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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

25/SEPT/2003

MEMORANDUM

Subject:	Name of Pesticide Product:	Quilt™
	EPA Reg. No. /File Symbol:	100-RRTI
	DP Barcode:	D290242
	Decision No:	212036
	PC Code:	122101, 128810
From:	Rick J. Whiting, Biologist	RJW
	Technical Review Branch	
	Registration Division (7505C)	
To:	Carl Grable, PM Team 21	
	Fungicide Branch	
	Registration Division (7505C)	
Applicant:	Syngenta Crop Protection, Inc.	
	P.O. Box 18300	
	Greensboro, NC 27419	

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
128810	Azoxystrobin	7.0%
122101	Propiconazole	11.7%
	Inert Ingredient(s):	81.3%
	Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data for Quilt™, EPA File Symbol 100-RRTI.

BACKGROUND: Syngenta Crop Protection, Inc. has submitted a six pack of acute toxicity studies in support of registration of Quilt™, EPA File Symbol 100-RRTI. The studies were assigned MRID numbers 459164-03 to -08. The product is referred to as CGA-64250/Azoxystrobin 200 SE-H (FL-021841)" or "Propiconazole.Azoxystrobin 200 SE" in the study reports.

The acute oral (45916403) study was conducted at Stillmeadow, Inc., Sugar Land, Texas and used CGA-64250/Azoxystrobin 200 SE-H (FL-021841) (Purity: 12.0% CGA-64250; 7.16% ASF819; Lot No. FL-021841, A13705H) as the test material. The acute dermal (45916404), acute inhalation (45916405), primary eye irritation (45916406) primary dermal irritation (45916407) and dermal sensitization (45916408) studies were conducted at Central Toxicology Laboratory, Alderly Park, Macclesfield, Cheshire, UK and used Propiconazole/Azoxystrobin 200 SE (Purity: CGA64250 - 12.0% w/w; ASF819 - 7.16% w/w; Batch No. FL021841, A-13705H) as the test material.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable. The acute toxicity profile for Quilt™, EPA File Symbol 100-RRTI, is as follows:

Acute oral toxicity	III	Acceptable	MRID 45916403
Acute dermal toxicity	IV	Acceptable	MRID 45916404
Acute inhalation toxicity	IV	Acceptable	MRID 45916405
Primary eye irritation	IV	Acceptable	MRID 45916406
Primary skin irritation	IV	Acceptable	MRID 45916407
Dermal sensitization	Negative	Acceptable	MRID 45916408

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 #: 000100-01178

PRODUCT NAME: Quilt™

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if swallowed. Wear: Long-sleeved shirt and long pants, socks, 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.

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.

Useer Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco

DATA EVALUATION RECORD

STUDY TYPE: ACUTE ORAL TOXICITY TESTING (870.1100 formerly §81-1)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: CGA-64250/Azoxystrobin 200 SE-H (FL-021841); Purity: 12.0% CGA-64250; 7.16% ASF819; Lot No. FL-021841, A13705H

CITATION: Kuhn, J. (2003) CGA-64250 (Propiconazole)/ASF819 (AZOXYSTROBIN) 200 SE (A13705H). Stillmeadow, Inc., Laboratory Project Number: 7328-02: 1832-02. March 7, 2003. MRID No. 45916403. Unpublished study.

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

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID No. 45916403), young adult female Sprague-Dawley rats (Age: 8-9 weeks; Weight: 163-210 g; Source Texas Animal Specialties, Humble, TX) were given a single oral dose of CGA-64250/Azoxystrobin 200 SE-H (Purity: 12.0% CGA-64250; 7.16% ASF819; Lot No. FL-021841, A13705H) using the Up and Down Procedure. "The test substance, CGA-64250/Azoxystrobin 200 SE-H (FL-021841), was evaluated for its acute toxicity potential in albino rats when administered as a gavage dose at a level of 5050 mg/kg. Since the test substance failed the limit test, the main test was conducted following the up-and-down procedure (UPD) at 175, 550, 1750 and 5000 mg/kg. The study was terminated following the stopping rules of this procedure." Body weights were obtained just prior to dosing and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality at least three times on the day of dosing and at least once daily thereafter for 14 days. A gross necropsy examination was performed on all animals at scheduled euthanasia.

Oral LD_{50} Females = 1750 mg/kg with 95% confidence interval of 1239 - 4450 mg/kg

CGA-64250/Azoxystrobin 200 SE-H (FL-021841) is classified as Toxicity Category III based on the LD_{50} value in female rats.

