VOLUME____OF____OF SUBMISSION

MK 936 FS (400) (A14024C): FINAL REPORT

TITLE

MK 936 FS (400) (A14024C): Acute
Oral Toxicity Study in the Rat – Up and Down Procedure

DATA REQUIREMENT

EPA Guideline Number OPPTS 870.1100

AUTHOR

Mrs. A. Brammer

COMPLETION DATE

April 14, 2004

PERFORMING LABORATORY

Central Toxicology Laboratory
Alderley Park, Macclesfield
Cheshire, UK

LABORATORY STUDY IDENTIFICATION

CTL Number AR7447

SUBMITTER/SPONSOR

Syngenta Crop Protection, Inc.
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419

VOLUME 1 OF 1 OF STUDY

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1) *The following statement applies to submissions to regulatory agencies in the United States of America.*

STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10 (d) (1) (A), (B), or (C).

Company: Syngenta Crop Protection, Inc.

Company Representative: Carolyn Brinkley

Title: Senior Regulatory Product Manager

Signature: Carolyn Brinkley Date: May 17, 2004

These data are the property of Syngenta Crop Protection, Inc. and, as such, are considered to be confidential for all purposes other than compliance with the regulations implementing FIFRA Section 10.

Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality, which may exist under any other provision of common law or statute or in any other country.

2) *The following statement applies to submissions to regulatory agencies other than in the United States of America.*

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It should not be disclosed in any form to an outside party, nor should information contained herein be used by a registration authority to support registration of this product or any other product without the written permission of Syngenta Limited.

STATEMENT OF GLP COMPLIANCE AND AUTHENTICATION

I, the undersigned, declare that the objectives laid down in the protocol were achieved and that the data generated are valid. The report fully and accurately reflects the procedures used and the raw data generated in the above study.

The study (AR7447) was conducted in compliance with the UK Principles of Good Laboratory Practice (The United Kingdom GLP Regulations 1999, Statutory Instrument No. 3106). These Principles are in accordance with the OECD Principles of Good Laboratory Practice, revised 1997 (ENV/MC/CHEM(98)17).

Mrs A Brammer
Study Director

14 April 2004
Date

Merrill Tisdel
Representative of Submitter/Sponsor

MAY 6 2004
Date

Submitter/Sponsor: Syngenta Crop Protection, Inc.
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419

This page
may be required
by some
regulatory authorities.

NOT APPLICABLE

QUALITY ASSURANCE STATEMENT

In accordance with CTL policy and QA procedures for Good Laboratory Practice, this report has been audited and the conduct of this study has been inspected as follows:

Date	Audit/Inspection	Date of QA Report
26 Mar 2004	Draft report	29 Mar 2004
14 Apr 2004	Final report review	14 Apr 2004

In addition, inspections associated with this type of study were made as follows:

08 Jan 2004	Protocol	08 Jan 2004
28 Jan 2004	Dose administration, bodyweights, clinical observations	28 Jan 2004
08 Mar 2004	Post mortem	08 Mar 2004

Facilities and process based procedures associated with this type of study were inspected in accordance with QA Standard Operating Procedures.

So far as can be reasonably established, the methods described and the results given in the final report accurately reflect the raw data produced during the study, AR7447.

C Rooney ..... 14 April 2004

(CTL Quality Assurance Unit)

STUDY CONTRIBUTORS

The following contributed to this report in the capacities indicated:

Name	Title
Mrs A Brammer	Study Director
D R Beeston	Study Licensee
D Lees	Study Reviewer
A M Leah	Report preparation

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TABLES

APPENDIX

1. SUMMARY

1.1 Study design

Female Alpk:APfSD (Wistar-derived) rats received a single oral dose of 17.5, 55 or 175mg/kg of MK 936 FS (400) (A14024C). The animals were observed daily for the following 14 days for mortality and any signs of systemic toxicity.

Bodyweights were recorded at intervals during the study. At the end of the study all animals were killed and examined *post mortem*.

1.2 Results

Following a dose of 17.5mg/kg to three rats, none of the animals died. Signs of slight toxicity were seen in two animals, with complete recovery by day 2. All animals showed an overall bodyweight gain during the study. There were no macroscopic abnormalities at examination *post mortem*.

