

**SYN545192**

**SYN545192 EC (A15457H) -  
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):** Istvánné Kiss, M.Sc.

**STUDY COMPLETION DATE:** 10 July 2012

**PERFORMING LABORATORY:** CiToxLAB Hungary Ltd.  
H-8200 Veszprém, Szabadságpuszta, Hungary

**LABORATORY PROJECT ID:** Report Number: 12/063-002P  
Study Number: 12/063-002P  
Task Number: TK0065144

**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.

*Kiss Istvánné*

Istvánné Kiss, M.Sc.  
Study Director

*10 July 2012*

Date

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

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**FLAGGING STATEMENT**

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## QUALITY ASSURANCE STATEMENT

Study Code: 12/063-002P

Study Title: SYN545192 EC (A15457H) - Acute Dermal Toxicity Study in Rats

Test Item: SYN545192 EC (A15457H)

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
01 March 2012	Study Plan	01 March 2012	01 March 2012
21 March 2012	Treatment	21 March 2012	21 March 2012
22 May 2012	Draft Report	23 May 2012	22 May 2012
10 July 2012	Final Report	10 July 2012	10 July 2012

Signature: \_\_\_\_\_



Date: 10 July 2012

Katalin Böröczki, M.Sc.  
On behalf of QA

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## STATEMENT OF THE MANAGEMENT

According to the conditions of the research and development agreement between Syngenta Limited (as Sponsor) and CiToxLAB Hungary Ltd. (as Test Facility) the study titled "SYN545192 EC (A15457H) - Acute Dermal Toxicity Study in Rats" was performed, in compliance with the Principles of Good Laboratory Practice.

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

10 July 2012

Christopher Banks, DABT  
Managing Director

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## GENERAL INFORMATION

### Contributors

The following contributed to this report in the capacities indicated:

Name	Function
Istvánné Kiss, M.Sc.	Study Director
Viktória Zelenák, 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
Claire Elliott	Syngenta Study Manager

### Study dates

Study initiation date:	01 March 2012
Experimental start date:	21 March 2012
Experimental termination date:	04 April 2012

### Retention of samples

See in other below

### Performing laboratory test substance reference number

12003A

### Other

The study documents:

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

will be archived according to the Hungarian GLP regulations and to applicable SOP's in the archives of CiToxLAB Hungary 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

A single administration of SYN545192 EC (A15457H) at a dose of 2000 mg/kg body weight was applied dermally to 5 male and 5 female CRL:(WI) rats, followed by a 14-day observation period. The test item was applied as supplied by the Sponsor. The application period was 24 hours.

Clinical observations were assessed in all animals 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. All animals were euthanized and subjected to a gross macroscopic examination at the end of the 14-day observation period (Day 14).

### 1.2 Results

No mortality occurred during the study.

No adverse clinical signs were observed after treatment with the test item during the 14 day observation period. Erythema was noted in all animals (10/10) on Day 1 only. All animals were symptom free from 2 days after the treatment.

There were no treatment related effects on body weight or body weight gain during the observation period.

There was no evidence of the test item-related observations at a dose level of 2000 mg/kg bw at necropsy.

### 1.3 Conclusion

The median lethal dose of SYN545192 EC (A15457H) after a single dermal administration was found to be greater than 2000 mg/kg bw in male and female CRL:(WI) rats.

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## 2.0 INTRODUCTION

### 2.1 Purpose

The purpose of the study was to assess the acute dermal toxicity of SYN545192 EC (A15457H) when administered to rats by a single semi-occlusive dermal application, 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 CiToxLAB Hungary 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:	SYN545192 EC (A15457H)
Batch number:	SMU1LP001
Product code:	A15457H
Purity:	Content of benzovindiflupyr (SYN545192) – 10.1 % w/w corresponding to 98.6 g/l Content of water – 0.74 % w/w
Density:	976 kg/m <sup>3</sup>
Appearance:	brown liquid
Recertification date:	End of July 2014
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

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 CiToxLAB Hungary 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<sup>®</sup> 40%  
Lot No.: 11H15 8  
Expiry Date: July 2014  
Produced by: Produlab Pharma B.V.

## 3.2 Experimental Design

### 3.2.1 Doses

A limit dose of 2000 mg/kg bw was chosen by the Sponsor as there is a regulatory requirement to test this dose level.

### 3.2.2 Experimental design

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

A single administration was performed by the dermal route and was followed by a 14-day observation period.

