

Cyproconazole/Chlorothalonil
**Cyproconazole/Chlorothalonil SC (A8384E) - Acute Oral
Toxicity Study in Rats (*Rattus norvegicus*) - Up-and Down
Procedure**
Final Report

DATA REQUIREMENT(S): OECD 425, 2008.

AUTHOR(S): Rejane Medeiros da Silva (MSc)

COMPLETION DATE: 18 June 2018

PERFORMING LABORATORY: TECAM Tecnologia Ambiental São Roque Ltda
Estrada do Carmo, 3001
CEP: 18130-970
São Roque/SP - Brazil

LABORATORY PROJECT ID: Report Number: **RL14950/2018TO-B**
Study Number: **14950/2018TO**
Task Number: **0378281**

SPONSOR(S): Syngenta Proteção De Cultivos Ltda
Av. Das Nações Unidas, 18.001 - 4º Andar
CEP: 04795-900
São Paulo

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

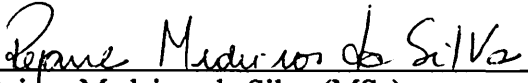
Study Title: Cyproconazole/Chlorothalonil SC (A8384E) – Acute Oral Toxicity Study in Rats (*Rattus norvegicus*) - Up-and-Down Procedure.

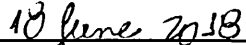
Study Number: 14950/2018TO

This study was conducted under my responsibility in accordance to NIT-DICLA-035 (INMETRO, Sep/11, Rev.02) and its complementary documents and the Good Laboratory Practice Principles as published by the OECD (N° 1 [ENV/MC/CHEM (98) 17]) which meet the United States Environmental Protection Agency Good Laboratory Practice Standards [40 CFR Part 160].

This study was conducted in accordance to the written study plan authorized by the Sponsor and TECAM Management and to TECAM standard operating procedures. This report represents a true and accurate record of the obtained results. There were no major known circumstances that may have affected the quality or integrity of the study.

All original raw data, including any storage medium for electronically recorded data, documentation, the signed study plan, the protocol amendments, the final report and a sample of the test substance will be retained in the GLP Archives at TECAM Tecnologia Ambiental.


Rejane Medeiros da Silva (MSc)
Study Director


Date

Performing Laboratory: TECAM Tecnologia Ambiental São Roque Ltda
Estrada do Carmo, 3001
CEP: 18130-970
São Roque/SP – Brazil

FLAGGING STATEMENT

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QUALITY ASSURANCE STATEMENT

Study Title: Cyproconazole/Chlorothalonil SC (A8384E) – Acute Oral Toxicity Study in Rats (*Rattus norvegicus*) - Up-and-Down Procedure.

Study Number: 14950/2018TO

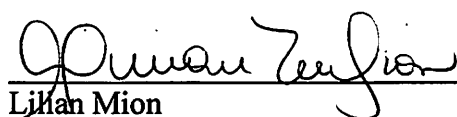
Based on a quality assurance review, it was concluded that the final report is a true reflection of the raw data.

The final report was examined with respect to the study plan, standard operating procedures and raw data. Proceedings of the study were inspected by process based inspections.

The inspections were carried out according to the standard operating procedures of the Quality Assurance of TECAM Tecnologia Ambiental.

Dates of inspections and the dates on which the findings were reported to the Study Director and Management are given below. These reports are kept in the GLP Archives at TECAM Tecnologia Ambiental.

Inspection	Date of inspection	Reporting Dates	
		To Study Director	GIT
Study Plan	19 February 2018	19 February 2018	19 February 2018
Experimental Phase	27 February 2018	05 March 2018	05 March 2018
Raw Data	15 May 2018	15 May 2018	15 May 2018
Draft Report	15 May 2018	15 May 2018	15 May 2018
Final Report	18 June 2018	18 June 2018	18 June 2018
English Version	18 June 2018	18 June 2018	18 June 2018


Lilian Mion
Quality Assurance
TECAM Tecnologia Ambiental

18 June 2018
Date

GENERAL INFORMATION

Contributors

The following contributed to this report in the capacities indicated:

