven (approximately 10 % area of the total body surface) approximately 24 hours prior to the treatment. Only those animals without injury or irritation on the skin were used in the test.

On test day 0, the test item was applied at a single dose of 5000 mg/kg body weight on males and females and 2000 mg/kg bw on females applied uniformly over the skin and remained on the skin throughout a 24- hour exposure period. Sterile gauze pads were placed on the skin of rats at the site of application. These gauze pads were kept in contact with the skin by a patch with adhesive hypoallergenic plaster. The entire trunk of the animal was then wrapped with semi occlusive plastic wrap for 24 hours. At the end of the exposure period, residual test item was removed, using body temperature water.

3.2.4 Clinical observations

A clinical examination was performed on the day of treatment, at 1 and 5 hours after the application of the test item, and once each day for 14 days thereafter.

Observations included the skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous system, and somatomotor activity and behaviour pattern. Particular attention was directed to the observation of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma.

3.2.5 Measurement of body weight

The body weight of surviving animals was recorded on Day 0 (beginning of the experiment) and on Days 7 and 14.

3.2.6 Animals

| | |
|----------------------------------|---|
| Species and strain: | RjHan:(WI) Wistar rats |
| Source: | JANVIER S.A.S. |
| Hygienic level at arrival: | SPF |
| Hygienic level during the study: | Standard housing conditions |
| Justification of strain: | Recognized by international guidelines as a recommended test system |
| Number of animals: | 5 animals/sex (at 5000 mg/kg bw), 5 female animal (at 2000 mg/kg bw) |
| Sex: | Male and female, female rats were nulliparous and non-pregnant. |
| Age of animals: | Young adult rats |
| Body weight range at dosing: | Between 206 g and 258 g |
| Acclimatization time: | 6 days |

3.2.7 Husbandry

| | |
|----------------|--|
| Animal health: | Only healthy animals were used for the study. The veterinarian certified health status. |
| Room-Box: | 244/7 and 245/2 |
| Housing: | Individual caging |
| Cage type: | Type II. polypropylene/polycarbonate |
| Bedding: | Laboratory bedding (Lignocel® Hygienic Animal Bedding produced by J. Rettenmaier & Söhne GmbH+Co.KG (Holzmühle 1, 73494 Rosenberger, Germany Bedding was available to animals during the study)) |
| Light: | 12 hours daily, from 6.00 a.m. to 6.00 p.m. |

Temperature: 20.3-24.9 °C
Relative humidity: 30- 68 %
Ventilation: 15-20 air exchanges per hour
Enrichment: Rodents are housed with deep wood sawdust bedding to allow digging and other normal rodent activities.

The temperature and relative humidity was recorded twice daily during the study.

3.2.8 Food and water supply

Animals received ssniff® SM R/M-Z+H "Autoclavable complete feed for rats and mice – breeding and maintenance" produced by ssniff Spezialdiäten GmbH, D-59494, Soest, Germany *ad libitum* (Lot number: 802 4830), and tap water from municipal supply, as for human consumption from 500 ml bottle *ad libitum*. The food was considered not to contain any contaminants that could reasonably be expected to affect the purpose or integrity of the study.

Water quality control analysis is performed once every three months and microbiological assessment is performed monthly, by Veszprém County Institute of State Public Health and Medical Officer Service (ÁNTSZ, H-8201 Veszprém, József A.u.36., Hungary). The quality control results are retained in the archives at LAB Research Ltd.

3.2.9 Identification

Animals were identified by numbers written on the tail with an indelible marker. The numbers were given on the basis of the LAB Research Ltd. master file, for each animal allocated to the study.

The boxes were identified by cards holding information on the study code, the sex of animals, the dose group, the cage number and the individual animal number.

3.3 Post Mortem Investigations

All animals were subjected to gross macroscopic examination. All animals were anaesthetised with Euthasol® 40% (details in 3.1.3.) and exsanguinated. After examination of the external appearance, the cranial, thoracic and abdominal cavities were opened and the appearance of the tissues and organs were observed. Any gross macroscopic findings were recorded.

3.4 Data Evaluation

The type, severity and duration of clinical observations were described. Body weight and body weight changes were summarized in tabular form. Necropsy findings were described and summarized in tabular form.

