



SYN524464

SYN524464 FS (A16148C) – Acute Inhalation Toxicity Study in Rats

Final Report

DATA REQUIREMENT(S): EPA Health Effects Test Guidelines,
OPPTS 870.1300
OECD Guidelines for Testing of Chemicals,
Procedure 403

AUTHOR(S): Vicki Crutchfield

STUDY COMPLETION DATE: June 30, 2008

PERFORMING LABORATORY: STILLMEADOW, Inc.
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Sugar Land, TX 77478 USA

LABORATORY PROJECT ID: Report Number: 11742-08
Study Number: 11742-08
Task Number: T012083-05

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STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with:

- United States Environmental Protection Agency FIFRA: Good Laboratory Practice Standards, 40 CFR 160
- United States Environmental Protection Agency TSCA 40 CFR 792
- Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice, Annex 2, C(98)17
- Japan Ministry of Agriculture, Forestry and Fisheries, Notification 11-Nousan-6283, Director- General of Agricultural Production Bureau

I, the undersigned, declare that the methods, results, and data contained in this report reflect the procedures used and the raw data collected in this study, according to the protocol.



Vicki Crutchfield
Study Director, STILLMEADOW, Inc.

30 June 2008
Date

Performing Laboratory: STILLMEADOW, Inc.
12852 Park One Drive
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Report Number: 11742-08

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QUALITY ASSURANCE STATEMENT

Test Substance: SYN524464 FS (500)


Study Title: SYN524464 FS (A16148C): Acute Inhalation Toxicity Study in Rats


The study report and data have been audited in accordance with Good Laboratory Practice Standards and STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The Quality Assurance Unit has not been involved in the actual conduct of this study.

The Quality Assurance Unit performed a recent facility inspection on 30 Apr 08. All findings were reported to Management, and the report and responses are kept in the Quality Assurance files.

The findings from any study inspections and audits were reported to the Study Director and Management as follows:

Critical Phase Inspected	Date Inspected	Reported to Study Director	Reported to Management
Protocol Review	13 Mar 08	13 Mar 08	13 Mar 08
Dosing	1 Apr 08	1 Apr 08	1 Apr 08
Report/Data Audit	30 Jun 08	30 Jun 08	30 Jun 08


Richard L. Martin, M.S., C.Ph.T.
Quality Assurance, STILLMEADOW, Inc.


Date

GENERAL INFORMATION

Contributors

The following contributed to this report in the capacities indicated:

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Study dates

Study initiation date: 24 Mar 08

Experimental start date: 1 Apr 08

Experimental termination date: 15 Apr 08

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1.0 EXECUTIVE SUMMARY

The test substance, SYN524464 FS (500) (A16148C), was evaluated for its acute inhalation toxicity potential in albino rats. Five males and five females were exposed for four hours in a nose-only inhalation system to an aerosol generated from the undiluted liquid test substance at a level of 2.56 mg/L, with a mass median aerodynamic diameter (MMAD) of 3.3 microns. There was no mortality during the study. Clinical signs included activity decrease and piloerection, which were no longer evident by Day 6. Body weights were unaffected by exposure except in one animal that lost weight during the first week. The gross necropsy revealed no observable abnormalities. As indicated by the data, the acute inhalation LC₅₀ is greater than 2.56 mg/L.

2.0 INTRODUCTION

The objective of this study was to determine the acute inhalation toxicity potential of the test substance in accordance with US EPA OPPTS 870.1300, which is intended to meet testing requirements of FIFRA 7 USC 136, *et seq*, and TSCA 15 USC 2601. This study was conducted for Syngenta Crop Protection, Inc., according to the approved protocol and STILLMEADOW, Inc. SOP's. There were no deviations from the protocol which affected the quality or outcome of the study. All procedures in this study are in compliance with Animal Welfare Act Regulations. In the opinion of the sponsor, the study did not unnecessarily duplicate any previous work. The protocol, raw data, this report and a sample of test substance are archived at STILLMEADOW, Inc. The study was initiated on 24 Mar 08, the pre-dose experimental portion began on 25 Mar 08, and the animals were exposed on 1 Apr 08 at 0832. The in-life portion of the study was terminated on 15 Apr 08.

3.0 MATERIALS AND METHODS

3.1 Test Substance

Reference Name:	SYN524464 FS (500)
Label Identification:	SYN524464 FS (500) ID 531363 A16148C
Date & Quantity Received:	14 Mar 08; 4819 g (Gr.Wt.)
Physical Description:	White liquid
Storage:	Room temperature
Purity (w/w):	45.4% active ingredient
Stability:	Reassay: Mar 2009

Records pertaining to stability, characterization, identity, synthesis methods and location of documentation are the responsibility of the sponsor. A copy of the sponsor's Analytical Report is retained in the study file.

