

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

21/APR/2004

MEMORANDUM

081901

Subject: Name of Pesticide Product: Tilt Bravo SE
EPA Reg. No. /File Symbol: 100-RROE
DP Barcode: D299536
Decision No: 334429
PC Codes: 081901, 122101

From: Eugenia McAndrew, Biologist *Em*
Technical Review Branch *TCR*
Registration Division (7505C)

To: Rose Kearns, RM Team 22
Fungicide Branch
Registration Division (7505C)

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

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>		<u>% by wt.</u>
122101	Propiconazole	2.9
081901	Chlorothalonil	38.5
<u>Inert Ingredient(s):</u>		<u>58.6</u>
Total:		100.0%

ACTION REQUESTED: RM requests review of acute toxicity data for Tilt Bravo SE, EPA File Symbol 100-RROE.

BACKGROUND: Syngenta Crop Protection, Inc. has submitted five acute toxicity studies to support the registration of Tilt Bravo SE, EPA File Symbol 100-RROE. The acute oral toxicity study was conducted at Product Safety Labs, Dayton, New Jersey. The acute dermal toxicity, acute inhalation toxicity, primary eye irritation and primary skin irritation studies were conducted at Central Toxicology Laboratory, Cheshire, UK. The assigned MRID numbers are 460797-03 to -07. The Registrant states that the product is a known sensitizer; therefore, a dermal sensitization toxicity study was not submitted.

RECOMMENDATIONS: The five acute toxicity studies have been reviewed and are classified as acceptable. The dermal sensitization study is waived and the product is classified as a sensitizer.

The acute toxicity profile for Tilt Bravo SE, EPA File Symbol 100-RROE, is as follows:

acute oral toxicity	III	Acceptable	MRID 46079703
acute dermal toxicity	IV	Acceptable	MRID 46079704
acute inhalation toxicity	IV	Acceptable	MRID 46079705
primary eye irritation	I	Acceptable	MRID 46079706
primary skin irritation	IV	Acceptable	MRID 46079707
dermal sensitization	Positive	Waived	Known sensitizer

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 #: 000100-01192

PRODUCT NAME: Tilt Bravo SE

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: DANGER

SPANISH SIGNAL WORD: PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wear: Long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

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.

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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Note to PM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical 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.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Reviewer: Eugenia McAndrew
Product Manager (EPA): 22

April 21, 2004

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

TEST MATERIAL: Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

CITATION: Merkel, D. Propiconazole (CGA-64250/Chlorothalonil SE: Final Report. Acute Oral Toxicity Up and Down Procedure in Rats. Product Safety Laboratories, Dayton, New Jersey. Laboratory Report Number 12966. January 29, 2003. MRID 46079703. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46079703), nine female Sprague-Dawley albino rats (Source: Ace Animals, Inc., Boyertown, PA; 165-225 g) were given a single oral dose of Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid) using the Up and Down Method. An initial limit dose of 5000 mg/kg was administered to one healthy female by gavage. Due to mortality in this animal, the study proceeded to the full test. In the main test, eight additional animals were dosed at levels of 175, 550, 1750 and 5000 mg/kg following the up and down procedure. Animals were then observed for 14 days.

In the limit test, the animal dosed at 5000 mg/kg died. In the main test, the three animals dosed at 5000 mg/kg died. Toxic signs noted prior to death included hypoactivity, prone posture, ano-genital staining and/or diarrhea. Animals dosed at 175, 550 and 1750 mg/kg survived. Clinical signs noted included ano-genital staining, soft feces and/or diarrhea. The animals recovered by day 3. All surviving animals gained body weight during the study. Gross necropsy of animals that died on test revealed discoloration of the lungs and intestines. No gross abnormalities were noted for animals surviving to study termination.

Oral LD₅₀ Females = 3129 mg/kg bw (95% C.L. 1750-5000 mg/kg bw)

Toxicity based on the LD₅₀ in females. EPA Toxicity Category III.

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:

Limit Test

Dosing Sequence	Animal No.	Dose level (mg/kg)	24 hour Outcome	14 Day Outcome
1	6213	5000	D	D

Main Test

Dosing Sequence	Animal No.	Dose level (mg/kg)	24 hour Outcome	14 Day Outcome
1	6271	175	S	S
2	6276	550	S	S
3	6358	1750	S	S
4	6370	5000	D	D
5	6372	1750	S	S
6	6428	5000	D	D
7	6442	1750	S	S
8	6453	5000	D	D

D = died; S = survived

Statistics - The oral LD₅₀ was calculated using the AOT425 Stat program supplied by the EPA.