4.0 RESULTS AND DISCUSSION

4.1 Mortality

Propiconazole/Fenpropidin EC (A9050B) caused mortalities at 5000 mg/kg bw (4/5) in females and (1/5) in males. No mortality occurred following a dermal application at 2000 mg/kg bw in female rats.

4.2 Clinical Signs

Clinical signs were noted in all animals. Activity decreased, hunched back, piloerection were observed in the animals.

Additionally, dermal signs were noted in all animals. These included erythema, oedema, fur loss, wound, scab, tough and thickening of the treated skin

4.3 Body Weight

Two males treated at 5000 mg/kg bw were observed with slight bodyweight loss during the first week of the observation period. Additionally, one female treated at 5000 mg/kg bw and three female at 2000 mg/kg bw was observed with slight bodyweight loss during the first week of the observation period.

4.4 Necropsy

Treatment-related thickening of the treated skin in or missing fur/scab at the dorsal/right thoracic/flank area were found in 3/5 premature deceased female rats. Dark/red/red-black discoloration of the collapsed/non-collapsed lungs or thymus and pale mottling of the liver were also observed in these animals and are considered to be agonal or post mortem changes.

In surviving animals treatment-related missing/thin fur and/or scab at the dorsal/right thoracic and/or lumbar area were noted at dose levels of 2000 and 5000 mg/kg. The uterus in estrus was also seen in the female 4592.

5.0 CONCLUSIONS

The median lethal dose of Propiconazole/Fenpropidin EC (A9050B) after a single dermal administration was found to be greater than 5000 mg/kg bw in male RjHan:(WI) Wistar rats and between 2000 mg/kg bw and 5000 mg/kg bw in female RjHan:(WI) Wistar rats.

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GLOSSARY FOR TABLE 1

Grading of Skin Reactions

ERYTHEMA AND ESCHAR FORMATION

| | |
|---|---|
| No erythema..... | 0 |
| Very slight erythema..... | 1 |
| Well-defined erythema..... | 2 |
| Moderate to severe erythema..... | 3 |
| Severe erythema (beef redness) or eschar formation (injuries in depth preventing erythema) reading..... | 4 |

OEDEMA FORMATION

| | |
|--|---|
| No oedema..... | 0 |
| Very slight oedema (barely perceptible)..... | 1 |
| Slight oedema (edges of area well-defined by definite raising)..... | 2 |
| Moderate oedema (edges raised approximately 1 mm)..... | 3 |
| Severe oedema (raised more than 1 mm and extending beyond the area of exposure)..... | 4 |

TABLE 1 Clinical Observations

INDIVIDUAL CLINICAL OBSERVATIONS
STUDY CODE: 10/290-002P
TEST SYSTEM: RjHan: WI Rat
TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)

DOSE LEVEL: 5000 mg/kg bw

SEX: MALE

| Cage No. | Animal No. | Observations | Observation days | | | | | | | | | | | | | | Frequency | | |
|----------|------------|--|------------------|----|---|---|---|---|---|---|---|---|---|----|----|----|-----------|------|-------|
| | | | 0 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | 13 | 14 |
| | | | 1h | 5h | | | | | | | | | | | | | | | |
| 1 | 3354 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | - | 12/16 |
| | | Hunched back | - | - | + | - | - | - | + | + | + | + | + | + | + | + | - | - | 9/16 |
| | | Piloerection | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | - | 8/16 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Oedema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 |
| | | Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 2/16 |
| 2 | 3355 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | - | 12/16 |
| | | Hunched back | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | - | 8/16 |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | - | 7/16 |
| | | Piloerection | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | - | 8/16 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Oedema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 |
| Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 | | |
| 3 | 3356 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | - | 12/16 |
| | | Hunched back | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | - | 8/16 |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | - | 8/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | - | - | + | + | + | + | - | - | 4/16 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Oedema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 |
| Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 2/16 | |
| 4 | 3357 # | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/6 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 2 | - | - | - | - | - | - | - | - | - | - | 4/6 |
| | | Hunched back | - | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | 1/6 |
| | | Piloerection | - | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | 1/6 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/6 |
| | | Oedema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/6 |
| | | Found dead | - | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 5 | 3358 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | - | 12/16 |
| | | Hunched back | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | - | 8/16 |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | - | 6/16 |
| | | Piloerection | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | - | 8/16 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Oedema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 |
| Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 2/16 | |