Rejane Medeiros da Silva (MSc)	Study Director.
Cynthia B. Pestana (PhD)	Test Facility Manager.
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Bruna Daniely Silvério	Biologist.
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Daiana Zonta Ramos	Technical Support
Iasmin Ferreira de Araujo	Biologist
Merielen Garcia Nascimento Pontes	Syngenta Study Manager

Study Dates

Study Initiation Date:	19 March 2018.
Acclimatization:	21 to 26 March 2018 (animal 1 - 5000 mg/kg bw); 28 March to 02 April 2018 (animal 2 - 5000 mg/kg bw); 04 to 09 April 2018 (animal 3 - 5000 mg/kg bw);
Experimental Starting Date:	27 March 2018 (animal 1 - 5000 mg/kg bw); 03 April 2018 (animal 2 - 5000 mg/kg bw); 10 April 2018 (animal 3 - 5000 mg/kg bw);
Experimental Termination Date:	10 April 2018 (animal 1 - 5000 mg/kg bw); 17 April 2018 (animal 2 - 5000 mg/kg bw); 24 April 2018 (animal 3 - 5000 mg/kg bw);
Study Completion Date:	18 June 2018
English Version:	18 June 2018.

Performing Laboratory

The present study was conducted at TECAM Tecnologia Ambiental São Roque, located at Estrada do Carmo, 3001, São Roque, SP – Brazil.

The physico-chemical analysis in water was subcontracted and monitored by the Quality Assurance of TECAM.

Study Plan Adherence

No deviations or amendments were recorded from the study plan.

Archives

All the original raw data and records of this study are the property of the Sponsor. Data will be properly registered, signed and stored in TECAM's archives for five years. Test item will

be properly stored during the test and after that will be returned to the Sponsor. When possible a sample will be retained for two years or until the expiry date.

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1.0 EXECUTIVE SUMMARY

1.1 Study Design

The present study was carried out to provide information about acute toxicity following single oral administration to rats of test substance **Cyproconazole / Chlorothalonil SC (A8384E)**. The method followed was the OECD 425, 2008.

Three young adults and healthy female Wistar rats (*Rattus norvegicus*) were selected and maintained under controlled environmental conditions. The animals were fasted *overnight* before the administration of test substance. The administration volume were calculated at 0.43 mL/100 g at doses of 5000 mg / kg bw (body weight) based on the mass over volume of the test substance and at the dose selected. One female received the test substance undiluted at the dose of 5000 mg/kg bw. After 7 days of the treatment, as no mortality was not observed, two additional animals received the same dose (treated sequentially). Body weights were measured immediately prior to the administration (day 0), 7 and 14 days after administration. After dosing, animals were observed individually during the first 24 hours, with special attention given during the first 4 hours, and during all the 14 days of test. The animals were euthanized with carbon dioxide and submitted to necropsy after euthanasia.

1.2 Results

Clinical signs of toxicity were observed between the animals treated with the dose of 5000 mg/kg bw, such as, piloerection and diarrhea

At the end of the test, the animals presented body weight gain. In relation to necropsy, in the no macroscopic alterations were observed in the treated animals.

1.3 Conclusion

Under the test conditions, the acute oral LD₅₀ for test substance **Cyproconazole/Chlorothalonil SC (A8384E)** was greater than 5000 mg/kg bw in female rats.

2.0 INTRODUCTION

2.1 Study Purpose

The present study was carried out to provide information about acute toxicity after single oral dose in rats of test substance **Cyproconazole/Chlorothalonil SC (A8384E)**, through the determination of the median lethal dose (LD₅₀).

2.2 Study Guidelines

The study was performed according to:

OECD Guideline for testing of chemicals. Acute Oral Toxicity: Up-and-Down Procedure, 425, 27p., 2008.

2.3 Weight of Evidence Analysis

For reasons related to animal welfare, prior to conducting the study a weight of evidence analysis was carried out with the available and relevant data of the test substance. The testing strategy includes data evaluation of toxic effects of the test substance in human and/or animals. Test substances that are known to cause marked pain and distress due to corrosive or severely irritant actions do not need to be tested.

