PC Codes: 122101, 128810
EPA FILE SYMBOL: 100-RERA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 22, 2004

MEMORANDUM

Subject:	Name of Pesticide Product:	Banner Heritage MAXX™	
	EPA File Symbol:	100-RERA	
	DP Barcode:	D309590	
	Decision No.:	348205	
	PC Codes:	128810	Azoxystrobin
		122101	Propiconazole

From: Breann Hanson, Toxicologist B Hanson JCR
Technical Review Branch
Registration Division (7505C)

To: John Bazuin, RM Team 22
Fungicide Branch
Registration Division (7505C)

Applicant: Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

FORMULATION FROM LABEL:

Active Ingredients:			% by wt.
128810	Azoxystrobin	CAS No. 131860-33-8	5.73%
122101	Propiconazole	CAS No. 60207-90-1	9.54%
Inert Ingredients:			84.72%
		Total:	100.00%

ACTION REQUESTED:
The Product Manager requests:

> "Syngenta has submitted a new product containing both Azoxystrobin and Propiconazole as active ingredien.. They submitted a full 6-pack of acute toxicity studies. Please review these studies and comment on their acceptability to support the registration of this new product. Please also comment on the appropriateness of the label language in light of the acute toxicity of this product."

BACKGROUND: Syngenta Crop Protection, Inc. has submitted a six pack of acute toxicity studies in support of registration for Banner Heritage MAXX™, EPA File Symbol: 100-RERA. The submission included a CSF, label, application and letter from the sponsor. The studies were conducted at Stillmeadow, Inc., Sugar Land, TX with assigned MRID numbers 463505-03 through -08.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable. The acute toxicity profile for Banner Heritage MAXX™, EPA File Symbol: 100-RERA, is:

Acute oral toxicity	III	Acceptable	MRID 46350503
Acute dermal toxicity	IV	Acceptable	MRID 46350504
Acute inhalation toxicity	IV	Acceptable	MRID 46350505
Primary eye irritation	III	Acceptable	MRID 46350506
Primary skin irritation	IV	Acceptable	MRID 46350507
Dermal sensitization	Negative	Acceptable	MRID 46350508

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: **000100-01216**

PRODUCT NAME: Banner Heritage MAXX™

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: **CAUTION**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear: Long-sleeved shirt and long pants, Socks and Shoes.

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

3

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Acute Oral Toxicity - SD rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid)

CITATION: Kuhn, J. (2004) Propiconazole/Azoxystrobin EC (A14212C) : Acute Oral Toxicity Study in Rats. Laboratory Study Identification: 7922-03. Unpublished study prepared by Stillmeadow, Inc. June 28, 2004. MRID 46350503.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46350503), 15 female Sprague-Dawley rats (Age: young adult, Weight: 154-215 g; Source: Texas Animal Specialties, Humble, TX) were given a single oral dose of Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid) by oral gavage. The study was initiated at a dose of 5,000 mg/kg in one female, but due to the death of that animal an additional 14 females were dosed at either 175, 550, 1,750 or 5,000 mg/kg following the up-and-down procedure. Individual animal body weights were recorded prior to test substance administration and again on days 7 and 14, or at the time of discovery after death. Clinical checks for mortality, signs of toxicity and behavioural changes were made at least three times post-dosing and at least once daily for 14 days. All surviving animals were necropsied on study day 14.

Oral LD_{50} Females = 2,176 mg/kg (95% C.I.= 776-12,600 mg/kg)

Based on the LD_{50} in female rats, Propiconazole/Azoxystrobin EC (A14212C) is classified as EPA Toxicity Category III.

The one animal dosed at 175 mg/kg survived, gained weight and appeared healthy throughout the study. No gross internal findings were observed at necropsy.

The 3 animals dosed at 550 mg/kg survived and gained weight throughout the study. One animal had piloerection on study days 2 and 3, but appeared healthy for the remainder of the study. The other animals appeared healthy throughout the study. No gross internal findings were observed at necropsy.