Animals dosed with 175 and 550 mg/kg survived. One animal dosed with 1750 mg/kg died two hours after dosing. Three animals dosed with 5000 mg/kg died, two died one hour after dosing and the other on day 2. All surviving animals gained weight during the study. The gross necropsy findings in animals that died on study included: crusted/wet muzzle; discolored lungs and contents of stomach/large intestine; and empty small intestine. The gross necropsy findings in animals surviving to termination of study revealed no observable abnormalities except pale kidneys in two animals.

This study is classified as Acceptable (870.1100) and satisfies the guideline requirement for an acute oral study in the rat.

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

DOSING: From Page 10 of the study report:

Dosing Sequence	Animal No.	Dose level (mg/kg)	Time of Death*
1	292	175	Day 14
2	293	550	Day 14
3	294	1750	2 Hours
4	295	5000	1 Hour
5	3	1750	2 Hours
6	4	550	Day 14
7	5	1750	Day 14
8	6	5000	Day 2
9	7	1750	Day 14
10	8	5000	1 Hour
	291	5050	2 Hours

* - Indicates time of discovery after death (Day of dosing considered Day 0; Day 14 is terminal sacrifice). If discovery was between scheduled observations, the time of death was recorded under the next scheduled observation .

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

Date/Time: Wednesday, September 17, 2003, 2:59:10 PM
Data file name: 45916403.dat
Last modified: 9/17/2003 2:59:06 PM

Test/Substance: CGA-64250/Azoxystrobin 200 SE-H (FL-021841)
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	292	175	O	O
2	293	550	O	O
3	294	1750	O	O
4	295	5000	X	X
5	3	1750	X	X
6	4	550	O	O
7	5	1750	O	O
8	6	5000	X	X
9	7	1750	O	O
10	8	5000	X	X

(X = Died, O = Survived)

Dose Recommendation: Stop dosing animals. Observe the previously dosed animals for 14-days and record the long-term outcomes.

Stopping criteria met: LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	2	0	2
1750	3	1	4
5000	0	3	3
All Doses	6	4	10

Statistical Estimates:

The estimated LD_{50} is 1750 mg/kg with 95% confidence interval of 1239 - 4450 mg/kg

OBSERVATIONS: Animals dosed with 175 and 550 mg/kg survived. One animal dosed with 1750 mg/kg died two hours after dosing. Three animals dosed with 5000 mg/kg died, two died one hour after dosing and the other on day 2. All surviving animals gained weight during the study.

GROSS NECROPSY: The gross necropsy findings in animals that died on study included: crusted/wet muzzle; discolored lungs and contents of stomach/large intestine; and empty small intestine. The gross necropsy findings in animals surviving to termination of study revealed no observable abnormalities except pale kidneys in two animals.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: Propiconazole/Azoxystrobin 200 SE; Purity: CGA64250 - 12.0% w/w; ASF819 - 7.16% w/w; Batch No. FL021841, A-13705H

CITATION: Johnson, I. (2003) Propiconazole/Azoxystrobin 200 SE (A-13705H): Acute Dermal Toxicity Study in the Rat. Central Toxicology Laboratory, Laboratory Project Number: CR3605: 2114-02. March 19, 2003. MRID No. 45916404. Unpublished study.

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

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID No. 45916404), five young adult Alpk:AP$_f$SD (Wistar-derived) rats/sex (Age: 8-12 weeks; Weight: 332-376 g males; 204-232 g females; Source: Rodent Breeding Unit, Alderley Park, Macclesfield, Cheshire, UK) were dermally exposed to a single application of Propiconazole/Azoxystrobin 200 SE (Purity: CGA64250 - 12.0% w/w; ASF819 - 7.16% w/w; Batch No. FL021841, A-13705H) at 5000 mg/kg for 24 hours. The test material was applied undiluted and a volume of 5 ml/kg body weight was applied. Body weights were recorded before dosing (day 1) and on days 8 and 15. Animals were examined for clinical signs twice following application on day (1) and once daily up to day 15. A gross necropsy examination was performed on all animals at the time of scheduled euthanasia.

Dermal LD_{50} Males => 5000 mg/kg (observed); Dermal LD_{50} Females => 5000 mg/kg (observed)

Propiconazole/Azoxystrobin 200 SE is classified as Toxicity Category IV based on the observed LD_{50} value in both sexes.

All animals survived and gained weight during the study. Slight skin irritation was seen in all animals but had completely resolved by day 12. No gross abnormalities were noted a necropsy.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

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

RESULTS:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

OBSERVATIONS: All animals survived and gained weight during the study. Slight skin irritation was seen in all animals but had completely resolved by day 12.