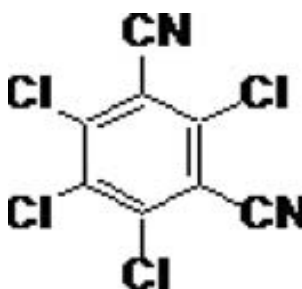
2.4 Animal Welfare

Animals are maintained in the test facility according to local and international requirements described in the current SOPs (Standard Operating Procedures), based on the Guide for the Care and Use of Laboratory Animals (ILAR-NRC, 2011). Animals showing continuing signs of severe distress and/or pain at any stage of the test are humanely killed and the test substance assessed. Procedures for animal care and criteria for making the decision to humanely kill moribund and severely suffering animals are described in detail in the SOPs, based on the *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation* (OECD 19, 2000).

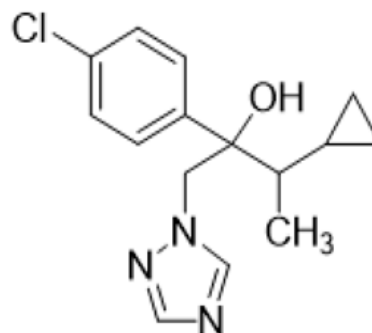
3.0 MATERIALS AND METHODS

3.1 Test Substance

Identification:	Cyproconazole / Chlorothalonil SC (A8384E)
Test substance number:	1800641*
Received on:	02 October 2017
Batch N°:	FER 001-010-001
Study number:	14950/2018TO
RET Number:	1439/2016
Active ingredient (a.i.):	Chlorothalonil; Cyproconazole
Declared concentration of a.i.:	Chlorothalonil - 375 g/L; Cyproconazole - 40 g/L
Analysed concentration of a.i.:	Chlorothalonil - 380.24 g/L; Cyproconazole - 38.81 g/L * (Appendix 1)
IUPAC name of a.i.:	Chlorothalonil - tetrachloroisophthalonitrile; Cyproconazole - (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol ***
Number CAS of a.i.:	Chlorothalonil - 1897-45-6; Cyproconazole - 94361-06-5 ***
Class:	Fungicide **
Structural formula:	



Chlorothalonil***



Cyproconazole ***

Molecular formula:	Chlorothalonil-C ₈ H ₄ Cl ₄ N ₂ ; Cyproconazole - C ₁₅ H ₁₈ ClN ₃ O ***
Molecular weight:	Chlorothalonil – 265.9 g/mol; Cyproconazole – 291.8 g/mol ***
Manufactured on:	September 2017

Expiry date: 01 September 2019
Formulation: SC (suspension concentrate)
Physical state: Liquid
Synonymy: A8384E
Homogeneity: Homogeneous (Visual Inspection) *
Stability: Stable ambient temperature and accelerated stability 14 days at 54 °C. **
Test substance supplied by: SYNGENTA PROTEÇÃO DE CCULTIVOS LTDA

* Information provided by TECAM Tecnologia Ambiental

** Sponsor information

*** The Online Pesticide Manual (17th ed. 2015).

3.2 Test System

Species: *Rattus norvegicus*.
Strain: Wistar (albino rats).
Source: TECAM Tecnologia Ambiental.
Justification of species: The albino rat is the model species recommended by regulatory agencies for evaluation of acute toxicity.
Number and sex: 3 nulliparous and non-pregnant females.
Body weight range and age: Young adult with 8-10 weeks at start of treatment with body weight between 152.9 g and 193.7 g; the weight variation among the animals on day 0 did not exceed 20% of the group mean weight.
Acclimatization: Animals were acclimatized for 5 days prior to dosing in a climate-controlled room; animals exhibiting abnormal signs were not used for the study.
Housing: Polysulfone rodent cages with 3 animals per cage.
Identification: Cage cards displaying animal number, sex, date of birth, sample code, dose and study dates were fixed to each cage; animals were weighed and identified individually with tail marking.

3.3 Animal Health and Environmental Monitoring Program

As a program of animal health and environmental monitoring, the following procedures are performed periodically to ensure that contaminant levels are below those that might impact the scientific integrity of the study:

Health status: Only healthy rats were used for this study. The animals were not vaccinated or treated with anti-infective substances either during the acclimatization and study periods.
Feeding: Pelleted commercial diet for rodents (Quimtia S.A.) was provided *ad libitum* throughout acclimatization and test periods (except before administration). Food is analyzed by TECAM/SP periodically for microbiological contaminants. The commercial

food was considered not to contain any contaminant at levels that affected the purpose or integrity of the study.

