GRUPO MICROQUIM

MICROQUIM S.A.
LABORATORIO DE INVESTIGACIONES CIENTIFICAS POR CONTRATO
Av. Triunvirato 3447 • (C 1427 AAH) Buenos Aires, Argentina
Tel.: (5411) 4554-1415 • Fax: (5411) 4554-7860
E-mail: info@microquim.com • http://www.microquim.com

QUALITY ASSURANCE UNIT STATEMENT

TITLE: Acute Oral Toxicity of NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO in Rats (*Rattus norvegicus*)

TEST SUBSTANCE: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

STUDY NUMBER: BIBR 6 - 30390

This study was audited during its different stages. For this study, the final report was compared with the study plan and the Standard Operating Procedures (SOP).

The report is in accordance with the obtained data.

The audit was carried out according to the Standard Operating Procedures (SOP) established in the Procedures Manual of MICROQUIM S.A.

The audit report was remitted to Direction and the Study Director, filing a copy of it in the "Internal Audits" archive of the Quality Assurance Unit of MICROQUIM S.A.

Audit Nº	**Audited area / Details**	**Audit Date**
8639.a	Audit´s Study Plan	03.18.10
8639.b	Audit´s Study	04.01.10
8639.c	Final report revision.	07.16.10
8639.d	Audit´s Report to Direction and the Study Director	07.19.10

Dr. Ana Inés Chanfreau
Veterinarian
GLP Quality Assurance Unit

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Acute Dermal Toxicity of

NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

in Rats (*Rattus norvegicus*)

Guideline OECD N° 402

Test number:

BIBR 6 – 30391

ID **50907**

Ref. 6-2154

Date:

May 23th, 2010

Sponsor:

AJIM S.R.L Y JORGE NATALIO FELIPE PEISAJOVICH GALANTE - AGROSERVICIOS NES - MEXICO

Av. Borrini 225

Resistencia, CP (3500), Chaco

Argentina

Study conducted by

MICROQUIM S.A.

Department of Biological Studies

6MIC4100101304a

Consejo Profesional de Química

C.P.Q.

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Quality Assurance Unit Statement

GRUPO MICROQUIM

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A) STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICES

TITLE: ACUTE DERMAL TOXICITY OF NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO IN RATS (*Rattus norvegicus*)

TEST SUBSTANCE: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

STUDY NUMBER: BIBR 6 – 30391

This study was conducted according to the OECD series on principles of Good Laboratory Practices and compliance monitoring, N°1, ENV/MC/CHEM (98) 17 OECD and pursuant to the written study plan, authorized by the Sponsor and the Technical Management of MICROQUIM. S.A. following the Standard Operating Procedures (SOP) stated in the Procedures of MICROQUIM S. A.

This report is a true and accurate record of the results obtained, and there were no known circumstances that could have affected the quality and integrity of the data. This certificate can only be reproduced with the approval of the laboratory.

The results obtained, as well as any storage medium for electronically recorded data, all documentation, study plan and final report are retained in the corresponding archives at MICROQUIM S.A.

Juan Manuel Catoyra
Veterinarian
Study Director

Date: 08/07/10

B) PREFACE

B.1) GENERAL

Title: Acute dermal toxicity of NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO in rats (*Rattus norvegicus*).

Sponsor: AJIM S.R.L Y JORGE NATALIO FELIPE PEISAJOVICH GALANTE - AGROSERVICIOS NES – MEXICO, Av. Borrini 225, Resistencia, CP (3500), Chaco, Argentina

Test number: BIBR 6 – 30391

Test substance: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

Test system: Sprague Dawley Rat, strain Crl: CD®(SD) IGS-BR.

Testing Institution: MICROQUIM S.A., Av. Triunvirato 3447, (1427) Buenos Aires, Argentina.

Test facility: BIOMICRO S.A., Costa Rica 4776, Malvinas Argentinas.

Address of the Study Director: BIOMICRO S.A., Costa Rica 4776, Malvinas Argentinas.

B.2) STAFF

Technical Director:	Dr. Alejandro Lucini Chemistry Degree
Study Director:	Dr. Juan Manuel Catoyra Veterinarian
Animal Health Responsible	Dr. Juan Manuel Catoyra Veterinarian
Test Performance:	Silvana Sabatini Biotery Technician
Final Report Confection:	Gisele Keim
Archive Responsible:	Silvina López

B.3) SCHEDULE

Date of entrance of the sample: 11.10.09

Start of the experimental phase (beginning of the acclimatization): 03.19.10

Date of the First dose: 03.30.10

Observation period: 14 days after the administration of the dose.