GROSS NECROPSY: No gross abnormalities were noted a necropsy.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: Propiconazole/Azoxystrobin 200 SE (A13705H) formulation; Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, Y06654/167

CITATION: Kilgour, J. (2003) Propiconazole/Azoxystrobin 200 SE Formulation (A13705H): 4-Hour Acute Inhalation Toxicity Study in Rats. Central Toxicology Laboratory, Laboratory Project Number: HR2418. March 21, 2003. MRID No. 45916405. Unpublished study.

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

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID No. 45916405), five young adult Alpk:AP$_f$SD (Wistar-derived) rats/sex (Age: 9-10 weeks; Weight: 322-391 g males; 226-262 g females; Source: Rodent Breeding Unit, Alderley Park, Macclesfield, Cheshire, UK) were exposed by nose only inhalation Propiconazole/Azoxystrobin 200 SE (A13705H) formulation (Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, Y06654/167) at 3.05 mg/L for four hours. Body weights were recorded on day -1, 1, 8 and prior to termination on day 15. All animals were observed for clinical signs of toxicity and mortality during and following exposure over a 14-day observation period. A gross necropsy examination was performed on all animals at the scheduled euthanasia.

Inhalation LC_{50} Males => 3.05 mg/L (observed); Inhalation LC_{50} Females = > 3.05 mg/L (observed)

Propiconazole/Azoxystrobin 200 SE (A13705H) formulation is classified as Toxicity Category IV based on the observed LC_{50} values in both sexes.

All animals survived and gained weight during the study. Wet fur, hunched posture, piloerection and chromodacryorrhoea (2 males only) were observed in all animals post exposure. All animals were salivating and had test material around the nose. Other observations included decreased activity in males, increased response to touch in 1 male, reduced righting reflex in 1 female and irritation of the upper respiratory tract (abnormal respiratory noise, breathing rate reduced and depth increased, salivation) were observed in all test animals. Female animals had improved by day 3 of study and males day 5 of study. All animals had fully recovered by day 8 of study. No significant gross abnormalities were noted at necropsy.

The gravimetric chamber concentration was 3.05 mg/L. The mass median aerodynamic diameter was estimated to be 4.00 µm with a geometric standard deviation of 1.54 at 1 hour into exposure and 3.81 µm with a geometric standard deviation of 1.68 at 3 hours into exposure.

This study is classified as Acceptable (870.1300) and satisfies the guideline requirement for an acute inhalation study in the rat.

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

RESULTS:

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
3.05	0/5	0/5	0/10

Chamber Atmosphere			
Gravimetric conc.	Time into Exposure (hours : minutes)	MMAD	GSD
3.05 mg/L	1:00	3.57 µm	1.54
	3:00	3.81 µm	1.68

Chamber Environment[a]	
Chamber Volume	27.6 L
Airflow	30.0 LPM
Temperature	20.8 - 21.3°C
Relative Humidity	44 - 74%

[a] Nose only

OBSERVATIONS: All animals survived and gained weight during the study. Wet fur, hunched posture, piloerection and chromodacryorrhoea (2 males only) were observed in all animals post exposure. All animals were salivating and had test material around the nose. Other observations included decreased activity in males, increased response to touch in 1 male, reduced righting reflex in 1 female and irritation of the upper respiratory tract (abnormal respiratory noise, breathing rate reduced and depth increased, salivation) were observed in all test animals. Female animals had improved by day 3 of study and males day 5 of study. All animals had fully recovered by day 8 of study.

GROSS NECROPSY: No significant gross abnormalities were noted at necropsy.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY EYE IRRITATION TESTING (870.2400 formerly §81-4)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: Propiconazole/Azoxystrobin 200 SE formulation; Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H

CITATION: Johnson, I. (2003) Propiconazole/Azoxystrobin 200SE Formulation (A-13705H): Eye Irritation Study in the Rabbit. Central Toxicology Laboratory, Laboratory Project Number: FB5987: 2114-02. March 26, 2003. MRID No. 45916406. Unpublished study.

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

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID No. 45916406), 0.1 ml of Propiconazole/Azoxystrobin 200 SE formulation (Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H) was placed into the conjunctival sac of one eye of each of three adult female New Zealand White rabbits (Source: Charles River UK Limited, Margate, Kent, UK). All animals were observed for ocular irritation and lesions at one hour and 1, 2, and 3 days after instillation. Ocular examination following staining with fluorescein was used in all readings from 1 day after instillation.