Drinking water: Filtered water was provided *ad libitum* throughout acclimatization and test periods. The drinking water is analyzed periodically for chemical and microbiological contaminants. The drinking water was considered not to contain any contaminant at levels that affected the purpose or integrity of the study.

Bedding: Aspen wooden chips previously prepared by Biotécnicas and irradiated with gamma radiation were provided for the animals and were changed twice a week.

3.4 Environmental Conditions

The environmental conditions in the room were monitored and recorded daily. The average temperature was 20.8 °C (animal 1), 21.0°C (animal 2) and 21.5 °C (animal 3). The average relative humidity was 66.6 % (animal 1, 65.3 % (animal 2) and 62.5 % (animal 3). The animals were subjected to photoperiod, automatically controlled 12 hours of light (only artificial light from 7 a.m to 7 p.m.) and 12 hours of dark. The ventilation of the room was approximately 10 to 12 air changes per hour.

3.5 Procedures

The test substance was evaluated using a limit test, according to Guideline OECD 425 (2008).

A limit dose of 5000 mg/kg bw was selected by the Study Director after justification by the Sponsor that there is specific regulatory requirement to test this dose level. One animal was initially tested at 5000 mg/kw bw. As no mortality was recorded, then two additional animals were dosed, sequentially, at the same dose.

Animals were fasted overnight prior to the test substance administration and returned to *ad libitum* feeding approximately three hours after treatment. Access to water was not interrupted. On the day of test substance administration, all animals were weighed and identified with colorful pens. The test substance was administered in a single oral dose by gavage using syringe and appropriate cannula. The dose volume was calculated considering the initial body weight, the test substance concentration and the selected dose level. The test substance was administered undiluted.

The dose level, intervals and dose volume used are shown in the table below:

Animal Number	Dose Level (mg/kg bw)	Dose Volume (mL/100 g bw)	Intervals between Dose Levels (Days)	Mortality
1	5000	0.43	0	No

2	5000	0.43	7	No
3	5000	0.43	7	No

3.6 Clinical Observation

Body weights were recorded shortly before administration (fasted body weight), weekly thereafter (day 7) and at the end of the study (day 14). Animals were observed individually after dosing during the first 24 hours with special attention given during the first 4 hours. During the 14-days observation period, animals were observed daily for the presence of clinical signs of toxicity. Clinical observations included, but were not limited to, changes in skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavioural patterns such as salivation tremors and convulsions, changes in the level of motor activity, changes in the behaviour, changes in the level of activity, gait and posture, reactivity to handling or sensory stimuli, altered strength, and stereotypes or bizarre behavior (*e.g.* self mutilation).

3.7 Necropsy

Animals were euthanized via CO₂ inhalation at the end of the 14-day observation period. Gross necropsies were performed on all animals. Necropsy findings were registered for bladder, central nervous system (CNS), gastrointestinal tract (esophagus, stomach, duodenum, jejunum, ileum, cecum), heart, kidney, liver, lymph nodes, muscles, ovaries, pancreas, respiratory tract (lungs, trachea, bronchi, diaphragm), spleen, thyroid and uterus.

3.8 Results Evaluation

The determination of LD50 was done according to the Guideline OECD Guideline for testing of chemicals. Acute Oral Toxicity: Up-and-Down Procedure, 425.

4.0 RESULTS AND DISCUSSION

4.1 Mortality and Clinical Signs

There was no mortality between treated animals, Table 1. The treatment with Cyproconazole / Chlorothalonil SC (A8384E) caused piloerection and diarrhea. Two animals were symptom free from 24 hours after treatment and one animal was symptom free from 48 hours after treatment. Individual clinical observations results are presented in Tables 3 and 4.

4.2 Body Weight

Individual and group mean body weights of treated animals on days 0, 7 and 14, as well as body weight changes after 14 days of test and volume of administration are presented in Table 2. At the end of the test, all animals presented body weight gain.

4.3 Necropsy

There was no evidence of abnormal macroscopic observations at a dose level of 5000 mg/kg bw. The individual findings of all animals are shown in Table 5.