Remark: # = Found dead

+: present

Treatment day= Day 0

h=hour (s)

Frequency of observation = number of occurrence of observation / total number of observations

Severities: 1=Slight/Small/Few; 2=Moderate/Medium; 3=Marked/Large/Many

TABLE 1 Clinical Observations (Continued)

INDIVIDUAL CLINICAL OBSERVATIONS
STUDY CODE: 10/290-002P
TEST SYSTEM: RjHan: WI Rat
TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)

DOSE LEVEL: 5000 mg/kg bw

SEX: FEMALE

| Cage No. | Animal No. | Observations | Observation days | | | | | | | | | | | | | | Frequency | | | |
|------------|------------|--|------------------|----|---|---|---|---|---|---|---|---|---|----|----|------|-----------|------------|------------|-------|
| | | | 0 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | 13 | 14 | |
| | | | 1h | 5h | | | | | | | | | | | | | | | | |
| 6 | 3364 # | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | Found dead | 2/14 |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 12/14 |
| | | Hunched back | - | - | + | - | - | - | + | + | + | + | + | + | + | + | + | + | | 10/14 |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | | 6/14 |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 6/14 |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | | 4/14 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | | 1/14 |
| | | Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | | 1/14 |
| Found dead | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | | | |
| 7 | 3365 # | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | Found dead | 2/7 | |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 2 | - | - | - | - | - | - | - | - | | 5/7 | |
| | | Hunched back | - | - | + | - | - | - | + | - | - | - | - | - | - | - | - | | 2/7 | |
| | | Piloerection | - | - | - | - | - | - | + | - | - | - | - | - | - | - | - | | 1/7 | |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 5/7 | |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 5/7 | |
| | | Found dead | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | | - | |
| 8 | 3366 # | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | Found dead | 2/8 | |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 2 | - | - | - | - | - | - | - | | 6/8 | |
| | | Hunched back | - | - | - | - | - | - | + | + | - | - | - | - | - | - | - | | 2/8 | |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | | 1/8 | |
| | | Piloerection | - | - | - | - | - | - | + | + | - | - | - | - | - | - | - | | 2/8 | |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 5/8 | |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 2/8 | |
| Found dead | - | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | | | | |
| 9 | 3367 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | Found dead | 2/16 | |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | | 12/16 | |
| | | Hunched back | - | - | - | - | - | - | + | + | + | + | + | + | + | + | - | | 8/16 | |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | - | + | + | + | + | + | + | - | - | | 6/16 | |
| | | Piloerection | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | | 10/16 | |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 5/16 | |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 4/16 | |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | | 3/16 | |
| Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 3/16 | | | | |
| 10 | 3368 # | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | Found dead | 2/8 | |
| | | Activity decreased | - | - | 1 | 1 | 1 | 1 | 1 | 2 | - | - | - | - | - | - | - | | 6/8 | |
| | | Hunched back | - | - | - | - | - | - | - | + | + | - | - | - | - | - | - | | 2/8 | |
| | | Tough and thickening of the treated skin | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | | 1/8 | |
| | | Piloerection | - | - | - | - | - | - | + | + | - | - | - | - | - | - | - | | 2/8 | |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 5/8 | |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | | 3/8 | |
| Found dead | - | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | | | | |

Remarks: # = Found dead

Treatment day= Day 0

+: present

h=hour (s)

Frequency of observation = number of occurrence of observation / total number of observations

Severities: 1=Slight/Small/Few; 2=Moderate/Medium; 3=Marked/Large/Many

TABLE 1 Clinical Observations (Continued)

INDIVIDUAL CLINICAL OBSERVATIONS
STUDY CODE: 10/290-002P
TEST SYSTEM: RjHan: WI Rat
TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)

