



Propiconazole/Pydiflumetofen

**Propiconazole/Pydiflumetofen SE (A21573C) -
Primary Skin Irritation Study in Rabbits**

Final Report

DATA REQUIREMENT(S): OECD 404 (2015)
EPA 870.2500 (1998)
EC No 440/2008, B.4 (2008)

AUTHOR(S): Máté Weisz, M.Sc.

COMPLETION DATE: 26 April 2018

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

LABORATORY PROJECT ID: Report Number: 17/349-006N
Study Number: 17/349-006N
Task Number: TK0186808

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

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS UNDER SPECIFIED FIFRA PROVISIONS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Company: Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

Submitter: Adora Clark
Adora Clark, Ph.D.

Date: May 21, 2018

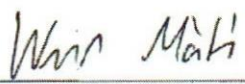
Syngenta is the owner of this information and data. Syngenta has submitted this material to the United States Environmental Protection Agency specifically under the provisions contained in FIFRA as amended and, hereby, consents to use and disclosure of this material by EPA according to FIFRA. In submitting this material to EPA according to method and format requirements contained in PR Notice 2011-3, we do not waive any protection or right involving this material that would have been claimed by the company if this material had not been submitted to the EPA, nor do we waive any protection or right provided under FIFRA Section 3 (concerning data exclusivity and data compensation) or FIFRA Section 10(g) (prohibiting disclosure to foreign and multinational pesticide companies or their agents).

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

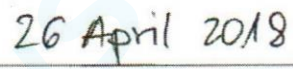
This study has been performed in accordance with the Principles of Good Laboratory Practice (Hungarian GLP Regulations: 42/2014. (VIII. 19.) EMMI decree of the Ministry of Human Capacities which corresponds to the OECD GLP, ENV/MC/CHEM (98) 17.).

This study was conducted in accordance with a written Study Plan, authorized by the Sponsor and Citoxlab Hungary Ltd. Management, and followed applicable Standard Operating Procedures.

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.



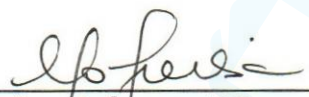
Máté Weisz, M.Sc.
Study Director



Date

Performing Laboratory:

Citoxlab Hungary Ltd.
H-8200 Veszprém, Szabadságpuszta,
Hungary



Monique Inforzato, BS
Representative of Submitter/Sponsor



Date

Sponsor:
Syngenta Ltd
Jealott's Hill International Research Centre
Bracknell, Berkshire, RG42 6EY, United Kingdom

Submitter:
Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

FLAGGING STATEMENT

This page is intentionally left blank.

QUALITY ASSURANCE STATEMENT

Study Number: 17/349-006N

Study Title: Propiconazole/Pydiflumetofen SE (A21573C) - Primary Skin Irritation Study in Rabbits

Test Item: Propiconazole/Pydiflumetofen SE (A21573C)

This study has been inspected, and this report was 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:

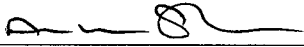
Date of Inspection	Phase(s) Inspected/Audited	Date of report to	
		Management	Study Director
08 January 2018	Study Plan	08 January 2018	08 January 2018
16 January 2018	Observation	16 January 2018	16 January 2018
22 March 2018	Draft Report	22 March 2018	22 March 2018
25 April 2018	Final Report	25 April 2018	25 April 2018

Signature: *Ivett Schleicher*
Ivett Schleicher, Ph.D.
On behalf of QA

Date: 26 April 2018

MANAGEMENT STATEMENT

According to the conditions of the research and development agreement between Syngenta Ltd. (as Sponsor) and Citoxlab Hungary Ltd. (as Test Facility) the study titled "Propiconazole/Pydiflumetofen SE (A21573C) - Primary Skin Irritation Study in Rabbits" was performed, in compliance with the Principles of Good Laboratory Practice.