Following a dose of 55mg/kg to three rats, all the animals showed signs of severe toxicity and were killed *in extremis* on day 1. There were no macroscopic abnormalities at examination *post mortem*.

Following a dose of 175mg/kg to one rat, the animal showed signs of severe toxicity and was killed *in extremis* on day 1. There were no macroscopic abnormalities at examination *post mortem*.

1.3 Conclusion

Based on the Acute Oral Toxicity Statistical Programme(AOT 425 Stat Pgm), the acute oral median lethal dose of MK 936 FS (400) (A14024C) was estimated to be 29.57mg/kg (approximate 95% confidence interval 17.5-55mg/kg) to female rats.

2. INTRODUCTION

2.1 Purpose

The purpose of this study was to assess the acute oral toxicity of MK 936 FS (400) (A14024C) to female rats, following a single oral dose.

The study was carried out according to the Modified Up-and-Down Procedure (ASTM, 1987).

2.2 Regulatory guidelines

The study has been done in accordance with the following Regulatory Guidelines:

a) OECD guideline reference 425 (2001): Acute Oral Toxicity - Up-and-Down Procedure.

b) United States Environmental Protection Agency, Health Effects Test Guidelines (2002), OPPTS 870.1100, Acute Oral Toxicity.

2.3 Justification for test system selection

The albino rat was used because it is the species generally recommended for the assessment of toxicity. The Alpk:APfSD strain of rat was used because of the substantial background data available for this strain, in this Laboratory, relating to studies of this type. The oral route was chosen as this represents a possible route of human exposure.

2.4 Dose level selection

Dose levels were selected using the modified up and down procedure (Appendix A).

An initial dose level of 175mg/kg was chosen using the default values in the statistical program (AOT 425 Stat Pgm). A single animal was dosed at this level. Further dose levels of 17.5 and 55mg/kg were chosen using the criteria in Appendix A. A minimum of 48 hours was allowed between dosing each animal in the sequence.

2.5 Study dates

The study was initiated on 27 November 2003. The experimental phase started on 1 December 2003 and was completed on 27 January 2004.

2.6 Data storage

An original report, the study protocol and all raw data, samples and specimens, pertaining to this study are retained in the Archives, Central Toxicology Laboratory (CTL), Alderley Park, Macclesfield, Cheshire, UK.

3. TEST SUBSTANCE

Name:	MK 936 FS (400)
Source:	Syngenta Crop Protection Münchwilen AG.
Colour:	Pink
Physical state:	Liquid
Batch reference number:	SEZ3JL002
CTL test substance reference number:	Y12230/009
Formulation reference no:	A14024C
AI content of formulation (w/w):	396g/l
Expiry date:	October 2005
Storage conditions:	Ambient temperature in the dark

The sample was tested as supplied.

A certificate of analysis (dated 6th November 2003) is retained in the CTL Archives. The test substance characterisation was carried out by Syngenta.

4. EXPERIMENTAL PROCEDURES

4.1 Experimental design

4.1.1 Animals

Species:	Rat
Strain:	Alpk:AP_fSD
Source:	Rodent Breeding Unit, Alderley Park, Macclesfield, Cheshire, UK.
Sex/number used:	Seven females
Age and weight range at start of study	Approximately 8-12 weeks old. Bodyweight 193-269g.

4.1.2 Accommodation and husbandry

Animals were individually housed, in cages suitable for animals of this strain and the weight range expected during the course of the study.

The animal room was designed to give the environmental conditions shown as follows:

Temperature:	22±3°C
Relative humidity:	30-70%
Air changes:	A minimum of 15 changes per hour
Light cycle:	Artificial, giving 12 hours light, 12 hours dark

Both temperature and relative humidity were recorded daily. The recorded values were within the specified ranges.

Diet (RM1), supplied by Special Diets Services Limited, Witham, Essex, UK, and mains water, supplied by an automatic system, were available *ad libitum*, except that each rat was fasted overnight immediately prior to dosing to ensure its stomach was empty (the presence of food could affect the rate of absorption of the test substance).

Each batch of diet is routinely analysed for composition and for contaminants. Water is also periodically analysed for contaminants. No contaminants were found in the diet or water at levels considered likely to interfere with the purpose or outcome of the study. Certificates of analyses are retained in the CTL Archives.

4.1.3 Acclimatisation

The animals were housed under the experimental conditions for at least 5 days, prior to the start of dosing.