A. Mortality - as noted in table.

B. Clinical observations - Toxic signs noted prior to death in the 5000 mg/kg group included hypoactivity, prone posture, ano-genital staining and/or diarrhea. Animals dosed at 175, 550 and 1750 mg/kg survived. Clinical signs noted included ano-genital staining, soft feces and/or diarrhea. The animals recovered by day 3. All surviving animals gained body weight during the study.

C. Gross Necropsy - Gross necropsy of animals that died on test revealed discoloration of the lungs and intestines. No gross abnormalities were noted for animals surviving to study termination.

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

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

Date/Time: Tuesday, April 20, 2004, 6:46:42 AM

Data file name: Tilt.dat

Last modified: 4/20/2004 6:46:38 AM

Test/Substance: Tilt

Test type: **Limit Test**

Limit dose (mg/kg): **5000**

Assumed LD50 (mg/kg): Default

Assumed sigma (mg/kg): 0.5

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	6213	5000	X	X

(X = Died, O = Survived)

Dose Recommendation: Stop the limit test and conduct a main test at 175 mg/kg.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
5000	0	1	1
All Doses	0	1	1

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

Date/Time: Tuesday, April 20, 2004, 6:51:06 AM

Data file name: Tilt main.dat

Last modified: 4/20/2004 6:51:03 AM

Test/Substance: Tilt main

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	6271	175	O	O
2	6276	550	O	O
3	6358	1750	O	O
4	6370	5000	X	X
5	6372	1750	O	O
6	6428	5000	X	X
7	6442	1750	O	O
8	6453	5000	X	X

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: 5 reversals in 6 tests. LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	1	0	1
1750	3	0	3
5000	0	3	3
All Doses	5	3	8

Statistical Estimate based on long term outcomes:

Estimated LD50 = 3129 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 1750 to 5000.

Reviewer: Eugenia McAndrew
Product Manager (EPA): 22

April 21, 2004

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

TEST MATERIAL: Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

CITATION: Johnson, I.R. Propiconazole/Chlorothalonil SE (A-13817A): Acute Dermal Toxicity Study in the Rat. Central Toxicology Laboratory, Cheshire, UK. Laboratory Report Number CR3601. April 9, 2003. MRID 46079704. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46079704), five/sex of Alpk:AP_{SD} (Wistar derived) rats (Age: 8-12 weeks; Source: Rodent Breeding Unit, Alderley Park, Macclesfield, Cheshire, UK; 285-289 g males and 169-184 g females) were dermally exposed to Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid) applied to an area of approximately 7 cm x 7 cm on the back of each animal at a limit dose of 5000 mg/kg bw. Test sites were covered with an occlusive dressing for 24 hours. Animals were then observed for 14 days.

All animals survived and there were no signs of systemic toxicity. The test substance stained the application sites of the males brown. Signs of slight skin irritation were seen in all animals but resolved by day 14. All animals gained weight during the study. There were no macroscopic abnormalities at necropsy.

Dermal LD₅₀ Males => 5000 mg/kg bw
Dermal LD₅₀ Females => 5000 mg/kg bw
Dermal LD₅₀ Combined => 5000 mg/kg bw

Toxicity based on the LD₅₀ on lack of deaths at the limit dose. EPA Toxicity Category IV.

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 bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

A. **Mortality** - as noted in table.

B. **Clinical observations** - There were no signs of systemic toxicity. The test substance stained the application sites of the males brown. Signs of slight skin irritation were seen in all animals but resolved by day 14. All animals gained weight during the study.

C. **Gross Necropsy** - There were no macroscopic abnormalities at necropsy.

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

Reviewer: Eugenia McAndrew
Product Manager (EPA): 22

April 21, 2004

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

TEST MATERIAL: Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

CITATION: Rattray, N.J. Propiconazole/Chlorothalonil SE (A-13817A) Spray Strength Dilution: 4-Hour Acute Inhalation Toxicity Study in Rats. Central Toxicology Laboratory, Cheshire, UK. Laboratory Report Number HR2416. July 22, 2003. MRID 46079705. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46079705), five/sex of Alpk:AP₁SD (Wistar derived) rats (Age: 8-9 weeks; Source: Rodent Breeding Unit, Alderley Park, Macclesfield, Cheshire, UK ; 324-366 g males and 202-249 g females) were exposed nose only via the inhalation route to Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid) for 4 hours at concentration of 2.57 mg/L. The test sample was diluted 1.25% v/v in deionized water to give a spray strength dilution. Animals were then observed for 14 days.