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3.6 Generation of Test Atmosphere

The aerosol was generated by pumping the test substance into a pressure operated Spraying System Company air atomizer (1/4 JSS), and then spraying the resulting aerosol directly into the exposure chamber. Air flow into the chamber was maintained through the use of a calibrated orifice plate at a rate of 22.4 air changes per hour. Air flow was recorded at 30 minute intervals during the exposure period, and was sufficient to ensure an oxygen content of at least 19% of the exposure atmosphere. Temperature and humidity were recorded at 30 minute intervals during the exposure period from an Extech Instruments humidity/temperature pen 445580 inserted in an unused port of the exposure chamber.

3.7 Test Substance Administration

Healthy albino rats were released from quarantine, and five males and five females were selected for testing. The test substance was stirred continuously during the exposure. The animals were exposed to an aerosol generated from the undiluted liquid test substance for a period of four hours. When 99% concentration (t-99) was attained, the animals that were individually housed in polycarbonate exposure tubes were inserted into a 500 L stainless steel nose-only inhalation chamber for the specified exposure period. At the termination of the exposure period, the animals were returned to their stock laboratory cages.

3.8 Determination of Concentration

The concentration of test substance in the exposure atmosphere (taken from the breathing zone of the animals) was determined gravimetrically twice per hour and nominally at the end of the exposure. The gravimetric concentration was determined by passing a known volume of exposure air through a pre-weighed filter and dividing the amount of test substance deposited on the filter by the volume of air, which passed through the filter. The nominal concentration was determined by dividing the loss in weight of the test substance after the exposure by the total volume of air which passed through the chamber.

3.9 Particle Size Distribution

Particle size, taken from the breathing zone of the animals, was determined twice during the exposure, using a cascade impactor, at a rate of 7.4 L/minute for a duration of 40 seconds. The MMAD and particle size distributions are calculated from these data by a computer program utilizing probit analysis.

3.10 In-life Observations

Observations for mortality and signs of pharmacologic and/or toxicologic effects were made frequently on the day of exposure and at least once daily thereafter for 14 days (Day 0 is day of exposure). Individual body weights were recorded just prior to the inhalation exposure and on Days 7 and 14.

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3.11 Postmortem Observations

On Day 14 after exposure, each animal was euthanized by an intraperitoneal injection of Fatal Plus® (Vortech Pharmaceuticals, Lot 2506, Exp: Nov 09). All study animals were subjected to gross necropsy, and all abnormalities were recorded.

3.12 Statistical Analysis

In order to calculate a mean exposure, the Mean Value Theorem of Calculus was used to properly weight the concentration, since the concentrations could not be measured continuously (see Table 5). This method weights concentrations based on the time span of each concentration. A concentration can be calculated for each minute, which better represents the exposure concentration received by each animal.

4.0 RESULTS AND DISCUSSION

4.1 Mortality/Estimated LC₅₀ Values

There was no mortality during the study. As indicated by the data, the acute inhalation LC₅₀ is greater than 2.56 mg/L.

4.2 Body Weights

Individual body weights are presented in Table 1. Body weight gain was unaffected by the administration of the test substance except in one male that lost weight between Days 0 and 7.

4.3 Clinical Signs

A summary of clinical signs is presented in Table 2. Individual data are presented in Table 3. Prominent in-life observations included activity decrease and piloerection. Animals were asymptomatic by Day 6.

4.4 Necropsy Findings

Individual necropsy findings are presented in Table 1. The gross necropsy conducted on each animal at termination of the study revealed no observable abnormalities.

4.5 Inhalation Chamber Conditions

Chamber operating parameters are presented in Table 4. Concentration determinations and calculations are presented in Table 5. Particle size distributions are presented in Table 6. Pretest data are presented in Table 7. The exposure concentration of 2.56 mg/L had an average MMAD of 3.3 microns.

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5.0 CONCLUSIONS

SYN524464 FS (500) (A16148C) was evaluated for its acute inhalation toxicity potential in albino rats. There was no mortality during the study. As indicated by the data, the acute inhalation LC₅₀ is greater than 2.56 mg/L.