4.1.4 Animal identification

Animals were individually identified with a number, unique within the study, by ear punching.

A card was displayed on the front of each cage, identifying the animal within. A card was also displayed on the cage to indicate the date of the pre-dose fasting period.

4.1.5 Dose regime

Animals were dosed in the following order:

Step	Animal numbers	Dose level (mg/kg)	Comments
1	99	175	died
2	7	55	died
3	20	17.5	survived
4	24	55	died
5	2	17.5	survived
6	5220	55	died
7	35	17.5	survived

4.1.6 Dose administration

Dose levels were altered by adjusting the volume of the dosing preparations.

The volume of the dose was calculated for each animal according to its weight at the time of dosing.

For the 17.5 or 55mg/kg dose levels, a volume of 0.018 or 0.055ml/kg bodyweight of the dosing preparation was dosed by gavage, using a sleeved catheter and glass syringe. For the 175mg/kg dose level, a volume of 0.18ml/kg bodyweight was administered by gavage, using a stomach tube.

4.2 Clinical observations

Prior to dosing, all rats were examined to ensure that they were physically normal and behaved normally. The animals were observed for signs of systemic toxicity immediately after dosing and at least a further twice following dosing on day 1. Subsequent observations were made daily, up to day 15.

4.3 Bodyweights

The animals were weighed prior to fasting on the day before dosing (day -1), immediately before dosing (day 1) and on days 8 and 15.

4.4 Investigations *post mortem*

4.4.1 Termination

Animals were killed by an overdose of halothane vapour, followed by exsanguination.

4.4.2 Macroscopic examination

All animals were examined *post mortem*. All were examined as soon as possible after death.

The examination involved an external observation and a detailed examination of all thoracic and abdominal viscera. All abnormalities were recorded but tissues were not submitted for histopathological examination.

5. DATA EVALUATION

Data were evaluated using the Acute Oral Toxicity (OECD Test Guidelines 425) Statistical Programme (AOT 425 Stat Pgm).

6. RESULTS

6.1 Clinical observations and mortality (Table 1)

Following a dose of 17.5mg/kg to three rats, none of the animals died. Signs of slight toxicity were seen in two animals, with complete recovery by day 2.

Following a dose of 55mg/kg to three rats, all the animals showed signs of severe toxicity and were killed *in extremis* on day 1.

Following a dose of 175mg/kg to one rat, the animal showed signs of severe toxicity and was killed *in extremis* on day 1.

6.2 Bodyweights (Table 2)

All animals showed an initial weight loss due to the pre-dose fast. Animals dosed with 17.5mg/kg had exceeded their initial weight by day 8 and continued to gain weight for the remainder of the study. All other animals were killed *in extremis* on day 1.

6.3 Investigations *post mortem* (Table 3)

There were no macroscopic abnormalities at examination *post mortem*.

7. CONCLUSION

Based on the Acute Oral Toxicity Statistical Programme(AOT 425 Stat Pgm), the acute oral median lethal dose of MK 936 FS (400) (A14024C) was estimated to be 29.57mg/kg (approximate 95% confidence interval 17.5-55mg/kg) to female rats.

8. REFERENCES

ASTM (1987). Standard Test Method for Estimating Acute Oral Toxicity in Rats. American Society for Testing and Materials, Philadelphia, PA, E 1163 - 1187.

Acute Oral Toxicity (OECD Test Guideline 425) Statistical Programme (AOT 425 Stat Pgm). Version: 1.0, 2001. [http://www.oecd.org/pages/home/display general/0,3380,EN-document-524-nodirectorite-0-24-6775-8,FF.html).

GLOSSARY FOR ANIMAL DATA TABLES

NAD	-	no abnormalities detected
INCR/SD	-	increased
I	-	increased
NO	-	number
X	-	present
S	-	slight
M	-	moderate
E	-	extreme
N	-	absent
(D)	-	animal died/humanely killed on this day
wks	-	weeks
F	-	female

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 01 ANIMAL NO: 99 SEX: FEMALE START DATE: 2/12/03
DOSE: 175 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 1		---------^														
*** NAD ***	X	X														
ACTIVITY DECREASED		EN														
PROSTRATE		X														
TREMORS		EE														
KILLED IN EXTREMIS-TOXIC		X														
REDUCED SPLAY REFLEX		EN														

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 02 ANIMAL NO: 7 SEX: FEMALE START DATE: 3/12/03
DOSE: 55 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 1		---------^														
*** NAD ***	X	X														
PROSTRATE		X														
TREMORS		EE														
KILLED TERMINATION		X														
SPLAYED GAIT		MN														
TIP TOE GAIT		MN														
REDUCED SPLAY REFLEX		ME														

DAY: 1 COMMENT: ANIMAL APPEARS RIGID WHEN HELD.

