



SYN524464

SYN524464 FS (A16148C) – Skin Sensitization Study in Guinea Pigs

Final Report

DATA REQUIREMENT(S): EPA Health Effects Test Guidelines,
OPPTS 870.2600
OECD Guidelines for Testing of Chemicals,
Procedure 406

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STUDY COMPLETION DATE: June 27, 2008

PERFORMING LABORATORY: STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478 USA

LABORATORY PROJECT ID: Report Number: 11745-08
Study Number: 11745-08
Task Number: T003934-07

SPONSOR: Syngenta Crop Protection, Inc.
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STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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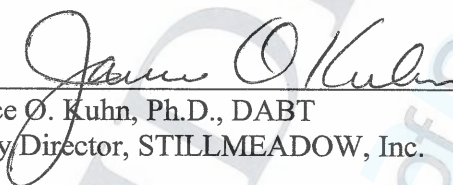
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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

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.



Janice O. Kuhn, Ph.D., DABT
Study Director, STILLMEADOW, Inc.

27 Jun 08
Date

Performing Laboratory: STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478 USA

QUALITY ASSURANCE STATEMENT

Test Substance: SYN524464 FS (500)


Study Title: SYN524464 FS (A16148C): Skin Sensitization Study in Guinea Pigs

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
Observations	24 Apr 08	24 Apr 08	24 Apr 08
Report/Data Audit	18 Jun 08	18 Jun 08	18 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: 23 Apr 08

Experimental termination date: 30 May 08

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1.0 EXECUTIVE SUMMARY

A skin sensitization study was conducted on 15 male and 15 female short-haired albino guinea pigs to determine if test substance SYN524464 FS (500) (A16148C) produced a sensitizing reaction. Animals were assigned to each of two groups, designated Groups I and II. Group I animals (5/sex) remained untreated during the induction phase of the study and served as a naive control group. Group II animals (10/sex), the test group, were treated with 0.4 mL of undiluted test substance (selected from previous screening). The animals were treated nine times during a three-week period. After a two-week rest period, all animals (Groups I and II) were challenged at a virgin test site with an application of 0.4 mL of undiluted test substance.

The test substance produced no irritation in the test animals (Group II) or the naive control animals (Group I) after the challenge treatment, and therefore did not elicit a sensitizing reaction in guinea pigs.

2.0 INTRODUCTION

The objective of this study was to determine the sensitizing potential of the test substance using a modification of the Buehler method (H.L. Ritz and E.V. Buehler, "Planning, Conduct, and Interpretation of Guinea Pig Sensitization Patch Tests," Current Concepts in Cutaneous Toxicity, p. 25-42, Academic Press, NY, 1980), in accordance with OPPTS 870.2600, 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 that affected the quality or outcome of the study. All procedures in this study are in compliance with the 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, and the experimental range-finding began on 20 Apr 08. The animals were treated as follows and the study was terminated on 30 May 08:

Group	Induction Treatments (Date / Day)		Challenge Treatment
	First	Last	
I Naive Control (5/sex)	--	--	28 May 08
II Test (10/sex)	23 Apr 08 / Day 1	12 May 08 / Day 20	28 May 08

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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 (GW)
Physical Description: White liquid
Storage: Room temperature
Purity (w/w): 45.4 % active ingredient
Stability: Reassay: Mar 2009
Conc. Administered: Induction: 100% as received
Challenge: 100% as received

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.

3.2 Experimental Animals

Species & Strain: Guinea Pig; Hartley-Albino
Justification of Species: The guinea pig is the preferred species for use in dermal sensitization testing.
Source: Charles River Laboratories; Wilmington, MA
Quantity & Sex: 2/sex (Irritation Screening); 15/sex (Definitive Study);
females nulliparous and non-pregnant
Acclimation Period: At least 5 days
Date Born: 11 & 15 Mar 08
Date Received: 14 Apr 08
Animal Identification: Ear punch
Weight When Tested: Males: 345-401 g; Females: 328-375 g

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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3.3 Animal Husbandry

Cage Type: Suspended, wire bottom, stainless steel
Housing: 1-4 per cage (males separate from females)
Environmental Controls
Set to Maintain: •Temperature 20°C±3° •Relative Humidity 30-70%
•12-hour light/dark cycle •10-12 air changes/hour
Actual Temp/Rel. Humidity: 12-24° C / 36-95%
Protocol deviation: Humidity and temperature outside protocol range but did not affect study outcome.
Food: PMI Feeds, Inc. Guinea Pig Diet 5025; available *ad libitum*
Water: Municipal water supply analyzed by TCEQ Water Utilities Division, available *ad libitum* from water bowls

Animal husbandry and housing at STILLMEADOW, Inc. comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals" (NRC Publ.). No contaminants were expected to have been present in the feed or water, which would have interfered with or affected the results of the study.