DOSE LEVEL: 2000 mg/kg bw

SEX: FEMALE

| Cage No. | Animal No. | Observations | Observation days | | | | | | | | | | | | | | Frequency | | | |
|----------|------------|--------------------|------------------|----|---|---|---|---|---|---|---|---|---|----|----|----|-----------|----|------|-------|
| | | | 0 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | 13 | 14 | |
| | | | 1h | 5h | | | | | | | | | | | | | | | | |
| 11 | 4590 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 | |
| | | Activity decreased | - | - | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | 2/16 | |
| | | Skin scab | - | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | + | 10/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | 6/16 |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | - | - | 4/16 |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | - | 5/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | + | 3/16 |
| 12 | 4591 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 3/16 | |
| | | Activity decreased | - | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | - | 2/16 | |
| | | Skin scab | - | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | + | 9/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | 6/16 |
| | | Erythema | - | - | 1 | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | 6/16 |
| | | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | - | 5/16 |
| 13 | 4592 | Symptom Free | + | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 2/16 | |
| | | Wound | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | 8/16 |
| | | Skin scab | - | - | - | - | - | + | + | + | + | + | + | + | + | + | + | + | + | 10/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | 6/16 |
| | | Fur loss | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | + | 3/16 |
| | | Erythema | - | - | 2 | 2 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | 6/16 |
| 14 | 4593 | Oedema | - | - | 1 | 1 | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | 5/16 | |
| | | Symptom Free | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - | 3/16 | |
| | | Activity decreased | - | - | - | - | - | - | - | 1 | 1 | 1 | - | - | - | - | - | - | - | 3/16 |
| | | Skin scab | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | + | + | 10/16 |
| | | Wound | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + | 2/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | - | - | 6/16 |
| | | Erythema | - | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 1/16 |
| 15 | 4594 | Oedema | - | - | 1 | 1 | 1 | - | - | - | - | - | - | - | - | - | - | - | 3/16 | |
| | | Symptom Free | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - | 3/16 | |
| | | Activity decreased | - | - | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | - | 2/16 |
| | | Skin scab | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | + | + | 10/16 |
| | | Wound | - | - | - | - | - | - | - | - | + | + | + | + | + | + | + | + | + | 8/16 |
| | | Piloerection | - | - | - | - | - | - | - | - | + | + | - | - | - | - | - | - | - | 2/16 |

Remarks: +: present
 -: absent
 h=hour (s)

Treatment day= Day 0

Frequency of observation = number of occurrence of observation / total number of observations
 Severities: 1=Slight/Small/Few; 2=Moderate/Medium; 3=Marked/Large/Many

TABLE 2 Body Weight and Body Weight Gain

INDIVIDUAL BODY WEIGHT AND BODY WEIGHT GAIN
STUDY CODE: 10/290-002P
TEST SYSTEM: RjHan: WI Rat
TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)

DOSE LEVEL: 5000 mg/kg bw

SEX: MALE

| Cage No. | Animal No. | Body weight (g) Days | | | Body Weight Gain (g) | | |
|----------------------------|------------|-------------------------|-------|-------|----------------------|------|------|
| | | 0 | 7 | 14 | 0-7 | 7-14 | 0-14 |
| 1 | 3354 | 242 | 242 | 282 | 0 | 40 | 40 |
| 2 | 3355 | 258 | 242 | 256 | -16 | 14 | -2 |
| 3 | 3356 | 242 | 256 | 302 | 14 | 46 | 60 |
| 4 | 3357 # | 245 | - | - | - | - | - |
| 5 | 3358 | 226 | 215 | 236 | -11 | 21 | 10 |
| Mean: | | 242.6 | 238.8 | 269.0 | -3.3 | 30.3 | 27.0 |
| Standard deviation: | | 11.4 | 17.2 | 29.0 | 13.3 | 15.2 | 28.2 |

DOSE LEVEL: 5000 mg/kg bw

SEX: FEMALE

| Cage No. | Animal No. | Body weight (g) Days | | | Body Weight Gain (g) | | |
|----------------------------|------------|-------------------------|-------|-------|----------------------|------|------|
| | | 0 | 7 | 14 | 0-7 | 7-14 | 0-14 |
| 6 | 3364 # | 212 | 204 | - | -8 | - | - |
| 7 | 3365 # | 215 | - | - | - | - | - |
| 8 | 3366 # | 217 | - | - | - | - | - |
| 9 | 3367 | 213 | 197 | 209 | -16 | 12 | -4 |
| 10 | 3368 # | 206 | - | - | - | - | - |
| Mean: | | 212.6 | 200.5 | 209.0 | -12.0 | 12.0 | -4.0 |
| Standard deviation: | | 4.2 | 4.9 | - | 5.7 | - | - |