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 02 ANIMAL NO: 24 SEX: FEMALE START DATE: 23/12/03
DOSE: 55 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 1		---------^														
*** NAD ***	X	X														
ACTIVITY DECREASED		ME														
CLONIC CONVULSIONS		X														
TREMORS		EE														
KILLED IN EXTREMIS-TOXIC		X														
SPLAYED GAIT		MN														
TIP TOE GAIT		SSN														
UPWARD CURVATURE OF SPINE		MMMM														
REDUCED SPLAY REFLEX		EE														

DAY: 1 COMMENT: ANIMAL GOES RIGID WHEN HELD.

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 02 ANIMAL NO: 5220 SEX: FEMALE START DATE: 9/01/04
DOSE: 55 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 1		---------^														
*** NAD ***	X	X														
PROSTRATE		X														
SHAKING		XXX														
TAIL ERECTION		MN														
KILLED IN EXTREMIS-TOXIC		X														
SPLAYED GAIT		MMMN														
SEE FREE TEXT		XXX														
UPWARD CURVATURE OF SPINE		MMMN														
REDUCED SPLAY REFLEX		EEEN														

DAY: 1 COMMENT: ANIMAL GOES RIGID WHEN HELD

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 03 ANIMAL NO: 2 SEX: FEMALE START DATE: 7/01/04
DOSE: 17.5 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 15																^
*** NAD ***	X	XX		X	X	X	X	X	X	X	X	X	X	X	X	X
RESPONSE TO SOUND		IN														
INCR/SD RESPONSE TO TOUCH		XX	N													
TREMORS		MMN														
KILLED TERMINATION																X
SPLAYED GAIT		SN														
TIP TOE GAIT		SSN														
PILOERECTION		SS	N													
SEE FREE TEXT		XXN														
REDUCED SPLAY REFLEX		MES	N													

DAY: 1 COMMENT: ANIMAL APPEARS TO GO SLIGHTLY RIGID WHEN HELD.

TABLE 1 - CLINICAL OBSERVATIONS

GROUP NO: 03 ANIMAL NO: 20 SEX: FEMALE START DATE: 17/12/03
DOSE: 17.5 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 15	----------															^
*** NAD ***	X	XX		X	X	X	X	X	X	X	X	X	X	X	X	X
ACTIVITY DECREASED		S	N													
RESPONSE TO SOUND		IN														
KILLED TERMINATION																X
PILOERECTION		S	N													
SKIN SENSITIVE TO TOUCH		X	N													

GROUP NO: 03 ANIMAL NO: 35 SEX: FEMALE START DATE: 13/01/04
DOSE: 17.5 MG/KG

CLINICAL OBSERVATION	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
DIED ON DAY 15	----------															^
*** NAD ***	X	XXX	X	X	X	X	X	X	X	X	X	X	X	X	X	X
KILLED TERMINATION																X

TABLE 2 - BODYWEIGHTS (g)

DOSE: 175 MG/KG

ANIMAL NUMBER	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
FEMALES																
99	238	214 (D)														

TABLE 2 - BODYWEIGHTS (g)

DOSE: 55 MG/KG

ANIMAL NUMBER	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15
FEMALES																
7	193	184 (D)														
24	269	249 (D)														
5220	223	196 (D)														

TABLE 2 - BODYWEIGHTS (g)

DOSE: 17.5 MG/KG

ANIMAL NUMBER	DAY -1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15	
FEMALES																	
2	218	194	-	-	-	-	-	-	238	-	-	-	-	-	-	259	(D)
20	244	227	-	-	-	-	-	-	264	-	-	-	-	-	-	272	(D)
35	236	219	-	-	-	-	-	-	250	-	-	-	-	-	-	271	(D)