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TABLES SECTION

TABLE 1 Body Weights, Time of Death and Gross Necropsy

ACUTE INHALATION TOXICITY IN RATS

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

Animal Number	Body Weights (g)			Time of Death*	Gross Necropsy Findings
	Day 0	Day 7	Final		
131-M	289	308	334	Day 14	NOA
132-M	305	331	358	Day 14	NOA
133-M	306	325	352	Day 14	NOA
134-M	287	307	334	Day 14	NOA
135-M	294	247	341	Day 14	NOA
Mean Wt.	296	304	344		
136-F	202	214	227	Day 14	NOA
137-F	201	207	240	Day 14	NOA
138-F	212	215	222	Day 14	NOA
139-F	219	221	227	Day 14	NOA
140-F	202	207	239	Day 14	NOA
Mean Wt.	207	213	231		

* - Day of dosing considered Day 0; Day 14 is terminal sacrifice.

M - Male; F - Female; NOA - No Observable Abnormalities

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TABLE 2 Summary of Pharmacologic and/or Toxicologic Signs**ACUTE INHALATION TOXICITY IN RATS**

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

Sex: Males and Females

Reaction and Severity	Time After Exposure Begins																		
	HOURS					DAYS													
	0.5	1.0	2.5	4.5	6.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<u>Males</u>																			
Piloerection (v-s)	0	0	0	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0	0
Activity decrease (v-s)	0	0	0	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0	0
<u>Females</u>																			
Piloerection (v-s)	0	0	0	5	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0
Activity decrease (v-s)	0	0	0	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0	0

v - very slight; s - slight; m - moderate; e - extreme

Note: Digits indicate number of animals exhibiting reaction.

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TABLE 3 Individual Pharmacologic and/or Toxicologic Signs**ACUTE INHALATION TOXICITY IN RATS**

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

Animal#	Reaction and Severity	Time After Exposure Begins																		
		HOURS					DAYS													
		0.5	1.0	2.5	4.5	6.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
131-M	Piloerection	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
132-M	Piloerection	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
133-M	Piloerection	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
134-M	Piloerection	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
135-M	Piloerection	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
136-F	Piloerection	-	-	-	s	s	s	s	v	v	v	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
137-F	Piloerection	-	-	-	s	s	s	s	v	v	v	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
138-F	Piloerection	-	-	-	s	s	s	s	v	v	v	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
139-F	Piloerection	-	-	-	s	s	s	s	v	v	v	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-
140-F	Piloerection	-	-	-	s	s	s	s	v	v	v	-	-	-	-	-	-	-	-	-
	Activity decrease	-	-	-	s	s	s	s	v	v	-	-	-	-	-	-	-	-	-	-

M = Male; F = Female; v = very slight; s = slight; m = moderate; e = extreme; p = present; - = reaction not observed; D = death

NOTE: If an observation was between scheduled observations, the observation is presented under the next observation time.

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TABLE 4 Chamber Operating Parameters

ACUTE INHALATION TOXICITY IN RATS

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

<u>Time (Hour)</u>	<u>Temp (°C)</u>	<u>RH (%)</u>	<u>Air Flow (Lpm)</u>
0.0	23.1	72.0	187
0.5	22.7	72.1	187
1.0	22.6	72.0	187
1.5	22.5	71.9	187
2.0	22.6	71.8	187
2.5	22.7	71.7	187
3.0	22.6	71.8	187
3.5	22.9	69.2	187
4.0	22.8	69.3	187
Mean:	23	71	187

t-99 Determination

Initial Chamber Air Flow 187 Lpm
Exposure Chamber Size 500 L
t-99 Value 12 min

Air Atomizer Setting

Sprayer Air Flow 26 Lpm
Sample Intake 3.3 mL/min

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TABLE 5 Gravimetric Conc. Calculations and Determination

ACUTE INHALATION TOXICITY IN RATS

Test Substance: SYN524464 FS (500)

Sample Time	Weight (g)	Conc. (mg/L)	Sample Time	Weight (g)	Conc. (mg/L)
0850	0.0179	2.503	1050	0.0184	2.573
0920	0.0182	2.545	1120	0.0185	2.587
0950	0.0184	2.573	1150	0.0187	2.615
1020	0.0183	2.559	1220	0.0183	2.559

$$\text{Concentration} = \frac{\text{Weight X 1000 mg/g}}{1.864 \text{ Lpm X 6 min X 0.63943 Solid}}$$