Signature:  Date: 26 April 2018
Alyson Leyshon, M.Sc.
Managing Director



GENERAL INFORMATION

Contributors

The following contributed to this report in the capacities indicated:

Name	Function
Máté Weisz, M.Sc.	Study Director
Erika Rosos-Matting, M.Sc.	Assistant Scientist
Leila Merazga, M.Sc.	Quality Assurance Inspector
Ivett Schleicher, Ph.D.	Quality Assurance Inspector
László Székelyhidi, D.V.M.	Veterinary Care
Tamás Mészáros, Ph.D.	Pharmacy
Monique Trevisan Inforzato, B.Sc.	Syngenta Study Manager

Other trained, competent personnel worked on the study as required.

Study dates

Study Initiation Date:	10 January 2018
Experimental Starting Date:	16 January 2018
Experimental Completion Date:	21 January 2018
Receipt of animals:	10 January 2018
Acclimatization:	10 – 15 / 17 January 2018
Treatment:	16 / 18 January 2018
Observation:	16 / 18 – 19 / 21 January 2018

Deviations from the guideline

There was no deviation during the Study.

Performing laboratory test substance reference number

170356

Other

The study documents and samples:

- 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 SOPs in the archives of Citoxlab Hungary Ltd. 8200 Veszprém, Szabadságpuszta, Hungary. This is for a period of 15 years.

After the retention time 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.

TABLE OF CONTENTS

STATEMENT OF DATA CONFIDENTIALITY CLAIMS	2
GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT	3
FLAGGING STATEMENT	4
QUALITY ASSURANCE STATEMENT	5
MANAGEMENT STATEMENT	6
GENERAL INFORMATION	7
TABLE OF CONTENTS	9
1.0 EXECUTIVE SUMMARY	11
1.1 Study Design.....	11
1.2 Results	11
1.3 Conclusion.....	11
2.0 INTRODUCTION	12
2.1 Purpose	12
2.2 Guidelines.....	12
2.3 Test Facility	12
3.0 MATERIALS AND METHODS	13
3.1 Test Substance	13
3.1.1 Identification and receipt.....	13
3.1.2 Formulation	13
3.2 Experimental Design.....	14
3.2.1 Animals	14
3.2.2 Husbandry.....	14
3.2.3 Food and feeding	14
3.2.4 Water supply and quality control.....	15
3.3 Administration of the Test Item.....	15
3.4 <i>Post Mortem</i> Investigations.....	16
3.4.1 Matherials used for euthanasia	16
3.5 Data Evaluation.....	16
4.0 RESULTS AND DISCUSSION	18
4.1 Skin Irritation.....	18
4.2 Clinical Observations	18
4.3 Duration of the In-Life Phase	18
4.4 Body Weight.....	18

5.0	CONCLUSIONS	18
6.0	REFERENCES	19
	TABLES SECTION	20
	GLOSSARY FOR TABLE 1	21
	TABLE 1 Skin Irritation Scores - Individual Values	22
	TABLE 2 Skin Irritation Scores - Mean Values after 24, 48 and 72 Hours	22
	TABLE 3 Clinical Signs	22
	TABLE 4 Body Weights.....	23
	APPENDICES SECTION	24
	APPENDIX 1 Certificate of Analysis	25
	APPENDIX 2 Individual Local Findings	27
	APPENDIX 3 GLP Certificate.....	30

1.0 EXECUTIVE SUMMARY

1.1 Study Design

The primary skin irritation potential of Propiconazole/Pydiflumetofen SE (A21573C) was investigated according to the following guidelines: OECD 404 (2015), OPPTS 870.2500 (1998) and EC No 440/2008, B.4 (2008). Three young adult New Zealand White rabbits were treated by topical application of 0.5 mL test item to their intact shaved dorsal area. The duration of treatment was 4 hours. The scoring of skin reactions was performed at approximately 1, 24, 48 and 72 hours after removal of the dressing. The primary irritation index (P.I.I.) was calculated by totalling the mean cumulative scores at 24, 48 and 72 hours and then dividing by the number of data points.

1.2 Results

The primary irritation index was 0.00.

No local dermal signs were observed in the treated animals at approximately 1, 24, 48 and 72 hours after patch removal.

No clinical signs of systemic toxicity were observed in the animals during the study, and no mortality occurred.

As no clinical signs were observed at 72 hours after patch removal, the study was terminated after 72 hours of observation of the second and third rabbits.