3/6 animals dosed at 1,750 mg/kg died on study day 1. The surviving animals gained weight and appeared healthy throughout the study. Findings at necropsy for 2/3 animals found dead during the study included mottled liver, think yellow fluid in stomach, empty small intestines and green paste in the large intestine or mottled lungs and/or dark red liver. The other animal found dead

4

during the study and the survivors had no gross internal findings at necropsy.

4/5 animals dosed at 5,000 mg/kg died by study day 1. The surviving animal gained weight and appeared healthy throughout the study. Findings at necropsy for the animals found dead during the study included red crusted noses, mottled lungs, gas in stomach and intestines, yellow/clear liquid in stomach and/or stained muzzle. The lone survivor had no gross internal findings at necropsy.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Individual animals were dosed as follows:

Main Test

Dosing Sequence	Animal No.	Sex	Dose level (mg/kg)	Sort-Term Outcome	Long-Term Outcome
1	42	F	175	S	S
2	43		550	S	S
3	44		1750	D	D
4	45		550	S	S
5	46		1750	S	S
6	47		5000	D	D
7	48		1750	S	S
8	49		5000	S	S
9	50		5000	D	D
10	51		1750	D	D
11	52		550	S	S
12	53		1750	S	S
13	54		5000	D	D

14	55		1750	D	D

S = survival D = death

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Friday, November 19, 2004, 3:14:41 PM
Data file name: work.dat
Last modified: 11/19/2004 3:14:40 PM

Test/Substance: Prop/Azoxy
Test type: Main Test
Limit dose (mg/kg): 5000
Assumed LD50 (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 5000, 1750, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	42	175	O	O
2	43	550	O	O
3	44	1750	X	X
4	45	550	O	O
5	46	1750	O	O
6	47	5000	X	X
7	48	1750	O	O
8	49	5000	O	O
9	50	5000	X	X
10	51	1750	X	X
11	52	550	O	O
12	53	1750	O	O
13	54	5000	X	X
14	55	1750	X	X

(X = Died, O = Survived)
Dose Recommendation: The main test is complete.
Stopping criteria met: LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	3	0	3
1750	3	3	6
5000	1	3	4
All Doses	8	6	14

Statistical Estimate based on long term outcomes:
Estimated LD50 = 2176 (Based on maximum likelihood).
95% PL Confidence interval is 776.3 to 12600.

A. Mortality - As noted in table.

B. Clinical observations - The one animal dosed at 175 mg/kg survived, gained weight and appeared healthy throughout the study.

The 3 animals dosed at 550 mg/kg survived and gained weight throughout the study. One animal had piloerection on study days 2 and 3, but appeared healthy for the remainder of the study. The other animals appeared healthy throughout the study.

3/6 animals dosed at 1,750 mg/kg died on study day 1. The surviving animals gained weight and appeared healthy throughout the study.

4/5 animals dosed at 5,000 mg/kg died by study day 1. The surviving animal gained weight and appeared healthy throughout the study.

C. Gross Necropsy - No gross internal findings were observed at necropsy for the animals dosed at 175 or 550 mg/kg.

Findings at necropsy for 2/3 animals dosed at 1,750 mg/kg found dead during the study included mottled liver, think yellow fluid in stomach, empty small intestines and green paste in the large intestine or mottled lungs and/or dark red liver. The other animal found dead during the study and the survivors had no gross internal findings at necropsy.

Findings at necropsy for the animals dosed at 5,000 mg/kg found dead during the study included red crusted noses, mottled lungs, gas in stomach and intestines, yellow/clear liquid in stomach and/or stained muzzle. The lone survivor had no gross internal findings at necropsy.

D. Reviewer's Conclusions: Agree with study author.

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Acute Dermal Toxicity - SD Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid)

CITATION: Kuhn, J. (2004) Propiconazole/Azoxystrobin EC (A14212C): Acute Dermal Toxicity Study in Rats. Laboratory Study Identification: 8213-04. Unpublished study prepared by Stillmeadow, Inc. June 21, 2004. MRID 46350504.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46350504), 5/sex of Sprague-Dawley rats (Age: young adult; Weight: 247-314 g males, 187-221 g females; Source: Texas Animal Specialties, Humble, TX) were dermally exposed to a single application of Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid) at 5,050 mg/kg. The test material was applied to each exposure area, not less than 10% of the total BSA, covered with a gauze patch and then wrapped and secured with tape for 24 hours. Individual animal body weights were recorded prior to test substance administration and again on days 7 and 14. Clinical checks for mortality, signs of toxicity and behavioural changes were made at least three times post-application and at least once daily for 14 days. All animals were necropsied on study day 14.