Date of the end of the experimental phase: 04.13.10

B.4) TEST GUIDELINE

This test was performed in agreement with the following method: Guideline for Chemical Tests N°402 "Acute Dermal Toxicity" by the Organization for Economic Cooperation and Development (OECD). Adopted on 24.02.1987 and SOP: "Acute Dermal Toxicity in rats" (POE 111-BM/02).

B.5 GOOD LABORATORY PRACTICES

This study will assure the performance of the standard operation procedures. The Quality Assurance Unit will periodically inspect test procedures and inspection dates will be included in the report.

This study will be performed according to the OECD principles of good laboratory practices, 1998. Established by SENASA Resolution No. 230/2000.

B.6) CERTIFICATIONS, REGISTRATION, ACCREDITATIONS AND REGISTERS

- ´ Certification in accordance with principles of Good Laboratory Practices (1998), issued by OAA.
- **GLP** Certification in accordance with: EPA 40 CFR PART 160 "Principles of Good Laboratory Practice and Compliance Monitoring" ENV/MC/CHEM (98) 17 OECD. SENASA 230/2000 Resolution. Commission Directive 2004/10/EC of de European Parliament. Issued by **Bureau Veritas Certification**.
- **ISO 9001:2008** Certification for the Quality Management System, issued by **Bureau Veritas Certification** with accreditation of:

OAA (Argentina)

ANAB (U.S.A.)
UKAS (United Kingdom)
INMETRO (Brazil)

- **COFILAB** (Laboratories Control Committee)
- **CALIBA** (Argentine Chamber of Independent Laboratories of Bromatological, Environmental and Other Related Analysis)
- **SENASA** Accreditation (National Health Service and agro food quality) LR 0060 as laboratory of agrochemicals analysis to perform physicochemical, toxicological studies and determination of pesticide residues in vegetal matrixes.
- Animal facility subscribed at **SENASA** (National Health Service and agro food quality) according to regulations of Resolution 617/02 for the production of toxicological and ecotoxicological data.
- **AACyTAL** (Argentinian Asociation of Science and Technology of Laboratory animals) No. 09-0076
- **Colombian Agricultural Institute (ICA)**, part of the Treaty of the Andean Pact, Resolution No. 03431 as a Quality Control Laboratory of chemical pesticides for agricultural use.
- **EPA** (Environmental Protection Agency) assigned laboratory code number 955079.
- **Environment Aptitude certificate** issued by the Government of the Autonomous City of Buenos Aires Res. 077 A.A. 123/2000 Law.
- **Provincial Agency for Sustainable** Development Accreditation as Laboratory of Industrial Analysis according to the provisions of Resolution No. 504/01. Registration No. 31.
- **SEDRONAR** (Secretaryship of Programs to prevent the drug addiction and fight against the drug trafficking) Nº RN 858 PQ

B.7) AMENDMENT PROCEDURE

This final report can be amended by the Study Director and the Sponsor by the Sponsor in the event that his request. The Study Director will sign detailed descriptions of all amendments. The amendment will be effective at the time of Study Director's signature.

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B.8) ARCHIVES

The laboratory will preserve the following data at least for 6 years: study plan, report and original data, in the general archive situated at Triunvirato 3447, (1427) Buenos Aires, Argentina. During that period no data will be discarded without the Sponsor's consent.

B.9) COMMITMENT OF CONFIDENTIALITY

The signatories of this final report are committed to safeguarding the confidentiality of all information involved in this study, both delivered by the Sponsor as that generated by this laboratory.

B.10) SAFETY PRECAUTIONS

Gloves, cap, mask with filters and protective goggles (if required) will be used to ensure proper safety and personal health and avoid inhalation and skin contact with the substance of test. In case of contact with eyes, wash them thoroughly with water and will seek medical treatment. In case of contact with skin, wash with soap and water with subsequent medical help.

C) SUMMARY

Title: Acute dermal toxicity of NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO in rats (*Rattus norvegicus*).

Test substance: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

Dose leve: 4000 mg/kg, body weight

Median lethal dose: > 4000 mg/kg

No animal mortality was recorded during the observation period.