5.0 CONCLUSIONS

Under the test conditions, the acute oral LD 50 for test substance **Cyproconazole/Chlorothalonil SC (A8384E)** was greater than 5000 mg/kg bw in female rats.

6.0 REFERENCES

Acute Oral Toxicity (OECD Test Guideline 425) Statistical Programme (AOT 425 StatPgm). Version: 1.0, 2006.

ILAR. Institute for Laboratory Animal Resources - National Research Council. Guide for care and use of laboratory animals. Washington: National Academy Press, 2011. 220p.

INMETRO. NIT-DICLA-035 – “Principles of Good Laboratory Practice – GLP”, Rev. 02, September/2011 and its complementary documents.

OECD Environmental Health and Safety Publications, Series on Testing and Assessment. Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation. No. 19. Paris, 2000.

OECD Guideline for Testing of Chemicals. Acute Oral Toxicity - UP and Down Procedure, 27p.,2008.

Turner, J.A. The Online Pesticide Manual. 17.ed. United Kingdom: BCPC, 2015. Available at: <http://www.bcpc.org/>.

TABLES SECTION

TABLE 1 Mortality Among Treated Animals

Dose (mg/kg bw)	Number of Animals	Number of Deaths	Mortality (%)
5000	3	0	0

TABLE 2 Individual (bw) and Mean Body Weight and Volume of Administration of Females Treated with 5000 mg/kg bw of Cyproconazole / Chlorothalonil SC (A8384E).

Female number	Volume of administration (mL)	Administration time	Body weight (g)			
			Day 0*	Day 7	Day 14	Day 14 - Day 0*
1	0,80	9h20	186.1	204.2	216.9	+ 30.8
2	0,83	9h10	193.7	192.0	205.2	+ 11.5
3	0,66	8h24	152.9	170.4	182.0	+ 29.1
Body weight mean			177.6	188.9	201.4	23.8

Day 0: fasted body weight.

TABLE 3 Clinical Observation of Females Treated with 5000 kg/kg bw of Cyproconazole / Chlorothalonil SC (A8384E) in the First 4 Hours After Administration of Test Substance.

Female Number	Clinical Observation (Hours)				
	0.5	1	2	3	4
1	NA	NA	7,9	7,9	7,9
2	NA	NA	9,7	9,7	7,9
3	NA	NA	9	9	9

Code	Signs	Code	Signs
NA	No alterations	8	Mucosal alterations
1	Death	9	Diarrhea
2	Coma	10	Salivation
3	Convulsions	11	Dyspnea
4	Prostration	Mi	Mild
5	Ataxia	M	Moderate
6	Tremors	S	Severe
7	Alterations of skin and fur (piloerection)		

TABLE 4 Clinical Observation of Females Treated with 5000 mg/kg bw of Cyproconazole / Chlorothalonil SC (A8384E) on the Days 1-14.

Female Number	Clinical Observation (Days)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Code	Signs	Code	Signs
NA	No alterations	7	Alterations of skin and fur
ND	No dead or moribund animals	8	Mucosal alterations
1	Death	9	Diarrhea
2	Coma	10	Salivation
3	Convulsions	11	Dyspnea
4	Prostration	Mi	Mild
5	Ataxia	M	Moderate
6	Tremors	S	Severe

TABLE 5 Individual Necropsies of Females Treated with 5000 mg/kg bw of Cyproconazole / Chlorothalonil SC (A8384E).

Macroscopic Observations	Female Number		
	1	2	3
SNC	NA	NA	NA
Pulmões	NA	NA	NA
Coração	NA	NA	NA
Tireóide	NA	NA	NA
Traquéia	NA	NA	NA
Esôfago	NA	NA	NA
Diafragma	NA	NA	NA
Fígado	NA	NA	NA
Baço	NA	NA	NA
Rins	NA	NA	NA
Estômago	NA	NA	NA
Pâncreas	NA	NA	NA
Intestinos	NA	NA	NA
Bexiga	NA	NA	NA
Músculos	NA	NA	NA
Linfonodos	NA	NA	NA
Útero	NA	NA	NA
Ovários	NA	NA	NA

CNS: Central Nervous System.