The body weights of all rabbits were considered to be within the normal range of variability.

1.3 Conclusion

The application of Propiconazole/Pydiflumetofen SE (A21573C) did not result in any signs of skin irritation.

According to the Draize classification criteria, Propiconazole/Pydiflumetofen SE (A21573C) is considered to be a “non-irritant” to rabbit skin (P.I.I. = 0.00).

2.0 INTRODUCTION

2.1 Purpose

The purpose of this primary skin irritation study was to assess the irritation potential of Propiconazole/Pydiflumetofen SE (A21573C) from a single dose placed on the skin of rabbits for 4 hours.

This study provides a rational basis for hazard classification.

Based on an *in vitro* skin irritation study (Citoxlab Hungary study code: 17/349-043B) that was conducted using the EpiSkin™ model with Propiconazole/Pydiflumetofen SE (A21573C), the test item was indicated to be non-irritant.

The study was designed such that the minimum numbers of animals were used.

The test item was administered at 0.5 mL/animal, the dose specified in the test guidelines for a liquid test item.

2.2 Guidelines

The study was conducted according to the following guidelines:

- OECD Guidelines for Testing of Chemicals, Section 4, number 404 “Acute Dermal Irritation / Corrosion”, adopted July 28, 2015.
- United States Environmental Protection Agency, Health Effects Division Test Guidelines, OPPTS 870.2500 Acute Dermal Irritation EPA 712-C-98-196, August 1998.
- Commission Regulation (EC) No 440/2008, B.4 (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 authorised the conduct of the study.

3.0 MATERIALS AND METHODS

3.1 Test Substance

The following information was provided by the Sponsor.

Name:	Propiconazole/Pydiflumetofen SE (A21573C)
Batch number:	1007839
Active Ingredient Content:	Pydiflumetofen – 13.7% (w/w), corresponding to 151 g/L Propiconazole – 11.6 % (w/w), corresponding to 128 g/L
Appearance:	Beige liquid
Density:	1.100 g/cm ³
Recertification date:	31 October 2020
Storage conditions:	Room temperature (<30 °C)
Safety precautions:	Enhanced safety precautions were applied considering the supplied safety datasheet to assure personnel health and safety.
Hazards:	Causes skin irritation. May cause an allergic skin reaction. Causes eye irritation. May cause cancer. May cause damage to organs through prolonged or repeated exposure.

No correction for purity of the test item was applied.

The Certificate of Analysis is shown in Appendix 1.

3.1.1 Identification and receipt

The test item of a suitable chemical purity together with all precautions required in the handling and disposal of the test item were supplied by the Sponsor. The identification of the test item was made in the Pharmacy of Citoxlab Hungary Ltd. on the basis of the information provided by Sponsor.

3.1.2 Formulation

The test item was applied undiluted as supplied by the Sponsor.

3.2 Experimental Design

3.2.1 Animals

Species and strain:	New Zealand White Rabbit
Source:	S&K-Lap Kft. 2173 Kartal, Császárt út 135, Hungary
Number of animals:	3
Sex:	Male
Age when treated:	~10 weeks
Body weight at dosing:	2708 g – 2807 g
Identification:	The animals were identified by engraved ear tags. The cages were marked with individual identity cards with information about study number, sex, cage number, dose and individual animal number.
Acclimatisation:	Under laboratory conditions after health examination. Only animals without any visual signs of illness were used for the study.
Acclimatisation time:	6 and 8 days

3.2.2 Husbandry

Animal health:	Only healthy animals were used for the study, as certified by the staff Veterinarian.
Room number:	034
Housing / Enrichment:	Animals were housed individually in AAALAC approved metal wire rabbit cages. Cages are of an open wire structure, and cages are placed together to allow some social interaction with rabbit(s) in adjoining cages.
Lighting periods:	12 hours daily, from 6.00 a.m. to 6.00 p.m.
Temperature:	19.6 – 22.0 °C
Relative humidity:	32 – 53%
Ventilation:	15-20 air exchanges/hour.

The temperature and relative humidity values were measured continuously. The measured range was checked regularly during the acclimatisation and experimental phases.