3.4 Positive Control Material and Testing

Label: Alpha-Hexylcinnamaldehyde, 85%
Batch # 13102MO
Manufacturer: Aldrich
Physical Description: Clear yellow liquid
Storage: Room temperature
Conc. Administered: Induction: 0.4 mL undiluted
Challenge: 0.4 mL undiluted
Purity, Composition & Stability: Certificate of analysis available from manufacturer

The sensitivity of guinea pigs to a positive control material is confirmed in this laboratory periodically. The positive control animals used to conduct this study were supplied by Charles Rives Laboratories, and were tested according to the Buehler method (H.L. Ritz and E.V. Buehler, "Planning, Conduct, and Interpretation of Guinea Pig Sensitization Patch Tests," Current Concepts in Cutaneous Toxicity, Academic Press, NY, 1980).

STILLMEADOW, Inc. Study No. 10865-07
In-life started: 18 Apr 07; In-life completed: 25 May 07

Results: Data from this study are presented in Tables 4 and 5. A mean score of 0.9 for the test group after challenge treatment, when compared with naive control group mean score of 0.0, confirmed the sensitivity of guinea pigs to the positive control material.

3.5 Irritation Screening

Two male and two female albino guinea pigs were selected for irritation screening (Figure 1) to determine both the maximum dose producing no more than moderate irritation, and the maximum non-irritating dose. Concentrations tested in the screening were 100% (undiluted), and 75%, 50% and 25% v/v dilutions in deionized water, with each animal receiving 0.4 mL of each concentration at different test sites.

3.6 Animal Preparation

Five males and five females were selected for Group I, and ten males and ten females were selected for Group II. Group I animals served as a naive control group and Group II animals were designated as the test group. On the day prior to initial treatment, and as needed thereafter, the animals were prepared by clipping the back of the trunk free of hair to expose a longitudinal area at least 8 x 10 cm on each animal. Individual body weights were recorded on Days 0 and 38.

3.7 Test Substance Administration

Based on the results of the irritation screening, the dose administered was an application of 0.4 mL of undiluted test substance. For each induction treatment, Group II animals were treated by introducing the test substance beneath a 4 ply, 2.5 x 2.5 cm surgical gauze patch. Each gauze patch was placed laterally from the midline of the back on the left front quadrant of the exposure area (Figure 2) and secured with a strip of non-irritating adhesive tape. A strip of clear polyethylene film was placed over the patch and securely taped. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Group II animals were treated nine times during a three week period with 0.4 mL of undiluted test substance. Induction treatments were on Days 1, 3, 6, 8, 10, 13, 15, 17 and 20. The same treatment regimen and test site location was used for all induction treatments. Group I animals remained untreated during the induction phase of the study.

3.8 Challenge Treatment

After a two week rest period, all animals (Groups I and II) were each challenged at a virgin test site with an application of 0.4 mL of undiluted test substance. The challenge treatment was on Day 36. The dose was applied in a manner identical to the induction treatments, except the test site was placed laterally on the right rear quadrant of the exposure area with the edge of the gauze pad adjacent to the midline of the back (Figure 2).

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3.9 Observations and Scoring Methods

Observations for skin reactions at each test site were made approximately 24 hours after each treatment. In addition, observations for skin reactions were made approximately 48 hours after the first and last induction treatments, and 48 hours after the challenge treatment. If observations fell on a dosing day, observations were made prior to dosing on that day. The scoring scale used to grade skin reactions is as follows:

<u>Erythema</u>	<u>Score</u>
No reaction	0
Very faint, usually nonconfluent	0.5
Faint, usually confluent	1
Moderate	2
Strong, with or without edema	3

An average score for each time period was obtained by adding all of the scores for each time period and dividing by the number of test sites scored for that time period. The test substance is considered a sensitizer if the mean irritation scores, the total number of animals with scores, and/or the total number of scores for the virgin test site in the test group after the challenge treatment are appreciably greater than those for the naive challenge group.

4.0 RESULTS AND DISCUSSION

Results of irritation screening are presented in Figure 1. Test site locations are presented in Figure 2. Skin reactions and average skin reaction scores during induction and challenge are presented in Tables 1 and 2, respectively. Individual body weights are presented in Table 3. The average skin reaction scores for each group at challenge are as follows:

<u>Group</u>	<u>Mean Challenge Scores</u>
Naive Control	0.0
Test	0.0

5.0 CONCLUSIONS

The test substance, SYN524464 FS (500) (A16148C), produced no irritation in the test animals (Group II) or the naive control animals (Group I) after the challenge treatment, and therefore did not elicit a sensitizing reaction in guinea pigs.