The animals gained the expected body weight throughout the entire study period.

Conclusion:

The median lethal dose **(LD_{50})** by dermal administration of the test substance **NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO** in Sprague Dawley rats, strain Crl:CD®(SD)IGS-BR was **GREATER THAN 4000 mg/kg.**

D) PURPOSE

The aim of the study was the assessment of the acute toxicity of NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO from a short-term exposure by the dermal route, when it is administered in a single dose in rats, followed by a 14 day observation period.

This test provided a rational basis for the hazard evaluation associated with the use of NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO.

E) TEST SYSTEM AND MATERIALS

E.1) TEST ANIMALS

Test system: Sprague Dawley Rat, strain Crl:CD®(SD)IGS-BR.

Origin: Facultad de Ciencias Veterinarias, Universidad de Buenos Aires, Av. Chorroarín 280, C1427CWO - Buenos Aires, Argentina. Tel: 4524-8400.

Source: BIOMICRO. Costa Rica 4776, Malvinas Argentinas.

Animal Lot Number: R08/10

Number of animals for the test: 10, 5 males and 5 females. Females used were nulliparous and non-pregnant.

Age and weight at the start of the test: Young adult animals, between 8 and 12 weeks old. The weight variation in animals used in the test did not exceed ± 20% percent of the mean weight.

Identification: Marks on the tail with inerasable ink.

Acclimatization: Animals were acclimatized to the laboratory conditions 11 days prior to the start of the test. After acclimatization healthy animals were randomised and assigned individually to each cage.

E.2) HOUSING AND FEEDING CONDITIONS

Animals were housed under standard laboratory conditions. The animals' test room was provided with conditioned air filtered by HEPA filters with 10-15 air changes per hour.

The temperature of the animals' room was 22 ± 3°C and the relative humidity 30-70 per cent, although the upper range for humidity may have exceeded during the cleaning of the room.

Animals were provided with photoperiods of 12 hours light- 12 hours darkness and placed into individual cages made of steel with litter of autoclaved wood shavings. Lot number: (41 al 49) 26.10.09

The following diet was provided *ad libitum*: Balanced food Rat-Mouse Cooperaciòn supplied by Distribuidora Horacio Gilardoni. Lot number: 10007/09/38

Well water was provided *ad libitum*.

E.3) IDENTIFICATION AND CHARACTERISTICS OF THE TEST SUBSTANCE (According to information provided by the Sponsor)

- Label: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO
- Valuation of the active principle: AZUFRE: 13.68 % w/w; 14.91 % w/v, Batch N°: 025/2009
- Product description: Yellow-greens liquid.
- Storage conditions: Room temperature.
- Container: Plastic bottle

The sampling was made by the sponsor

E.4) PREPARATION OF THE TEST SUBSTANCE

- Physical state of the test substance:Liquid
- Solvent used: water.
- Test substance concentration in the solvent: 40% p/v

E.5) LIMIT TEST

A limit test of 4000 mg/Kg was performed. Since the test animals presented toxicology symptoms but not mortality, the test was finished.

E.6) DOSE LEVELS

A single dose of 4000 mg/kg body weight was performed (Administered on 03.30.10)

E.7) EXPOSURE/OBSERVATION PERIOD

The exposure time to the test substance was 24 hours.

The observation period was 14 days after the treatment.

F) TEST PERFORMANCE

F.1) DOSAGE

About 24 hours prior to the test, the trunk's dorsal area of the test animals was shaved, taking care not to abrade the skin, since this could alter the test.

Only healthy animals with intact skin were used.

The test substance was applied uniformly on the shaved area (approximately 10% of the total body surface area) using a graduated syringe with the previously calculated volume.

To maintain the contact, a non-irritant porous bandage was wrapped around the abdomen and was retained in place with non-irritant adhesive tape. The exposure period was 24 hours. Animals were not entirely immobilized.

After the exposure period, the residues of the test substance were removed with water.

F.2) CLINICAL EXAMINATION

The clinical examination was carefully performed once a day and more often during the first day. Additional observations were made daily.

The following observations were made for each cage including any modification or alteration of: skin and/or fur, eyes, mucous membranes, respiratory and circulatory systems, autonomous and central nervous system, somatomotor activity and behaviour pattern. Particular attention was directed to the observation of tremors, convulsions, salivation, diarrhea, lethargy, sleepiness and coma.