The application volume was 2.05 mL/kg bw ( $x 976 \text{ mg/mL} = 2000 \text{ mg/kg}$ ).

### 3.2.3 Procedure

The backs of the animals were shaven (approximately 10% area of the total body surface) approximately 24 hours prior to 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 2000 mg/kg body weight 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 assessments of the skin and fur, eyes and mucous membranes, the respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavior patterns. 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 all animals was recorded on Day 0 (beginning of the experiment) and on Days 7 and 14.

### 3.2.6 Animals

Species and strain:	CRL:(WI) rats
Source:	Charles River Laboratories, Research Models and Services, Germany GmbH, Sandhofer Weg 7, D-97633 Sulzfeld
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
Sex:	Male and female, female rats were nulliparous and non-pregnant
Age of animals:	Young adult rats
Body weight range at dosing:	Between 215 g and 280 g
Acclimatization time:	8 days

### 3.2.7 Husbandry

Animal health:	Only healthy animals were used for the study. The veterinarian certified the health status.
Room-Box:	242/5
Housing:	Individual caging
Cage type:	Type II. polypropylene/polycarbonate
Bedding:	Laboratory bedding was available to animals during the study (Lignocel® Hygienic Animal Bedding produced by J. Rettenmaier & Söhne GmbH+Co.KG).
Light:	12 hours daily, from 6.00 a.m. to 6.00 p.m.
Temperature:	22 ± 3 °C

Relative humidity: 30 - 70 %  
Ventilation: 15 - 20 air exchanges per hour  
Enrichment: Rodents were housed with deep wood sawdust bedding to allow digging and other normal rodent activities.

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

### 3.2.8 Food and water supply

Animals received ssniff® SM R/M-Z+H "Autoclavable complete diet for rats and mice – breeding and maintenance" produced by ssniff Spezialdiäten GmbH, D-59494, Soest, Germany *ad libitum* (Lot number: 719 6627). Tap water from the municipal supply (fit for human consumption) was provided *ad libitum* from 500 mL bottles. The food and water were 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 CiToxLAB Hungary Ltd.

### 3.2.9 Identification

Animals were identified by numbers written on the tail with an indelible marker. The numbers were allocated on the basis of the CiToxLAB Hungary Ltd. master file.

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 anesthetized 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

No mortality occurred on the study.

### 4.2 Clinical Signs

There were no adverse clinical signs noted in any animals throughout the study.

### 4.3 Local Dermal Signs

Erythema was noted in all animals (10/10) on Day 1. All animals were symptom free from 2 days after the treatment.

### 4.4 Body Weight

There were no effects on either body weight or body weight gain in any animal.

### 4.5 Necropsy

No treatment related macroscopic findings were observed.

There was no evidence of the test item-related observations at a dose level of 2000 mg/kg bw at necropsy.

## 5.0 CONCLUSIONS

The median lethal dose of SYN545192 EC (A15457H) after a single dermal administration was found to be greater than 2000 mg/kg bw in male and female CRL:(WI) rats.

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**TABLES SECTION**

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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****DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****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	1866	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	1867	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	1868	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	1869	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	1870	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-

**DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****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	1876	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	1877	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	1878	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	1879	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	1880	Symptom Free	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	15/16
		Erythema	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-

**Remarks:** + = present - = absent

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

## 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

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Todos os infratores poderão ser processados civil e criminalmente

**TABLE 2 Body Weight and Body Weight Gain****DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****SEX: MALE**

Cage No.	Animal No.	Body weight (g) Days			Body Weight Gain (g)		
		0	7	14	0-7	7-14	0-14
1	1866	280	331	379	51	48	99
2	1867	256	293	336	37	43	80
3	1868	266	324	343	58	19	77
4	1869	253	297	337	44	40	84
5	1870	271	300	340	29	40	69
<b>Mean:</b>		265.2	309.0	347.0	43.8	38.0	81.8
<b>Standard deviation:</b>		11.0	17.2	18.1	11.4	11.1	11.1

**DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****SEX: FEMALE**

Cage No.	Animal No.	Body weight (g) Days			Body Weight Gain (g)		
		0	7	14	0-7	7-14	0-14
6	1876	215	222	239	7	17	24
7	1877	217	224	231	7	7	14
8	1878	231	240	265	9	25	34
9	1879	237	247	253	10	6	16
10	1880	220	239	237	19	-2	17
<b>Mean:</b>		224.0	234.4	245.0	10.4	10.6	21.0
<b>Standard deviation:</b>		9.5	10.9	13.8	5.0	10.5	8.2

**RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS**

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**TABLE 3 Necropsy Findings****DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****SEX: MALE**

Cage No.	Animal No.	Necropsy Day	External Observations	Internal Observations	Organ/ Tissue
1	1866	Day 14	No external observations	No internal observations	Not applicable
2	1867	Day 14	No external observations	No internal observations	Not applicable
3	1868	Day 14	No external observations	No internal observations	Not applicable
4	1869	Day 14	No external observations	No internal observations	Not applicable
5	1870	Day 14	No external observations	No internal observations	Not applicable

**DOSE LEVEL: 2000 mg/kg bw, Treatment on Day 0****SEX: FEMALE**

Cage No.	Animal No.	Necropsy Day	External Observations	Internal Observations	Organ/ Tissue
6	1876	Day 14	No external observations	No internal observations	Not applicable
7	1877	Day 14	No external observations	No internal observations	Not applicable
8	1878	Day 14	No external observations	No internal observations	Not applicable
9	1879	Day 14	No external observations	No internal observations	Not applicable
10	1880	Day 14	No external observations	No internal observations	Not applicable

**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

**A15457H**  
**benzovindiflupyr EC (100)**  
**SMU1LP001**

<b>Batch Identification</b>	<b>SMU1LP001</b>
<b>Product Code</b>	<b>A15457H</b>
<b>Other Product Code(s)</b>	benzovindiflupyr EC (100) SYN545192 EC (100)
<b>Chemical Analysis (Active Ingredient Content)</b>	
- <b>Identity of the Active Ingredient(s)*</b>	<b>confirmed</b>
- <b>Content of benzovindiflupyr (SYN545192)*</b>	<b>10.1 % w/w corresponding to 98.6 g/l</b>
- <b>Content of water *</b>	<b>0.74 % w/w</b>
The Active Ingredient(s) content is within the FAO limits.	
<b>Methodology used for Characterization</b>	HPLC, Karl Fischer titration, OECD 109 (oscillating density meter)
<b>Physical Analysis</b>	
- <b>Appearance</b>	<b>brown liquid</b>
- <b>Density *</b>	<b>976 kg/m<sup>3</sup></b>
<b>Stability:</b>	
- <b>Storage Temperature</b>	<b>&lt; 30°C</b>
- <b>Recertification Date</b>	<b>End of July 2014</b>

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: 124140

Authorisation:

06 February 2012

E. Ebi  
Analytical Development & Product Chemistry

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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## APPENDIX 2 Pathology Report

### PATHOLOGY REPORT

#### Introduction

The objective of the study was to assess the acute dermal toxicity of SYN545192 EC (A15457H) 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

All rats survived until the scheduled termination of the study.

All animals were euthanized upon completion of the observation 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.

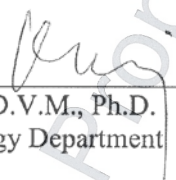
#### TERMINAL (DAY 14)

#### MACROSCOPIC FINDINGS

There was no evidence of the any observations at a dose level of 2000 mg/kg bw at necropsy.

#### Conclusion

A single 24 hour dermal application of SYN545192 EC (A15457H) to CRL:(WI) rats at a dose level of 2000 mg/kg bw followed by 14 days observation, was not associated with any macroscopic findings.

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

09 July 2012  
Date

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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## APPENDIX 3 GLP Certificate



ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET  
National Institute of Pharmacy

FŐIGAZGATÓ

1051 Budapest, Zrínyi u. 3.  
tel: (1) 8869-326  
fax: (1) 8869-480  
e-mail: szepezdi.zsuzsanna@ogyi.hu

Ref. no: OGYI/8242-11/2010

Admin.: Urbin 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

*Translation (from Hungarian to English):*

*Stamp Translation = Országos Gyógyszerészeti Intézet (OGYI) = National Institute of Pharmacy  
Főigazgató = Director-General*

*The facility name was LAB Research Ltd until 1<sup>st</sup> September 2011. From this date, the registered name is now CiToxLAB Hungary Ltd., this information has been transmitted to the GLP competent authority. The above GLP certificate is valid for this facility (now known as CiToxLAB Hungary Ltd.) until the certificate expires (16 December 2012).*

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

Report Number: 12/063-002P

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