TABLES SECTION

TABLE 1 Skin Reaction Scores

SKIN SENSITIZATION IN GUINEA PIGS
Test Substance: SYN524464 FS (500)

Animal No.	Hours After Day of Treatment										Challenge RR		
	Induction Treatments LF												
	Day 1		Day 3	Day 6	Day 8	Day 10	Day 13	Day 15	Day 17	Day 20		Day 36	
	24 hr	48 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	48 hr	24 hr	48 hr
Group I – Naive Control													
41-M												0	0
42-M												0	0
43-M												0	0
44-M												0	0
45-M												0	0
46-F												0	0
47-F												0	0
48-F												0	0
49-F												0	0
50-F												0	0
Group II – Test Group													
51-M	0	0	0	0	0	0	0	0	0	0	0	0	0
52-M	0	0	0	0	0	0	0	0	0	0	0	0	0
53-M	0	0	0	0	0	0	0	0	0	0	0	0	0
54-M	0	0	0	0	0	0	0	0	0	0	0	0	0
55-M	0	0	0	0	0	0	0	0	0	0	0	0	0
56-F	0	0	0	0	0	0	0	0	0	0	0	0	0
57-F	0	0	0	0	0	0	0	0	0	0	0	0	0
58-F	0	0	0	0	0	0	0	0	0	0	0	0	0
59-F	0	0	0	0	0	0	0	0	0	0	0	0	0
60-F	0	0	0	0	0	0	0	0	0	0	0	0	0
61-M	0	0	0	0	0	0	0	0	0	0	0	0	0
62-M	0	0	0	0	0	0	0	0	0	0	0	0	0
63-M	0	0	0	0	0	0	0	0	0	0	0	0	0
64-M	0	0	0	0	0	0	0	0	0	0	0	0	0
65-M	0	0	0	0	0	0	0	0	0	0	0	0	0
66-F	0	0	0	0	0	0	0	0	0	0	0	0	0
67-F	0	0	0	0	0	0	0	0	0	0	0	0	0
68-F	0	0	0	0	0	0	0	0	0	0	0	0	0
69-F	0	0	0	0	0	0	0	0	0	0	0	0	0
70-F	0	0	0	0	0	0	0	0	0	0	0	0	0

M – Male; F – Female; LF – Left Front test site; RR – Right Rear test site
Note: Observations were made for erythema.

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TABLE 2 Average Skin Reaction Scores

SKIN SENSITIZATION IN GUINEA PIGS

Test Substance: SYN524464 FS (500)

		Hours After Day of Treatment										Challenge RR		
		Induction Treatments LF								Day 20		Day 36		
		Day 1		Day 3	Day 6	Day 8	Day 10	Day 13	Day 15	Day 17				
		24 h	48 h	24 h	24 h	24 h	24 h	24 h	24 h	24 h	24 h	48 h	24 h	48 h
Group I	Naive Control											0.0	0.0	
Mean												0.0		
Group II	Test Group	0.0	0.0								0.0	0.0	0.0	0.0
Mean		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

LF – Left Front test site; RR – Right Rear test site

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TABLE 3 Body Weights

SKIN SENSITIZATION IN GUINEA PIGS
 Test Substance: SYN524464 FS (500)

Animal Number	Day of Study	
	Day 0	Day 38
Group I - Naive Control		
41-M	379	517
42-M	361	584
43-M	384	655
44-M	401	623
45-M	390	614
46-F	328	473
47-F	356	487
48-F	330	451
49-F	375	507
50-F	365	527
Group II – Test		
51-M	345	566
52-M	365	611
53-M	370	562
54-M	392	595
55-M	379	564
56-F	363	512
57-F	362	524
58-F	330	493
59-F	350	441
60-F	345	467
61-M	386	623
62-M	392	273
63-M	399	707
64-M	380	626
65-M	371	585
66-F	371	533
67-F	334	468
68-F	368	541
69-F	349	506
70-F	365	484
M – Male; F – Female		

Note: Body weights are in grams.