F.3) ANATOMY - PATHOLOGY

The general necropsy was carried out in all the test animals and a veterinarian recorded all gross pathological changes.

G) RESULTS

Results were summarized in a tabular form showing: test groups, number of animals at the beginning of the test and sex, number of animals displaying different toxicity signs, description of toxic effects and necropsy findings.

The report contains the test conditions, dose levels, incidence and importance of abnormalities, the effects on mortality as well as all the other toxicological effects.

Clinical behaviour of the animals under treatment is provided in (TABLE N° 1). No mortality was recorded during the test period, following treatment with the test substance.

The body weight of the animals was maintained within the physiological variability range of the test system (TABLE N° 2).

At the end of the test, animals were sacrificed with carbon dioxide (TABLE N° 3). No abnormalities were recorded at necropsy.

H) CONCLUSION

The median lethal dose **(LD_{50})** by dermal administration of the test substance **NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO** in Sprague Dawley rats, strain Crl:CD®(SD)IGS-BR was **GREATER THAN 4000 mg/kg.**

I) REFERENCES

Good Laboratory Practice – ENV/MC/CHEM (98) 17 OECD.

Guideline for Chemical Tests N°402 "Acute Dermal Toxicity" by the Organization for Economic Cooperation and Development (OECD). Adopted on 24.02.1987 and SOP: "Acute Dermal Toxicity in rats" (POE 111-BM/02)

The data contained in this report as well as the conclusion are the accurate reproduction of the raw data registered on the logbook **1.TDA** pages 004889 to 004897.

MICROQUIM S.A.
JUAN MANUEL CATOYRA
Médico Veterinario
M.P. N° 7553
Director de Estudio
Study Director

MICROQUIM S.A.
Dr. ALEJANDRO D. LUCINI
Director Técnico
Technical Director
M.N.7174/M.P. 4765

TABLE 1:

ACUTE DERMAL TOXICITY TEST

INDIVIDUAL CLINICAL OBSERVATIONS AND MORTALITY

ANALYZED SAMPLE: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

SPONSOR: AJIM S.R.L

DATE OF THE END OF THE TEST: 04.13.10

ANALYSIS NUMBER: BIBR 6 – 30391

Dose mg/kg	*Animal N° and sex*		*Observation effects Post-administration*																	
			Hours				*Days*													
			0	1	2	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
4000	11	Female	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	Female	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	13	Female	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	14	Female	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	15	Female	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	Male	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	17	Male	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	18	Male	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	19	Male	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	Male	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Notes:

0: NO TOXIC SIGNS WERE OBSERVED

1: TOXIC SIGNS WERE OBSERVED

2: ANIMAL MORTALITY

2*: EUTHANASIED ANIMAL

SIGNS

a.- MORTALITY DATA: No /Animal mortality was recorded during the observation period.

b.- CLINICAL OBSERVATION: Animals presented the following toxic sings: lethargy and piloerection.

c.- NECROPSIES: No abnormalities were observed.

TABLE 2:

ACUTE DERMAL TOXICITY TEST

INDIVIDUAL BODY WEIGHTS

ANALYZED SAMPLE: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

SPONSOR: AJIM S.R.L

DATE OF THE END OF THE TEST: 04.13.10

ANALYSIS NUMBER: BIBR 6 – 30391

Dose mg/kg	*Animal N° and sex*		*Weight (g) at days*		
			0	**7**	**14**
4000	11	Female	211	220	231
	12	Female	210	222	231
	13	Female	208	220	230
	14	Female	208	221	232
	15	Female	213	224	236
	16	Male	215	226	239
	17	Male	211	224	239
	18	Male	213	226	237
	19	Male	216	229	240
	20	Male	212	224	238

TABLE 3:

ACUTE DERMAL TOXICITY TEST

INDIVIDUAL NECROPSIES

ANALYZED SAMPLE: NES FUNGICIDA, ACARICIDA E INSECTICIDA SELECTIVO - LIQUIDO

SPONSOR: AJIM S.R.L

DATE OF THE END OF THE TEST: 04.13.10

ANALYSIS NUMBER: BIBR 6 – 30391

Dose mg/kg	*Animal N° and sex*		*Mortality time*	*Macroscopic Observations*
4000	11	Female	14 days (*)	No abnormalities were observed
	12	Female	14 days (*)	No abnormalities were observed
	13	Female	14 days (*)	No abnormalities were observed
	14	Female	14 days (*)	No abnormalities were observed
	15	Female	14 days (*)	No abnormalities were observed
	16	Male	14 days (*)	No abnormalities were observed
	17	Male	14 days (*)	No abnormalities were observed
	18	Male	14 days (*)	No abnormalities were observed
	19	Male	14 days (*)	No abnormalities were observed
	20	Male	14 days (*)	No abnormalities were observed

(*) Sacrificed animal after the observation period

ANNEX I

Reference to the Toxicological Classification

Toxicological classification of the World Health Organization (WHO), stated in the Guidelines for the classification of pesticides (2004) and toxicological classification of the Argentine Resolution 350/99 published in the Official Bulletin N° 29.225 of 08.09.1999, as it is detailed in the following table:

Class	WHO Classification according to hazard	LD_{50} (mg/Kg body weight)	
		Solid	Liquid
Ia	EXTREMELY HAZARDOUS	≤ 10	≤ 40
Ib	HIGHLY HAZARDOUS	10 to 100	40 to 400
II	MODERATELY HAZARDOUS	100 to 1000	400 to 4000
III	SLIGHTLY HAZARDOUS	> 1000	> 4000

GHS (Harmonized Classification System for Chemicals Substances and Mixtures). By OECD, UN Comité Experts on Transport of Dangerous Goods, ILO and IOMC.

GHS: Globally Harmonized Classification System (mg/Kg peso corporal)	
CATEGORY 1	> 0 – 50
CATEGORY 2	> 50 – 200
CATEGORY 3	> 200 – 1000
CATEGORY 4	> 1000 – 2000
CATEGORY 5	> 2000 – 5000
CATEGORY 5 OR NO CLASSIFICATION	

ANNEX II

GLP Certificate

OAA
Organismo Argentino de Acreditación

Av. Julio A. Roca 651 5° Sec. 8 y 9
(C1067ABB) Bs. As. Argentina
Telefax: 54-11 4349-3982 / 3 / 4
info@oaa.org.ar | www.oaa.org.ar

OAA- Organismo Argentino de Acreditación
F:13-(PRO-BPL) v2, F.e.V.= 01-diciembre-2009

CERTIFICATE OF COMPLIANCE WITH OECD PRINCIPLES OF GOOD LABORATORY PRACTICE

Granted to the Testing Facility

MICROQUIM S.A.

División Biomicro

The Argentine Accreditation Body -OAA- declares that according to the requirements of its Good Laboratory Practice Monitoring Program, the Test Facility MICROQUIM S.A. DIVISIÓN BIOMICRO carries out the non-clinical studies mentioned in this certificate in compliance with the Principles of Good Laboratory Practice of the Organisation for Economic Co-operation and Development -OECD- (1998).

REGISTRATION OF COMPLIANCE WITH GPL No 02

AUTHORIZED REPRESENTATIVE: Lic. Alejandro LUCINI

Area of expertise:

2- toxicity testing

4- environmental toxicity studies on aquatic and terrestrial organisms

These types of non-clinical studies are performed in AGROCHEMICAL.

Carried out in: MICROQUIM S.A., DIVISIÓN BIOMICRO

Address of the Facility: Costa Rica 4776 – Partido de Malvinas Argentinas

Inspection Date:

October 5 and 6, 2009 Inspection and study audit

President
Higinio B. Ridolfi

This certificate was issued in Buenos Aires on January 4, 2010.

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STUDY NUMBER: BIBR 6 - 30391

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The report is in accordance with the obtained data.

The audit was carried out according to the Standard Operating Procedures (SOP) established in the Procedures Manual of MICROQUIM S.A.

The audit report was remitted to Direction and the Study Director, filing a copy of it in the "Internal Audits" archive of the Quality Assurance Unit of MICROQUIM S.A.

Audit Nº	**Audited area / Details**	**Audit Date**
8640.a	Audit´s Study Plan	03.18.10
8640.b	Audit´s Study	04.01.10
8640.c	Final report revision.	07.16.10
8640.d	Audit´s Report to Direction and the Study Director	07.19.10

Dr. Ana Inés Chanfreau
Veterinarian
GLP Quality Assurance Unit