3.2.3 Food and feeding

The animals received UNI diet for rabbits produced by Cargill Takarmány Zrt., *ad libitum*. The batch number of the lot used in the study was: 0004634810, expiry date: 13 March 2018.

The food was considered not to contain any contaminants that could reasonably be expected to affect the purpose or integrity of the study. A detailed description of the contents of the lot used is archived with the raw data at Citoxlab Hungary Ltd.

3.2.4 Water supply and quality control

The animals received tap water, fit for human consumption, *ad libitum*, from the automatic system supplied by the communal water network. The water was considered not to contain any contaminants that could reasonably be expected to affect the purpose or integrity of the study.

The 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). Copies of the relevant Certificates of Analysis are retained in the archives at Citoxlab Hungary Ltd.

3.3 Administration of the Test Item

According to EC 2004/73, B.4 and OECD Guidelines 404, a test item does not need to be tested if the pH-value is equal/less than 2 or equal/greater than 11.5, owing to its predictable corrosive properties. The pH of the test item was measured before the study initiation date and was found to be 6.0.

Approximately 24 hours prior to the test, the hair was clipped from the dorsal area of the trunk of the animals with an electric clipper, exposing an area of approximately 100 cm² (10 cm x 10 cm).

Animals with overt signs of skin injury or marked irritation which may have interfered with the interpretation of the results were not used in the test.

On the day of treatment, 0.5 mL of test item was placed on a surgical gauze pad (ca. 2.5 cm x 2.5 cm). This gauze pad was applied to the intact skin of the clipped area and was kept in contact with the skin by a patch with a surrounding adhesive hypoallergenic plaster. The entire trunk of the animals was then wrapped with plastic wrap held in place with an elastic stocking.

The duration of treatment was 4 hours. The dressing was then removed and the skin was flushed with lukewarm tap water to clean the application site.

Initially, a single animal was treated. As neither a corrosive effect nor a severe irritant effect was observed after the 24-hour observation, the test was completed using the 2 remaining animals with an exposure period of 4 hours.

Clinical signs, including viability/mortality, were recorded daily from the day of application of the animals to the termination of the test.

Body weights were recorded on the day of application and at the end of the observation period.

3.4 Post Mortem Investigations

At the end of the observation period, animals were euthanised by intramuscular injections of Ketanest (10% Ketamine) and Nerfasin (2% Xylazine) followed by i.v. pentobarbital sodium (Euthanimal 40%) anaesthesia. Following confirmation of death, the carcasses were discarded without further examination. Details of materials employed for euthanasia are retained in the raw data and detailed in Section 3.4.1.

3.4.1 Materials used for euthanasia

Name: Ketanest (100 mg/mL Ketamine)
Batch No.: H1023-10
Expiry Date: 31 March 2019
Produced by: bela-pharm GmbH & Co. KG, Lohner Straße 19, D-49377 Vechta, Germany

Name: Nerfasin (20 mg/mL Xylazine)
Batch No.: 16A134
Expiry Date: 31 December 2018
Produced by: Le Vet B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Name: Euthanimal 40% (400 mg/mL Pentobarbital sodium)
Lot No.: 1609291-03
Expiry Date: 31 October 2019
Produced by: Alfasan Nederland BV, Kuipersweg 9, Woerden,
The Netherlands

3.5 Data Evaluation

The skin reaction was assessed according to the numerical scoring system listed in the Commission Directive 2004/73/EC, April 29, 2004 (based on the Draize scoring system). The skin reaction was assessed at approximately 1, 24, 48 and 72 hours after the end of exposure (removal of the dressing, gauze patch and test item).

Summarised in tables, data reported included the irritation scores for erythema and oedema for each individual animal at all measurement intervals. Lesions, if observed, were described by the degree and nature of irritation, corrosion or any other toxic effects, and their reversibility.

The mean score was calculated across 3 scoring times (24, 48 and 72 hours after patch removal) for each animal for erythema/eschar grades and for oedema grades, separately. An animal is positive when the mean score was 2 or greater. The test is positive for irritation when at least 2 animals were positive for the same endpoint (erythema/eschar or oedema).