DOSE LEVEL: 2000 mg/kg bw

SEX: FEMALE

| Cage No. | Animal No. | Body weight (g) Days | | | Body Weight Gain (g) | | |
|----------------------------|------------|-------------------------|-------|-------|----------------------|------|------|
| | | 0 | 7 | 14 | 0-7 | 7-14 | 0-14 |
| 11 | 4590 | 210 | 207 | 236 | -3 | 29 | 26 |
| 12 | 4591 | 209 | 210 | 232 | 1 | 22 | 23 |
| 13 | 4592 | 230 | 217 | 238 | -13 | 21 | 8 |
| 14 | 4593 | 222 | 215 | 233 | -7 | 18 | 11 |
| 15 | 4594 | 211 | 221 | 233 | 10 | 12 | 22 |
| Mean: | | 216.4 | 214.0 | 234.4 | -2.4 | 20.4 | 18.0 |
| Standard deviation: | | 9.2 | 5.6 | 2.5 | 8.6 | 6.2 | 8.0 |

Remarks: Treatment day= Day 0
 # = Found dead

TABLE 3 Necropsy Findings**INDIVIDUAL INTERNAL AND EXTERNAL MACROSCOPIC OBSERVATIONS****STUDY CODE: 10/290-002P****TEST SYSTEM: RjHan: WI Rat****TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)****DOSE LEVEL: 5000 mg/kg bw****SEX: MALE**

| Cage No. | Animal No. | Necropsy Date | External Observations | Internal Observations | Organ/ Tissue |
|----------|------------|------------------|-------------------------------------|---|----------------|
| 1 | 3354 | 22 December 2010 | Dorsal Thoracic: Missing Fur | No internal observations | Not applicable |
| 2 | 3355 | 22 December 2010 | Dorsal Thoracic: Thin Fur | No internal observations | Not applicable |
| | | | Chest (Right Thoracic): Missing Fur | | |
| | | | Lumbar: Scab, 2x2 cm, in size | | |
| 3 | 3356 | 22 December 2010 | Dorsal Thoracic: Thin Fur | No internal observations | Not applicable |
| | | | Lumbar: Missing Fur | | |
| 4 | 3357 # | 13 December 2010 | No external observations | Dark discoloration, red, diffuse, all lobes | Lungs |
| | | | | Dark discoloration, red, diffuse | Thymus |
| 5 | 3358 | 22 December 2010 | Lumbar: Scab, 1x3 cm, in size | No internal observations | Not applicable |

Remarks:

= Found dead

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

Estas informações, resultados de testes e outros dados não divulgados são confidenciais e de propriedade da SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei 10.603/02 e do artigo 195, XIV da Lei 9.279/96

É proibida a revelação ou divulgação, e vedado o uso, ainda que parcial ou por vias indiretas, a terceiros não autorizados.

Todos os infratores poderão ser processados civil e criminalmente

TABLE 3 Necropsy Findings (Continued)**INDIVIDUAL INTERNAL AND EXTERNAL MACROSCOPIC OBSERVATIONS****STUDY CODE: 10/290-002P****TEST SYSTEM: RjHan: WI Rat****TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)****DOSE LEVEL: 5000 mg/kg bw****SEX: FEMALE**

| Cage No. | Animal No. | Necropsy Date | External Observations | Internal Observations | Organ/ Tissue |
|----------|------------|------------------|---|---|----------------|
| 6 | 3364 # | 21 December 2010 | Flank: Scab, 0.5x1 cm in size, left and right | Mottled, pale area, 1x1 cm in size, left lateral lobe | Liver |
| | | | Dorsal Thoracic: Missing Fur | | |
| | | | Chest (Right Thoracic): Missing Fur | Dark discoloration, red, diffuse, all lobes | Lungs |
| | | | Flank: Missing Fur, right | Non collapsed | |
| 7 | 3365 # | 14 December 2010 | No external observations | Collapsed | Lungs |
| | | | | Dark discoloration, red, diffuse, all lobes | |
| 8 | 3366 # | 15 December 2010 | Treated skin: Thickening | Non collapsed | Lungs |
| | | | | Dark discoloration, red-black multifocal, all lobes | |
| 9 | 3367 | 22 December 2010 | Dorsal Thoracic: Missing Fur | No internal observations | Not applicable |
| | | | Dorsal Thoracic: Scab 1x1 cm in size | | |
| | | | Lumbar: Scab, 2x2 cm, in size | | |
| 10 | 3368 # | 15 December 2010 | Treated skin: Thickening | Non collapsed | Lungs |