Dose Level: 2.56 mg/L

Event*	Time Period	Concentration
Start-up	0820	
t-99 (begin exposure)	0832	
Extrapolation calculated	0832-0850	2.503 mg/L
Sample 1 taken	0850-0856	2.503 mg/L
Interpolation calculated	0856-0920	2.524 mg/L
Sample 2 taken	0920-0926	2.545 mg/L
Interpolation calculated	0926-0950	2.559 mg/L
Sample 3 taken	0950-0956	2.573 mg/L
Interpolation calculated	0956-1020	2.566 mg/L
Sample 4 taken	1020-1026	2.559 mg/L
Interpolation calculated	1026-1050	2.566 mg/L
Sample 5 taken	1050-1056	2.573 mg/L
Interpolation calculated	1056-1120	2.580 mg/L
Sample 6 taken	1120-1126	2.587 mg/L
Interpolation calculated	1126-1150	2.601 mg/L
Sample 7 taken	1150-1156	2.615 mg/L
Interpolation calculated	1156-1220	2.587 mg/L
Sample 8 taken	1220-1226	2.559 mg/L
Extrapolation calculated	1226-1232	2.559 mg/L
End exposure	1232	
MEAN EXPOSURE CONC.		2.56 mg/L
Nominal Concentration		40.1 mg/L

* - Sample # taken is the concentration measured during the sampling period.

Extrapolation is the measured concentration of the adjacent event period carried over to the present event period.

Interpolation is the concentration calculated as the average of the measured concentration before and after the present event period.

Mean exposure concentration is the sum of the actual time weighted concentrations divided by the sum of elapsed times and represents the mean value of the exposure concentration.

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TABLE 6 Particle Size Distribution

ACUTE INHALATION TOXICITY IN RATS

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

1 ¼ Hour Distribution

Stage	Size Range (microns)	EPD* (microns)	Amount Collected (mg)	% in Size Range	Cumulative % Less Than Size Range
1	>17.9	17.9	0.0	0.00	100.00
2	10.7 - 17.9	10.7	0.7	16.67	83.33
3	4.3 - 10.7	4.3	1.6	38.10	45.24
4	2.6 - 4.3	2.6	0.7	16.67	28.57
5	1.7 - 2.6	1.7	0.4	9.52	19.05
6	0.9 - 1.7	0.9	0.2	4.76	14.29
7	0.5 - 0.9	0.5	0.1	2.38	11.90
8	0.3 - 0.5	0.3	0.3	7.14	4.76
Backup Filter	0.0 - 0.3	0.0	0.2	4.76	0.00

Calculated $CHI^2 = 34.8$ with 6 Degrees of Freedom.

Values of T and CHI^2 for P=.05 are: T = 2.45 $CHI^2 = 12.6$

Particle Size (Microns)	% of Particles Collected
≤ 0.2	5
≤ 0.7	16
≤ 3.6	50
≤ 19.4	84
≤ 57.7	95

Mass Median Aerodynamic Diameter = 3.6 microns

Geometric Standard Deviation = 5.4

Based on Finney, D.J.: PROBIT ANALYSIS, 3rd ed., Chapters 3 and 4, 1971, Cambridge University Press.

* - Equivalent particle diameter @ 7.4 Lpm

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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TABLE 6 Particle Size Distribution (Continued)

ACUTE INHALATION TOXICITY IN RATS

Test Substance: SYN524464 FS (500)

Concentration: 2.56 mg/L

2 ¼ Hour Distribution

Stage	Size Range (microns)	EPD* (microns)	Amount Collected (mg)	% in Size Range	Cumulative % Less Than Size Range
1	>17.9	17.9	0.0	0.00	100.00
2	10.7 - 17.9	10.7	0.5	14.29	85.71
3	4.3 - 10.7	4.3	0.8	22.86	62.86
4	2.6 - 4.3	2.6	1.1	31.43	31.43
5	1.7 - 2.6	1.7	0.2	5.71	25.71
6	0.9 - 1.7	0.9	0.4	11.43	14.29
7	0.5 - 0.9	0.5	0.2	5.71	8.57
8	0.3 - 0.5	0.3	0.2	5.71	2.86
Backup Filter	0.0 - 0.3	0.0	0.1	2.86	0.00

Calculated $CHI^2 = 20.4$ with 6 Degrees of Freedom.

Values of T and CHI^2 for P=.05 are: T = 2.45 $CHI^2 = 12.6$

Particle Size (Microns)	% of Particles Collected
≤ 0.2	5
≤ 0.6	16
≤ 3.1	50
≤ 15.0	84
≤ 41.5	95

Mass Median Aerodynamic Diameter = 3.1 microns

Geometric Standard Deviation = 4.9

Based on Finney, D.J.: PROBIT ANALYSIS, 3rd ed., Chapters 3 and 4, 1971, Cambridge University Press.