The Cumulative Scores for the Skin Irritation Scores were calculated and represent the sum of all numerical scores for each animal at each time point. The resulting Mean Cumulative Skin Irritation Score was calculated for all animals at each time point.

The Primary Irritation Index (P.I.I.) was calculated by totalling the mean cumulative scores at 24, 48 and 72 hours and then dividing by the number of data points.

The irritation was classified according to the following criteria:

P.I.I. = 0	Not Irritant
$0 < \text{P.I.I.} \leq 2$	Mild irritant
$2 < \text{P.I.I.} \leq 5$	Moderate Irritant
$5 < \text{P.I.I.}$	Severe Irritant

Viability/mortality, clinical signs and dermal findings were recorded on data sheets.

Body weights were recorded on the day of the treatment and at the end of the observation period of each animal.

No statistical analysis was performed.

4.0 RESULTS AND DISCUSSION

4.1 Skin Irritation

Individual and mean skin irritation scores are presented in Tables 1 and 2. Individual local findings are shown in Appendix 2.

The primary irritation index was 0.00 (out of a maximum score of 8.0). No corrosive effects were noted on the treated skin of any animal at any of the observation intervals.

No local dermal signs were observed in the treated animals at approximately 1, 24, 48 and 72 hours after patch removal.

4.2 Clinical Observations

No clinical signs of systemic toxicity were observed in the animals during the study, and no mortality occurred (Table 3).

4.3 Duration of the In-Life Phase

As no clinical signs were observed at 72 hours after patch removal, the study was terminated after the 72-hour observation time point of the second and third rabbits.

4.4 Body Weight

The body weights of all rabbits were considered to be within the normal range of variability (Table 4).

5.0 CONCLUSIONS

The application of Propiconazole/Pydiflumetofen SE (A21573C) did not result in any signs of skin irritation.

According to the Draize classification criteria, Propiconazole/Pydiflumetofen SE (A21573C) is considered to be “non-irritant” to rabbit skin (P.I.I. = 0.00).

6.0 REFERENCES

Literature references listed are available upon request.

External references

Draize, J.H. (1959): Dermal Toxicity. In Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, pp. 46-49. Austin, Texas: Association of Food and Drug Officials of the United States.

Draize, J.H., Woodward, G. & Calvery, H.O. (1944): Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharmacol. Exper. Therap.* 83: 377-390.

Commission Directive 2004/73/EC of 29 April 2004.

TABLES SECTION

GLOSSARY FOR TABLE 1

Grading of Skin Reactions

ERYTHEMA AND ESCHAR FORMATION

No erythema.....	0
Very slight erythema (barely perceptible)	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

Primary Irritation Index (P.I.I.)

The irritation was classified according to the following criteria:

P.I.I. = 0	Not Irritant
$0 < \text{P.I.I.} \leq 2$	Mild Irritant
$2 < \text{P.I.I.} \leq 5$	Moderate Irritant
$5 < \text{P.I.I.}$	Severe Irritant

TABLE 1 Skin Irritation Scores - Individual Values

Animal Number	Sex	Evaluation Interval*	Erythema	Oedema	Cumulative	
					Score	Mean
2729	male	1 hour	0	0	0.00	0.00
2728	male		0	0	0.00	
2718	male		0	0	0.00	
2729	male	24 hours	0	0	0.00	0.00
2728	male		0	0	0.00	
2718	male		0	0	0.00	
2729	male	48 hours	0	0	0.00	0.00
2728	male		0	0	0.00	
2718	male		0	0	0.00	
2729	male	72 hours	0	0	0.00	0.00
2728	male		0	0	0.00	
2718	male		0	0	0.00	

* Examinations were performed at the specified times after removal of the dressing.

TABLE 2 Skin Irritation Scores - Mean Values after 24, 48 and 72 Hours

Animal Number	Sex	Erythema	N	Oedema	N	Primary Skin Irritation Index
2729	male	0.00	3	0.00	3	0.00
2728	male	0.00	3	0.00	3	
2718	male	0.00	3	0.00	3	
Mean score		0.00		0.00		
N= number of available data points.						