Propiconazole/Azoxystrobin 200 SE formulation is classified as Toxicity Category IV based on the observations in this study.

"Instillation into the eye caused practically no pain (class 1 on a 0-5 scale)." There was no corneal opacity or iritis observed in any of the treated eyes. There were no "positive" effects observed in any eyes during the study. Slight redness was observed in all animals at 1 hour (score "1") and in one animals at day 1 (score "1"). Slight chemosis was observed in all animals 1 hour after instillation (score "1") and a slight discharge was observed in two animals at 1 hour after instillation (score "1"). "In addition, all animals had a slight Harderian and/or lachrymatory discharge approximately 1 hour after instillation." All signs of conjunctival irritation were completely resolved within 2 days of instillation.

This study is classified as Acceptable (870.2400) and satisfies the guideline requirement for a primary eye irritation study in the rabbit.

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

RESULTS:

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

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

OBSERVATIONS: "Instillation into the eye caused practically no pain (class 1 on a 0-5 scale)." There was no corneal opacity or iritis observed in any of the treated eyes. There were no "positive" effects observed in any eyes during the study. Slight redness was observed in all animals at 1 hour (score "1") and in one animals at day 1 (score "1"). Slight chemosis was observed in all animals 1 hour after instillation (score "1") and a slight discharge was observed in two animals at 1 hour after instillation (score "1"). "In addition, all animals had a slight Harderian and/or lachrymatory discharge approximately 1 hour after instillation." All signs of conjunctival irritation were completely resolved within 2 days of instillation.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY DERMAL IRRITATION TESTING (870.2500 formerly §81-5)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: Propiconazole/Azoxystrobin 200SE formulation; Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H

CITATION: Johnson, I. (2003) Propiconazole/Azoxystrobin 200SE Formulation (A-13705H): Skin Irritation Study in the Rabbit. Central Toxicology Laboratory, Laboratory Project Number: EB4998: 2114-02. March 26, 2003. MRID No. 45916407. Unpublished study.

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

EXECUTIVE SUMMARY: In a primary skin irritation study (MRID No. 45916407), 0.5 ml of Propiconazole/Azoxystrobin 200SE formulation (Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H) was applied to the test site (approximate size 2.5 cm x 2.5 cm) on the left flank of three young female New Zealand White rabbits (Age: not reported; Source: Charles River UK Limited, Margate, Kent, UK). The duration of the single dermal application was for 4 hours. Animals were examined for signs of erythema and edema and the responses scored at 1 hour and 1, 2 and 3 days.

Propiconazole/Azoxystrobin 200SE formulation is classified as Toxicity Category IV based on the observations in this study.

Primary Dermal Irritation Index (PDII) = 0.92 Very slight erythema and edema was observed in all animals for 1 day. All signs of irritation had completely resolved with 2 days of application.

This study is classified as Acceptable (870.2500) and satisfies the guideline requirement for a primary skin irritation study in the rabbit.

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

RESULTS: Primary Dermal Irritation Index (PDII) = 0.92

OBSERVATIONS: Very slight erythema and edema was observed in all animals for 1 day. All signs of irritation had completely resolved with 2 days of application.

DATA EVALUATION RECORD

STUDY TYPE: DERMAL SENSITIZATION TESTING (870.2600 formerly §81-6)

Product Manager: 21 **Reviewer:** Rick J. Whiting

TEST MATERIAL PURITY: Propiconazole/Azoxystrobin 200SE formulation; Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H

CITATION: Johnson, I. (2003) Propiconazole/Azoxystrobin 200 SE Formulation (A-13705H): Skin Sensitization Study in the Guinea Pig. Central Toxicology Laboratory, Laboratory Project Number: GG7669: 2114-02. March 26, 2003. MRID No. 45916408. Unpublished study.

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

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID No. 45916408) conducted with Propiconazole/Azoxystrobin 200SE formulation (Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H), 30 young adult female Albino Dunkin-Hartley guinea pigs (Age: not reported; Source: David Hall, Newchurch, Burton on Trent, Staffs, UK) were tested using a method based on that described by Ritz and Buehler (1980).

Induction Phase: Animals were treated with a topical application of either 0.4 ml of the undiluted test material (test group, 20 animals) or a dry dressing only (control group, 10 animals). The induction process was repeated at the same siting during the next three weeks (three times a week for a total of nine, 6-hour exposures). Animals were left untreated for two weeks after the final induction exposure.