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 99 SEX: F DOSE: 175 MG/KG ON STUDY: 1 day (1 wk) INTERCURRENT

MACROPATHOLOGY

Killed by Halothane ; Animal killed and bled in cell by severing femoral artery. NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 7 SEX: F DOSE: 55 MG/KG ON STUDY: 1 day (1 wk) INTERCURRENT

MACROPATHOLOGY

Killed by Halothane ; Animal killed and bled in cell by severing femoral artery. NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 24 SEX: F DOSE: 55 MG/KG ON STUDY: 1 day (1 wk) INTERCURRENT

MACROPATHOLOGY

Killed by Halothane ; Animal killed and bled in cell by severing femoral artery. NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 5220 SEX: F DOSE: 55 MG/KG ON STUDY: 1 day (1 wk) INTERCURRENT

MACROPATHOLOGY

Killed by Halothane ; Animal killed and bled in cell by severing femoral artery. NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 2 SEX: F DOSE: 17.5 MG/KG ON STUDY: 15 days (3 wks) TERMINAL

MACROPATHOLOGY

Killed by Halothane ; NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 20 SEX: F DOSE: 17.5 MG/KG ON STUDY: 15 days (3 wks) TERMINAL

MACROPATHOLOGY

Killed by Halothane ; NAD.

----------END OF ANIMAL----------

TABLE 3 - MACROSCOPIC FINDINGS

ANIMAL NO: 35 SEX: F DOSE: 17.5 MG/KG ON STUDY: 15 days (3 wks) TERMINAL

MACROPATHOLOGY

Killed by Halothane ; NAD.

----------END OF ANIMAL----------

APPENDIX A - UP-AND-DOWN METHOD : DOSING REGIME

METHOD

The initial dose level is usually set at 175mg/kg (taking into account any known toxicity of the test substance).

If the animal dosed at the initial level survives, a single animal is dosed at the next highest level. If the animal dosed at the initial level dies, a single animal is dosed at the next lowest level. This procedure is repeated for subsequent animals until one of the following "stopping rules" is met:

a) 3 consecutive animals survive at the limit dose (2000mg/kg)

b) 5 reversals (U turn decisions) occur in 6 consecutive animals [e.g.: 175mg/kg (animal survives), 550mg/kg (animal dies) - first U turn decision, 175mg/kg (animal survives) - second U turn decision, 550mg/kg (animal dies) - third U turn decision, 175mg/kg (animal survives) - fourth U turn decision, 550mg/kg (animal dies), fifth U turn decision, 175mg/kg (animal survives) - study complete]

c) At least 4 animals have followed the first reversal (U turn) and the specified likelihood ratios exceed the critical value.

CERTIFICATE OF ANALYSIS

syngenta

GLP Testing Facility EZA
Analytical Development &
Product Chemistry GS2131

Syngenta Crop Protection
Münchwilen AG
Breitenloh 5
CH-4333 Münchwilen

Certificate of Analysis

A14024C
MK 936 FS (400)
SEZ3JL002

Batch Identification	**SEZ3JL002**
Product Code	**A14024C**
Other Product Code(s)	MK 936 FS (400)

Chemical Analysis
(Active Ingredient Content)

– **Identity of the Active Ingredient(s)***	**confirmed**
– **Content of MK 936 ***	**396 g/l**
Methodology used for Characterization / Reanalysis	HPLC,

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

Physical Analysis

– **Density ***	**1080 kg/m^3**

Stability:

– **Storage Temperature**	**< 30°C,**
– **Reanalysis date**	**October 2005**

The stability of this test substance will be controlled by reanalysis of material held in the inventory at Syngenta Crop Protection Münchwilen AG at the appropriate time.

This Certificate of Analysis is summarizing data which originate either from a single study or from several individual studies which have been performed in compliance with GLP. Tests marked with an asterisk (*) have been conducted within a single study/as individual studies. Raw data, documentation, study plans, any amendments to study plans and reports pertaining to this/these studie(s) are stored under the study number(s) referenced below within the archives of the GLP Testing Facility EZA at Syngenta Crop Protection Münchwilen AG. No GLP compliance is claimed for this certificate.

Characterisation: 111113 Reanalysis:

Authorisation:

November 06, 2003

Urs Spuhler
Analytical Development & Product Chemistry

Replaces Version, dated October 15, 2003