TABLE 3 Clinical Signs

Animal Number	Sex	Observations	Observation time				Frequency
			Day 0	Day 1	Day 2	Day 3	
2729	male	Symptom free	+	+	+	+	4/4
2728	male	Symptom free	+	+	+	+	4/4
2718	male	Symptom free	+	+	+	+	4/4

Remarks: + = present, Frequency: number of occurrence of observation/total number of observations

TABLE 4 Body Weights

Animal No.	Sex	Body weight (g)	
		Day of Treatment	End of observation period
2729	male	2708	2800
2728	male	2807	2842
2718	male	2799	2870

APPENDICES SECTION

APPENDIX 1 Certificate of Analysis



Syngenta Crop Protection, LLC
Analytical and Product Chemistry
Greensboro, NC 27409

Certificate of Analysis

A21573C
Batch ID 1007839 (GP170913)

Test Substance Name:	CGA64250/SYN545974 SE (125/150)
Common Name:	Propiconazole/Pydiflumetofen SE (125/150)
Design Code:	A21573C
Batch ID:	1007839
Other ID:	GP170913
Source:	Syngenta Crop Protection LLC.,US .410 Swing Road, Greensboro, NC 27409.

Chemical Analysis

AI	% w/w	g/L
Pydiflumetofen	13.7	151
Propiconazole	11.6	128

Identity of the Active Ingredients: Confirmed

Methodology Used for Characterization: LC , mass spectrometry, oscillating density meter

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

Isomer Assay

Analyte	Isomer	% w/w	g/L
CGA93590	1H-1,2,4-triazole, 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-, cis-	6.73	74
CGA93591	1H-1,2,4-triazole, 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-, trans-	4.84	53.2

COA Number: USGR170462

Page 1 of 2

APPENDIX 1 Certificate of Analysis (Continued)

Physical Analysis

Property	Value	Units
Density	1.100	g/cm ³

Appearance: Beige liquid

Storage Temperature: <30°C

Re-certification Date: End of Oct/2020

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

The stability of this test substance will be determined concurrently through reanalysis of material held in inventory under GLP conditions at Syngenta Crop Protection, LLC, Greensboro, NC.

This Certificate of Analysis is summarizing data from a study that has been performed in compliance with Good Laboratory Practices per 40 CFR Part 160. Raw data, documentation, protocols, any amendments to study protocols and reports pertaining to this study are maintained in the Syngenta Crop Protection Archives in Greensboro, NC.

Study Number: USGR170462

Authorization: Kirt Durand



Kirt Durand
Analytical and Product Chemistry Department

Oct. 13, 2017

Date

APPENDIX 2 Individual Local Findings

Animal No. 2729, Male

After 1 hour:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 24 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 48 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 72 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted

APPENDIX 2 Individual Local Findings (Continued)

Animal No. 2728, Male

After 1 hour:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 24 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 48 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 72 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted

APPENDIX 2 Individual Local Findings (Continued)

Animal No. 2718, Male

After 1 hour:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 24 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 48 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted
After 72 hours:	Erythema:	No abnormal findings noted
	Oedema:	No abnormal findings noted
	Flaking:	No abnormal findings noted
	Staining:	No abnormal findings noted

APPENDIX 3 GLP Certificate



H-1051 Budapest, Zrínyi u. 3.
1372 P.O. Box: 450.
Tel: +36 1 88 69-300, Fax: +36 1 88 69 460
E-mail: ogyei@ogyei.gov.hu, Web: www.ogyei.gov.hu

Ref. no: OGYI/19440-7/2015

Admin.: Szatmári Andrea

Date: 22 September, 2015

GOOD LABORATORY PRACTICE (GLP) CERTIFICATE

It is hereby certified that the test facility

CiToxLAB Hungary Ltd.

H-8200 Veszprém, Szabadságpuszta

is able to carry out

*physico-chemical testing, toxicity studies, in vitro studies and mutagenicity studies,
environmental toxicity studies on aquatic or terrestrial organisms, studies on behaviour in
water, soil and air; bio-accumulation, 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: **02-04. June 2015.**



Note: Translation of the Stamp on the official document (“Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet”): (“National Institute of Pharmacy and Nutrition”)