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TABLE 4 Positive Control Study Skin Reaction Scores

SKIN SENSITIZATION IN GUINEA PIGS
 Study No: 10865-07
 Positive Control Material: Alpha-Hexylcinnamaldehyde

Animal No.	Hours After Day of Treatment												Challenge RR	
	Induction Treatments										Day 20			
	LF												24 hr	
	Day 1		Day 3	Day 6	Day 8	Day 10	Day 13	Day 15	Day 17	Day 20		Day 36		
24 hr	48 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	24 hr	48 hr	24 hr	48 hr	
Group I – Naive Control														
281-M													0	0
282-M													0	0
283-M													0	0
284-M													0	0
285-M													0	0
286-F													0	0
287-F													0	0
288-F													0	0
289-F													0	0
290-F													0	0
Group II – Test Group														
291-M	0	0	0	0	0	0	0	0.5	0.5	0.5	0	1	1	
292-M	0	0	0	0	0	0	0	0.5	1	1	0	1	0.5	
293-M	0	0	0	0	0.5	0	0	1	1	1	0.5	1	0.5	
294-M	0	0	0	0	0	0	0	1	1	1	0.5	1	0.5	
295-M	0	0	0	0	0.5	0	0	1	1	1	0.5	2	1	
296-F	0	0	0	0	0	0	0	0	1	1	0.5	1	1	
297-F	0	0	0	0	0	0	0	0.5	1	1	0.5	1	0.5	
298-F	0	0	0	0	0.5	0	0	1	1	1	0	1	0.5	
299-F	0	0	0	0	0.5	0	0	0.5	1	0.5	0	1	1	
300-F	0	0	0	0	0	0.5	0	0.5	1	1	0.5	1	0.5	
M – Male; F – Female; LF – Left Front test site; RR – Right Rear test site														
Note: Observations were made for erythema.														

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TABLE 5 Positive Control Study Average Skin Reaction Scores

SKIN SENSITIZATION IN GUINEA PIGS
 Study No: 10865-07
 Positive Control Material: Alpha-Hexylcinnamaldehyde

		Hours After Day of Treatment										Challenge RR	
		Induction Treatments LF								Day 20		Day 36	
		Day 1		Day 3	Day 6	Day 8	Day 10	Day 13	Day 15				
		24 h	48 h	24 h	24 h	24 h	24 h	24 h	24 h	24 h	24 h	48 h	24 h
Group I Naive Control												0.0	0.0
Mean												0.0	
Group II Test Group												0.9	0.3
Mean		0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.6	1.0	0.6	1.1	0.7

LF – Left Front test site; RR – Right Rear test site

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

Estas informações, resultados de testes e outros dados não divulgados são confidenciais e de propriedade da SYNGENTA S.A. DE CULTIVOS LTDA., protegidos na forma da Lei 10.603/02 e do artigo 195, IV, da Lei 9.279/96

É proibida a revelação ou divulgação, e vedado o uso, ainda que parcial ou por vias indiretas, a terceiros não autorizados.

Todos os infratores poderão ser processados civil e criminalmente

FIGURES SECTION

FIGURE 1 Irritation Screening

Date of Dosing: 21 Apr 08

Note: A dose of 0.4 mL/site was used for each concentration.

31-M	
1	2
3	4

1 = 100%

32-M	
4	1
2	3

2 = 75%

33-F	
3	4
1	2

3 = 50%

34-F	
2	3
4	1

4 = 25%

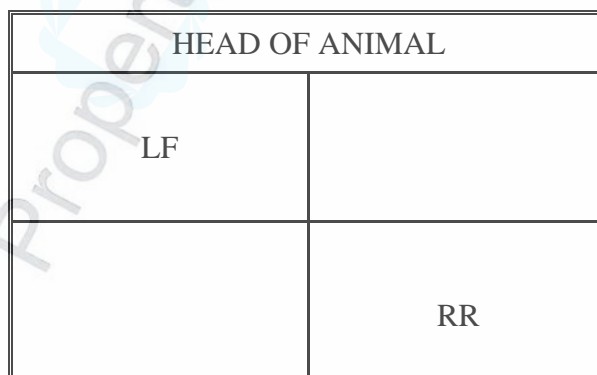
Animal Number	Body Wt (g)	Observation Time After Treatment							
		24 Hour Score*				48 Hour Score*			
		Front Site		Rear Site		Front Site		Rear Site	
31-M	379	0	0	0	0	0	0	0	0
32-M	374	0	0	0	0	0	0	0	0
33-F	379	0	0	0	0	0	0	0	0
34-F	371	0	0	0	0	0	0	0	0

* - Observations made for erythema; M - Male; F - Female

Level Selected for Induction: 100%

Level Selected for Challenge: 100%

FIGURE 2 Test Site Locations



LF - Left Front Test Site; RR - Right Rear Test Site

RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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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	SYN524464 FS (500)
Product by Common Name	SYN524464 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 SYN524464*	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 Jeffrey
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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