Remarks:

= Found dead

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

Estas informações, resultados de testes e outros dados não divulgados são confidenciais e de propriedade da SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei 10.603/02 e do artigo 195, XIV da Lei 9.279/96

É proibida a revelação ou divulgação, e vedado o uso, ainda que parcial ou por vias indiretas, a terceiros não autorizados.

Todos os infratores poderão ser processados civil e criminalmente

TABLE 3 Necropsy Findings (Continued)**INDIVIDUAL INTERNAL AND EXTERNAL MACROSCOPIC OBSERVATIONS****STUDY CODE: 10/290-002P****TEST SYSTEM: RjHan: WI Rat****TEST ITEM: Propiconazole / Fenpropidin EC (A9050B)****DOSE LEVEL: 2000 mg/kg bw****SEX: FEMALE**

| Cage No. | Animal No. | Necropsy Date | External Observations | Internal Observations | Organ/ Tissue |
|-----------------|-------------------|----------------------|------------------------------|------------------------------|----------------------|
| 11 | 4590 | 02 March 2011 | Lumbar: Scab | No internal observations | Not applicable |
| 12 | 4591 | 02 March 2011 | No external observations | No internal observations | Not applicable |
| 13 | 4592 | 02 March 2011 | Lumbar: Scab | In esturs | Uterus |
| 14 | 4593 | 02 March 2011 | Dorsal Thoracic: Scab | No internal observations | Not applicable |
| | | | Lumbar: Scab | | |
| 15 | 4594 | 02 March 2011 | Dorsal Thoracic: Scab | No internal observations | Not applicable |
| | | | Lumbar: Scab | | |

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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APPENDICES SECTION

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RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS
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APPENDIX 1 Certificate of Analysis



GLP Testing Facility WMU
Analytical Development &
Product Chemistry GS2131

Syngenta Crop Protection
Münchwilen AG
Breitenloh 5
CH-4333 Münchwilen

Certificate of Analysis

A9050B
propiconazole / fenpropidin EC (125/275)
SMO0G120

Batch Identification SMO0G120
Product Code A9050B
Other Product Code(s) CGA64250/CGA114900 EC (125/275)

Chemical Analysis (Active Ingredient Content)

- **Identity of the Active Ingredient(s)*** confirmed
- **Content of propiconazole *** 13.6 % w/w corresponding to 129 g/l
- **Content of fenpropidin *** 29.2 % w/w corresponding to 278 g/l

The Active Ingredient(s) content is within the FAO limits.

Methodology used for Characterization /
Recertification GC,

Physical Analysis

- **Appearance** brown, liquid
- **Density *** 952 kg/m³

Stability:

- **Storage Temperature** < 30°C
- **Recertification Date** End of September 2015

If stored under the conditions given above, this test substance can be considered stable until the recertification date is reached.

This Certificate of Analysis summarizes data which originates either from a single study or from several individual studies. Tests marked with an asterisk (*) have been conducted in compliance with GLP. Raw data, documentation, study plans, any amendments to study plans and reports pertaining to this/these study/studies are stored under the study number(s) referenced below within the archives of the GLP Testing Facility WMU at Syngenta Crop Protection Muenchwilen AG.

Study number of batch characterization: 121786
Study number(s) of batch recertification:

Authorisation: October 12, 2010

Dr. A.M. Dos Santos Alves
Analytical Development & Product Chemistry

APPENDIX 2 Pathology Report

PATHOLOGY REPORT

INTRODUCTION

The objective of the study was to assess the acute dermal toxicity of Propinoconazole/Fenpropidin EC (A9050B) when administered in a single 24 hour dermal application to rats at one or more defined dose levels followed by 14 days observation.