Code	Macroscopic findings	Code	Macroscopic findings
NA	No alteration	5	Bloody content
1	Congestion	6	Gas content
2	Multifocal pale areas	D	Discrete
3	Hemorrhagic focus	M	Moderate
4	Hemorrhagic spots	S	Severe

APPENDICES SECTION

APPENDIX 1 (A8384E)

Certificate of Analysis for Cyproconazole/Chlorothalonil SC



CERTIFICATE OF ANALYSIS N°: CA1719429-B-Version 2

Sponsor: SYNGENTA PROTEÇÃO DE CULTIVOS LTDA

Address: AV. DAS NAÇÕES UNIDAS, 18.001 - 4º Andar. CEP: 04795-900 - SÃO PAULO

1. TEST SUBSTANCE INFORMATION

Identification: Chlorothalonil/Cyproconazole SC (A8384E)
RET number: 1439/2016.
Synonym: A8384E.
TECAM code: 13223/2017CA.
Batch number: FER 001-010-001.
Manufactured on: September 2017.
Expiry date: 01 September 2019.
Active ingredient (a.i.): Chlorothalonil; Cyproconazole.
Declared concentration of a.i.: Chlorothalonil - 375 g/L; Cyproconazole - 40 g/L.
IUPAC name: Chlorothalonil - tetrachloroisophthalonitrile;
Cyproconazole - (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol.

2. EXPERIMENTAL

Equipment: High Performance Liquid Chromatograph (HPLC) 1260 Series AGILENT TECHNOLOGIES – TECAM N° 000905.

3. DATES

Initial date: 05 December 2017.

Final date: 15 December 2017.

4. RESULTS

Certificate of Analysis	Results	
CA1719429-B-Version 2	38.81 g/L Cyproconazole	380.24 g/L Chlorothalonil



5. METHODOLOGY

Sponsor Analytical Method: Cyproconazole and Chlorothalonil in formulation SC (A8384A).

6. SIGNATURES

	05-JUNE-2018		05-June-2018
Lais Sayuri Ribeiro de Morais	Date	Carolina Satie Hayashida	Date
Chemical Analyst		Quality Assurance	
CRQ 04163225			

APPENDIX 2 Recognition of Compliance with the Principles on Good Laboratory Practice

Federal Republic of Brazil Ministry of Industry, Foreign Trade and Services National Institute of Metrology, Quality and Technology - INMETRO		
General Coordination for Accreditation <i>Brazilian Compliance Monitoring Authority for the Principles of Good Laboratory Practice – GLP</i>		
<h3>Statement of GLP Compliance</h3>		
GLP Recognition No. GLP 0012		Inicial Recognition: 06-09-2002
Tecam Tecnologia Ambiental São Roque Ltda. Estrada do Carmo, 3.001 – Sorocamirim – São Roque - São Paulo - SP – Brasil		
<p><i>The General Coordination for Accreditation of Inmetro grants to the above mentioned test facility the recognition of compliance with the OECD Principles of Good Laboratory Practice as part of the Brazilian GLP Monitoring Program to carry out non-clinical health and environmental safety studies, as describe in the scope below:</i></p>		
Areas of expertise	Categories of Test Items	
Toxicity studies; Mutagenicity studies; Environmental toxicity studies on aquatic and terrestrial organisms.	Pesticides, Their Components and Suchlike; Pharmaceutical Products; Cosmetics; Wood Preservative; Food Additives; Feed Additives; Veterinary Products; Sanitizers; Industrial Chemical Products; Genetically Modified Organisms; Remedial for treatments of effluents and natural ecosystems.	
<p>Note: Categories of test items "pesticides", "pharmaceutical products", "cosmetics", "wood preservative", "feed additives", "veterinary products", "sanitizers", "remedial for treatments of effluents and natural ecosystems" and "industrial chemical" are covered by Brazil's full adherence to the OECD Council Acts related to the Mutual Acceptance of Data (MAD) on Good Laboratory Practice.</p>		
 Aldoney Freire Costa General Coordinator for Accreditation		Assinado de forma digital por ALDONEY FREIRE COSTA Dados: 2016.09.05 08:31:37 -03'00'
<p><i>The recognition status shall be checked at the address http://www.inmetro.gov.br/monitoramento_BPL/certificados</i></p>		

MOD-CGCRE-027 – Rev. 05 – Apr. JUN/16 – Pg. 01/01