Dermal LD_{50} Males => 5,050 mg/kg
Females => 5,050 mg/kg
Combined => 5,050 mg/kg

Based on the lack of mortality at 5,050 mg/kg, Propiconazole/Azoxystrobin EC (A14212C) is classified as EPA Toxicity Category IV.

All animals survived, gained weight and appeared healthy throughout the study. No dermal irritation was noted. No gross internal findings were observed at necropsy.

This acute dermal study is classified acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg)	Mortality/Number Tested		
	Males	Females	Combined
5050	0/5	0/5	0/10

A. **Mortality** - None, as noted in table.

B. **Clinical observations** - All animals survived, gained weight and appeared healthy throughout the study. No dermal irritation was noted.

C. **Gross Necropsy** - No gross internal findings were observed at necropsy.

D. **Reviewer's Conclusions**: Agree with study author.

9

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Acute Inhalation Toxicity -SD Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid)

CITATION: Carter, L. (2004) Propiconazole/Azoxystrobin EC (A14212C): Acute Inhalation Toxicity Study in Rats. Laboratory Study Identification: 8214-04. Unpublished study prepared by Stillmeadow, Inc. June 21, 2004. MRID 46350505.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46350505), 5/sex Sprague-Dawley rats (Age: young adult; Weight: 282-342 g males; 167-217 g females; Source: Texas Animal Specialities, Humble, TX) were exposed nose-only via the inhalation route to Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid) for 4 hours at an analytically determined concentration of 2.68 mg/L. Individual animal body weights were recorded prior to test substance administration and again on days 7 and 14. Clinical checks for mortality, signs of toxicity and behavioural changes were made frequently on the day of exposure and at least once daily for 14 days thereafter. All animals were necropsied on study day 14.

All animals survived and gained weight during the study. The only signs of clinical toxicity noted were decreases in activity and piloerection in all animals. Animals recovered from these symptoms by study day 2. No gross internal findings were at necropsy.

LC_{50} Males = > 2.68 mg/L (0/5 died)
LC_{50} Females => 2.68 mg/L (0/5 died)
LC_{50} Combined => 2.68 mg/L (0/10 died)

Based on the LC_{50} of 2.68 mg/L for both sexes, Propiconazole/Azoxystrobin EC (A14212C) is classified as EPA Toxicity Category IV.

This acute inhalation study is classified as acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Actual Conc. (Gravimetric) (mg/L)	MMAD µm	GSD µm	Mortality/Number Tested		
				Males	Females	Combined
3.37	2.68	2.4	4.2	0/5	0/5	0/10

Test Atmosphere / Chamber Description:

Gravimetric Conc:	**2.68 mg/L**
Chamber Volume:	**500 L**
Airflow:	**195 LPM**
Temperature:	**70-71 °F**
Relative Humidity:	**64%**
Time to Equilibrium:	**12 minutes**

Test atmosphere concentration - Samples were taken from the breathing zone of each animal and concentration determined analytically once and hour and nominally at the end of exposure. The analytical determination was made using a Spectrophotometer.

Particle size determination - A cascade impactor was used to determine the particle size distribution of the test atmosphere. Samples were taken at two intervals from the breathing zone of the animals. Samples were evaluated using probit analysis.

A. Mortality - None, as noted in table.

B. Clinical observations - All animals survived and gained weight during the study. The only signs of clinical toxicity noted were decreases in activity and piloerection in all animals. Animals recovered from these symptoms by study day 2.