Challenge Phase: "Approximately 0.1-0.2 ml of the 75% w/v preparation of the test substance in deionised water was applied to one lint patch and a similar volume of the 50% w/v preparation was applied to the second lint patch. The dressing was applied to the shorn flanks of the guinea pigs so the 75% w/v preparation was on the left and the 50% w/v preparation was on the right.... The patches were left in position for at least 6 hours...Skin sites were examined 1 and 2 days after removal of the dressings."

A positive control study using hexylcinnamaldehyde was conducted within six months of the main study to validate the test system.

Propiconazole/Azoxystrobin 200SE formulation is classified as a non-sensitizer based on the results of this study.

The test material stained the application site of each animal yellow. Signs of slight skin irritation (edema, erythema, desquamation and thickening) were seen in all test animals during the induction phase of the study. There were no signs of irritation in any of the control animals. Following the challenge with 75% or a 50% w/v preparation of the test material in deionised water, no dermal irritation was observed in any of the test animals. One control animal had scattered mild redness. Based on these results, the test substance is not considered to be a contact sensitizer. The positive response observed in the hexylcinnamaldehyde study validates the test system used in this study.

This study is classified as Acceptable (870.2600) and satisfies the guideline requirement for an dermal sensitization study in the guinea pig.

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

PROCEDURE: In a dermal sensitization study (MRID No. 45916408) conducted with Propiconazole/Azoxystrobin 200SE formulation (Purity: CGA64250 - 12.0%; ASF819 - 7.16% w/w; Batch No. FL021841, A13705H), 30 young adult female Albino Dunkin-Hartley guinea pigs (Age: not reported; Source: David Hall, Newchurch, Burton on Trent, Staffs, UK) were tested using a method based on that described by Ritz and Buehler (1980).

Induction Phase: Animals were treated with a topical application of either 0.4 ml of the undiluted test material (test group, 20 animals) or a dry dressing only (control group, 10 animals). The induction process was repeated at the same siting during the next three weeks (three times a week for a total of nine, 6-hour exposures). Animals were left untreated for two weeks after the final induction exposure.

Challenge Phase: "Approximately 0.1-0.2 ml of the 75% w/v preparation of the test substance in deionised water was applied to one lint patch and a similar volume of the 50% w/v preparation was applied to the second lint patch. The dressing was applied to the shorn flanks of the guinea pigs so the 75% w/v preparation was on the left and the 50% w/v preparation was on the right.... The patches were left in position for at least 6 hours...Skin sites were examined 1 and 2 days after removal of the dressings."

A positive control study using hexylcinnamaldehyde was conducted within six months of the main study to validate the test system.

RESULTS: The test material stained the application site of each animal yellow. Signs of slight skin irritation (edema, erythema, desquamation and thickening) were seen in all test animals during the induction phase of the study. There were no signs of irritation in any of the control animals. Following the challenge with 75% or a 50% w/v preparation of the test material in deionised water, no dermal irritation was observed in any of the test animals. One control animal had scattered mild redness. Based on these results, the test substance is not considered to be a contact sensitizer. The positive response observed in the hexylcinnamaldehyde study validates the test system used in this study.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D290242
2. **PC CODE:** 122101, 128810
3. **CURRENT DATE:** 25/SEPT/2003
4. **TEST MATERIAL:** * CGA-64250/Azoxystrobin 200 SE-H; Purity: 12.0% CGA-64250; 7.16% ASF819; Lot No. FL-021841, A13705H

** Propiconazole/Azoxystrobin 200 SE; Purity: CGA64250 - 12.0% w/w; ASF819 - 7.16% w/w; Batch No. FL021841, A-13705H

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat * Stillmeadow, Inc. 7328-02: 1832-02 / 03-07-03	45916403	LD_{50} = 1750 mg/kg (females)	III	A
Acute dermal toxicity / rat ** Central Toxicology Laboratory CR3605: 2114-02 / 03-19-03	45916404	LD_{50} => 5000 mg/kg (males and females)	IV	A
Acute inhalation toxicity / rat ** Central Toxicology Laboratory HR2418 / 03-21-03	45916405	LC_{50} => 3.05 mg/L (males and females)	IV	A
Primary eye irritation / rabbit ** Central Toxicology Laboratory FB5987: 2114-02 / 03-26-03	45916406	No positive results	IV	A
Primary dermal irritation/rabbit ** Central Toxicology Laboratory EB4998: 2114-02 / 03-26-03.	45916407	Non-irritating	IV	A
Dermal sensitization/guinea pig** Central Toxicology Laboratory GG7669: 2114-02 / 03-26-03	45916408	Non-sensitizer		A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**