RESULTS AND DISCUSSION

Surviving animals were euthanized upon completion of the treatment period on Day 14. Rats were anesthetized with pentobarbital, followed by exsanguination. Gross pathology consisted of an external examination, including identification of all clinically-recorded lesions, as well as a detailed internal examination. Histopathological examination was not performed.

MORTALITY

Five animals dosed at 5000 mg/kg bw were found dead between Days 5-13.

FOUND DEAD

Macroscopic Findings

Thickening of the treated skin in 2/5 rats, missing fur at the dorsal/right thoracic/flank area or scab (3364) were regarded as irritating effect related to the treatment.

Dark/red/red-black discoloration of the collapsed/non-collapsed lungs or thymus and pale mottling of the liver were considered to be agonal or post mortem changes.

TERMINAL (DAY 14)

Macroscopic Findings

Similar to found dead animals, treatment-related irritating effect was macroscopically observed at the skin.

Missing/thin fur and/or scab at the dorsal/right thoracic and/or lumbar area were observed in 5/5 rats at a dose level of 5000 mg/kg bw.

The scab at the dorsal thoracic and/or lumbar area was also seen in 4/5 animals dosed at 2000 mg/kg.

The uterus in estrus was seen in the female 4592.

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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APPENDIX 2 Pathology Report (Continued)

CONCLUSION

A single 24 hour dermal application of Propinoconazole/Fenpropidin EC (A9050B) to the Rj Han: (WI) rat at a dose level of 5000 mg/kg led to the death of five animals between Days 5-13. Treatment-related thickening of the treated skin in or missing fur/scab at the dorsal/right thoracic/flank area were found in 3/7 found/dead rats.

In animals surviving to the termination on Day 14, treatment-related missing/thin fur and/or scab at the dorsal/right thoracic and/or lumbar area were noted at dose levels of 2000 and 5000 mg/kg.


Peter Maslej, D.V.M., Ph.D.
Head, Pathology Department

11 May 2011
Date

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APPENDIX 3 GLP Certificates



ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET
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Phone: +36 1 8869-300

Fax: +36 1 8869-460

E-mail: ogyi@ogyi.hu

Budapest, 20th December 2008

No: 38625/48/2007

Our ref.: Szilvia Karsai

Subject: GLP Certificate

GOOD LABORATORY PRACTICE (GLP) CERTIFICATE

Based on the Inspection report and the discussion of follow up activities it is hereby certified that the test facility

LAB Research Ltd.
H-8201 Veszprém, Szabadságpuszta, Hungary

is able to carry out Physical-chemical testing, Toxicity studies, Mutagenicity studies, Environmental toxicity studies on aquatic and terrestrial organisms, Studies on behaviour in water, soil and air; bioaccumulation, Bioanalytical, Analytical and clinical chemistry testing compliance with the Principles of GLP (Good Laboratory Practice).

Date of the inspection: **13-22 October 2008.**

This GLP Certificate is valid for 2 years.


Zsuzsanna Szepezdi, Ph. D.
Director-General

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

Report Number: 10/290-002P

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APPENDIX 3 GLP Certificates (Continued)

 **ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET**
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Ref. no: OGYI/8242-11/2010
Admin.: Urbán Magdolna Zita
Date: 16 December, 2010

**GOOD LABORATORY PRACTICE (GLP)
CERTIFICATE**

It is hereby certified that the test facility

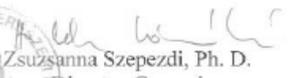
LAB Research Kft.
(Base facility: H-8201 Veszprém, Szabadságpuszta, Hungary)

is able to carry out

physico-chemical testing, toxicity studies, mutagenicity studies, environmental toxicity studies on aquatic or terrestrial organisms, studies on behaviour in water, soil and air; bio-accumulation, safety pharmacology testing, reproduction toxicology, inhalation toxicology, analytical chemistry and contract archiving

in compliance with the Principles of GLP (Good Laboratory Practice) and also complies with the corresponding OECD/European Community requirements.

Date of the inspection: **4-8 October, 2010.**


Zsuzsanna Szepezdi, Ph. D.
Director-General