C. Gross Necropsy - No gross internal findings were observed at necropsy.

D. Reviewer's Conclusions: Agree with study author.

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Primary Eye Irritation - NZW Rabbit, OPPTS 870.2400; OECD 405

TEST MATERIAL: Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid)

CITATION: Kuhn, J. (2004) Acute Eye Irritation Study in Rabbits. Laboratory Study Identification: 7914-03. Unpublished study prepared by Stillmeadow, Inc. January 8, 2004. MRID 46350506.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46350506), 0.1 mL of undiluted Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid) was instilled into the conjunctival sac of the right eye of young adult New Zealand albino rabbits (2 males, 1 female, Source: Nichols Rabbitry Inc., Lumberton, TX). The untreated left eye served as a control. Animals were then observed at 1, 24, 48, 72 hours and on days 4 and 7 post-instillation. Irritation was scored according to Draize.

No iritis was noted at any point during the study. One hour after instillation 3/3 eyes exhibited conjunctivitis redness, chemosis and discharge (score 2) and corneal opacity (score 1). At 72 hours 2/3 eyes exhibited corneal opacity (scores 1-2) and conjunctivitis (scores 1-3). No positive effects were noted on study day 7.

The test substance is moderately irritating. In this study, Propiconazole/Azoxystrobin EC (A14212C) is classified as EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

12

RESULTS AND DISCUSSION:

Observations	Number "positive"/number tested					
	Hours				Days	
	1	24	48	72	4	7
Corneal Opacity	3/3	3/3	2/3	2/3	2/3	0/3
Iritis	0/3	0/3	0/3	0/3	0/3	0/3
Conjunctivae:						
Redness*	3/3	3/3	1/3	1/3	1/3	0/3
Chemosis*	3/3	3/3	0/3	0/3	0/3	0/3
Discharge*	3/3	3/3	2/3	2/3	0/3	0/3

*Score of 2 or more required to be considered "positive"

A. **Observations** - No iritis was noted at any point during the study. One hour after instillation 3/3 eyes exhibited conjunctivitis redness, chemosis and discharge (score 2) and corneal opacity (score 1). At 72 hours 2/3 eyes exhibited corneal opacity (scores 1-2) and conjunctivitis (scores 1-3). No positive effects were noted on study day 7.

B. **Reviewer's Conclusions:** Agree with the study author.

13

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Primary Dermal Irritation - NZW Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid)

CITATION: Kuhn, J. (2004) Acute Dermal Irritation Study in Rabbits. Laboratory Study Identification: 7915-03. Unpublished study prepared by Stillmeadow, Inc. January 8, 2004. MRID 46350507.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46350507), 3 young adult New Zealand albino rabbits (2 males, 1 female; Source: Nichols Rabbitry Inc., Lumberton, TX) were dermally exposed to 0.5 mL of undiluted Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid). The test substance applied to the dose site on each animal, covered with a gauze patch and then secured with a semi-permeable dressing for 4 hours. Animals were then observed for 72 hours. Dermal irritation was scored according to the Draize system at 1, 24, 48 and 72 hours post-patch removal.

No dermal irritation was noted at any point during the study.

In this study, the formulation is non-irritating to the skin. Propiconazole/Azoxystrobin EC (A14212C) is classified as EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal Number	Sex	Hours			
		1	24	48	72
6512-M	M	0/0	0/0	0/0	0/0
6514-M		0/0	0/0	0/0	0/0
6511-F	F	0/0	0/0	0/0	0/0
Severity of Irritation - Mean Score		0/0	0/0	0/0	0/0

A. **Observations** -No dermal irritation was noted at any point during the study.

B. **Results** - Test substance is non-irritating to the skin. PDII = 0.0.

C. **Reviewer's Conclusions** - Agree with study author.

15

Reviewer: Breann Hanson **Date:** Nov. 22, 2004
Risk Manager (EPA): John Bazuin, RM 22

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: Propiconazole/Azoxystrobin EC (9.5/5.7% W/W) (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid)