* - Equivalent particle diameter @ 7.4 Lpm

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TABLE 7 Pretest Data

ACUTE INHALATION TOXICITY IN RATS
Test Substance: SYN524464 FS (500)

Trial assays were conducted to ascertain results, summarized below, under different chamber conditions.

<u>MMAD (microns)</u>	<u>Concentration (mg/L)</u>
ND	2.91
ND	2.22
2.9	2.71
2.3	3.15
ND	2.74

ND - Not determined

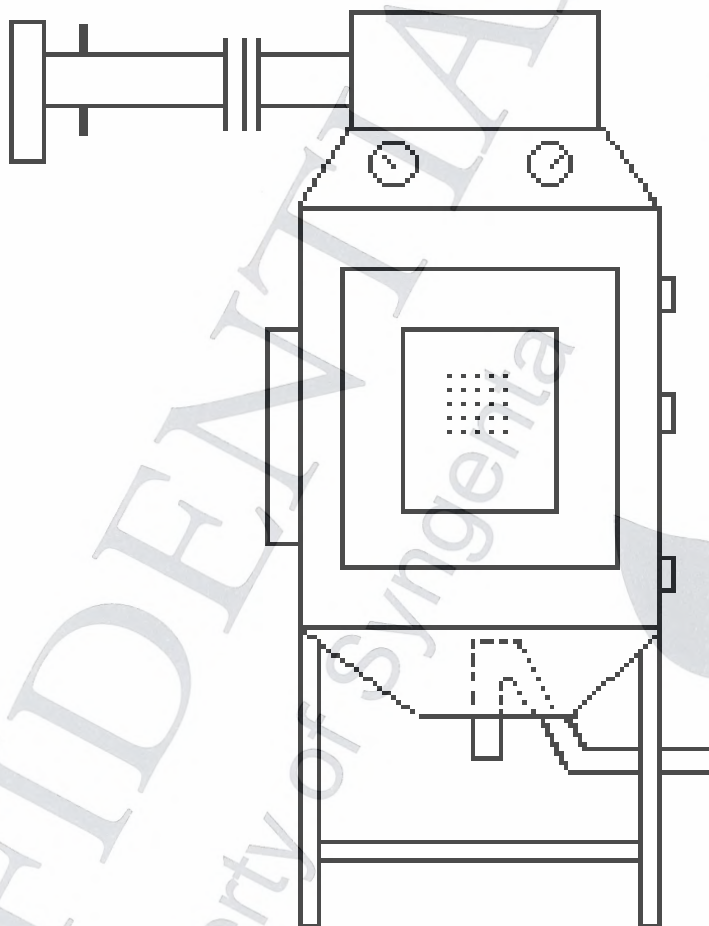


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FIGURES SECTION

FIGURE 1 Nose Only Inhalation Chamber



Air flows into the chamber at the top left. Air flow and negative pressure are measured at the circular gauges. There are 25 ports in the door. Animals in nose only tubes are placed in second and third row of ports. The fourth row and center port on the right side of the chamber are used for sampling ports. Air flow exits the chamber to the lower right. A drain is located at the bottom of the chamber.



Close up view of rat in nose only tube



Nose only tube

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APPENDICES SECTION

APPENDIX 1 Analytical Report



Syngenta Crop Protection, Inc.
Technology & Projects
Analytical & Product Chemistry
Greensboro, NC 27409

Certificate of Analysis

A16148C
Batch ID 531363 (GP-080206)

Batch Identification	531363
Product Design Code	A16148C
Product Denomination	SYNS24464 FS (500)
Product by Common Name	SYNS24464 FS (500)
Other Product Code(s)	GP-080206
Source	Technology & Projects, Syngenta Crop Protection, Inc.
Chemical Analysis	
(Active Ingredient Content)	
Identity of the Active Ingredient*	Confirmed
Content of SYNS24464*	45.4% (wt/wt) or 533.5 g/L
Methodology Used for Characterization	HPLC
The Active Ingredient content is within the FAO limits.	
Physical Analysis	
Appearance*	a white liquid
Density*	1.175 g/L
Stability*	
Storage Temperature	< 30°C
Expiration date	March 2009

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

This Certificate of Analysis is summarizing data (marked with an asterisk) 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.

Authorization:


Dorothea Jeffery
Group Leader I
Analytical & Product Chemistry Department

10 Mar 2008
Date

Document 10347429.doc
Page 1 of 1

Certificate of Analysis
Study T000597-08

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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