CITATION: Kuhn, J. (2004) Skin Sensitization Study in Guinea Pigs. Laboratory Study Identification: 7923-03. Unpublished study prepared by Stillmeadow, Inc. February 17, 2004. MRID 46350508.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 46350508) with Propiconazole/Azoxystrobin EC (9.5/5.7% W/W) (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid), 15/sex young adult Hartley guinea pigs (Weight: 467-687 g males, 386-471 g females; Source: Charles River Laboratories, Wilmington, MA) were tested using the Buehler method. Three times a week for 3 weeks, 0.4 mL of undiluted test substance was applied to the left side of each animal under a gauze patch and secured with non-irritating tape to 20 test animals. After 6 hours of exposure, the chambers were removed. 24 hours after each induction the animals were scored for dermal irritation. Additional scoring took place 48 hours after the first and last induction treatments. Two weeks after the last induction dose a challenge dose of 0.4 mL of undiluted test substance was applied to the right side of the test animals and to a set of 10 naive control guinea pigs for 6 hours. Approximately 24 and 48 hours after challenge, the animals were graded for dermal irritation. The procedures were validated using 1-chloro-2,4-dinitrobenzene (DNCB) as the positive control substance.

No dermal irritation was noted at any point during the study for either the test or positive control animals.

Based on the results of this study, Propiconazole/Azoxystrobin EC (9.5/5.7% W/W) (A14212C) does not have to be labeled as a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal sensitization study (OPPTS 870.2600; OECD 406) in the Guinea pig .

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

16

I. PROCEDURE

A. Induction - Three times a week for 3 weeks, 0.4 mL of undiluted test substance was applied to the left side of each animal under a gauze patch and secured with non-irritating tape to 20 test animals. After 6 hours of exposure, the chambers were removed. 24 hours after each induction the animals were scored for dermal irritation. Additional scoring took place 48 hours after the first and last induction treatments.

B. Challenge - Two weeks after the last induction dose a challenge dose of 0.4 mL of undiluted test substance was applied to the right side of the test animals and to a set of 10 naive control guinea pigs for 6 hours. Approximately 24 and 48 hours after challenge, the animals were graded for dermal irritation.

C. Naive Controls - A naive control group of 10 animals were tested with 0.4 mL of undiluted test substance at challenge only.

II. RESULTS and DISCUSSION:

A. Reactions and duration - No dermal irritation was noted at any point during the study for either the test or positive control animals.

B. Positive control - Results were appropriate with a DNCB study to validate test procedures. The positive control study was completed March 5, 2004. This test was performed from 02/25/04 - 03/31/04.

C. Reviewer's Conclusions: Agree with study author.

17

1. DP BARCODE: D309590
2. PC CODES: 122101, 128810
3. CURRENT DATE: 22/NOV/2004
4. TEST MATERIAL:
[a] Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.60%, Azoxystrobin: 5.66%; FL-040096; amber liquid)
[b] Propiconazole/Azoxystrobin EC (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid)
[c] Propiconazole/Azoxystrobin EC (9.5/5.7% W/W) (A14212C) (Propiconazole: 9.4%, Azoxystrobin: 5.6%; FL-031798; amber liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat [a] Stillmeadow, Inc. 7922-03/06-28-2004	46350503	LD_{50} = 2,176 mg/kg (95% C.I.= 776-12,600 mg/kg) (females)	III	A
Acute dermal toxicity/rat [a] Stillmeadow, Inc. 8213-04/06-21-2004	46350504	LD_{50} > 5,050 mg/kg (males, females combined)	IV	A
Acute inhalation toxicity/rat [a] Stillmeadow, Inc. 8214-04/06-21-2004	46350505	LC_{50} > 2.68 mg/L (males, females combined)	IV	A
Primary eye irritation/rabbit [b] Stillmeadow, Inc. 7914-03/01-08-2004	46350506	no iritis noted. 3/3 conjunctivitis and corneal opacity at 1 hour, no positive effects on day 7	III	A
Primary dermal irritation/rabbit [b] Stillmeadow, Inc. 7915-03/01-08-2004	46350507	no irritation	IV	A
Dermal sensitization/guinea pig [c] Stillmeadow, Inc. 7923-03/02-17-2004	46350508	is not a sensitizer	–	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived**

18