LC₅₀ Males => 2.57 mg/L
LC₅₀ Females => 2.57 mg/L
LC₅₀ Combined => 2.57 mg/L

All animals survived the exposure to the test substance. Clinical signs noted during the exposure included wet fur, salivation and staining around the nose. Clinical signs noted after removal from the exposure chamber included wet fur, hunched posture, piloerection, chromodacryorrhea, salivation, staining around the nose/mouth, decreased activity, diarrhea, vocalization, abnormal respiratory noise and increased breathing depth. All animals recovered from these symptoms by day 7. One female lost weight during the first week of the study but all animals gained weight by day 15. The gravimetric concentration was 2.57 mg/L. The mass median aerodynamic diameter was 2.13-2.36 µm with a geometric standard deviation of 1.62-1.66.

Toxicity based on lack of deaths at the limit dose. 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 Formulation Conc. (mg/L)	Total Formulation Concentration ^a gravimetric (mg/L)	MMAD μm	GSD μm	Mortality/Number Tested		
				Males	Females	Combined
6.2	2.57	2.13, 2.36	1.62-1.66	0/5	0/5	0/10

^a The study states that "the total formulation concentration of the spray strength dilution represents the total atmosphere to which the rats were exposed."

Test atmosphere concentration: "A target concentration of 2 mg/L of the active ingredients in a spray strength dilution was selected in order to determine the most appropriate hazard category for the maximum in-use spray strength concentration of the formulation. The total formulation concentration of the spray strength dilution represents the total atmosphere to which the rats were exposed, based on the chemical analysis of chlorothalonil in the particulate phase, and compensates for volatilisation of the solvent components."

Test Atmosphere / Chamber Description:

Chamber 27.6 L
Volume:
Airflow: 30 LPM
Temperature: 21°C
Relative Humidity: 36-37%
Time to Equilibrium: 30 minutes

A. Mortality - as noted in table.

B. Clinical observations - Clinical signs noted during the exposure included wet fur, salivation and staining around the nose. Clinical signs noted after removal from the exposure chamber included wet fur, hunched posture, piloerection, chromodacryorrhea, salivation, staining around the nose/mouth, decreased activity, diarrhea, vocalization, abnormal respiratory noise and increased breathing depth. All animals recovered from these symptoms by day 7. One female lost weight during the first week of the study but all animals gained weight by day 15.

C. Gross Necropsy - No macroscopic abnormalities were seen.

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

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Reviewer: Eugenia McAndrew
Product Manager (EPA): 22

April 21, 2004

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

TEST MATERIAL: Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

CITATION: Johnson, I.R. Propiconazole/Chlorothalonil SE (A-13817A): Eye Irritation Study in the Rabbit. Central Toxicology Laboratory, Cheshire, UK. Laboratory Report Number FB5971. April 8, 2003. MRID 46079706. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46079706), 0.1 mL of Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid) was instilled into the conjunctival sac of the left eye of three female young adult New Zealand albino rabbits (Source: Charles River UK Limited, Margate, Kent, UK). Animals were then observed at 1, 24, 48, 72 hours and up to 14 days post instillation. Irritation was evaluated using the methods of Draize and Kay and Calandra.

Corneal opacity and conjunctivitis were noted in all three eyes at the one hour observation. By 24 hours, 2/3 eyes exhibited iritis. The corneal opacity persisted in one eye through day 24. The iritis persisted in the same eye through day 24. No positive scores were noted for conjunctivitis by day 14. The study report states that "additional signs of irritation included lachrymatory or Harderian discharge; erythema, edema, thickening and convulsion of the eyelids; dried secretion around the periorbital skin, irregular corneal surface, hemorrhage of the conjunctiva and nictating membrane, hair loss around the eye and irregular corneal surface and neovascularisation. In two animals, all signs of irritation resolved within 17 days. In the third animal; convoluted eyelids and irregular corneal surface, together with ghost vessels in place of neovascularisation, were still apparent 28 days after instillation."

In this study, formulation is extremely irritating to the eye. EPA Toxicity Category I.

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.

RESULTS AND DISCUSSION:

Observations	Number "positive"/number tested											
	Hours				Days							
	1	24	48	72	4	7	10	14	17	21	24	28
Corneal Opacity	3/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	0/3
Iritis	0/3	2/3	2/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	0/3	0/3
Conjunctivae:												
Redness*	3/3	3/3	3/3	1/3	2/3	1/3	1/3	0/3	0/3	0/3	0/3	0/3
Chemosis*	3/3	3/3	3/3	2/3	2/3	1/3	1/3	0/3	0/3	0/3	0/3	0/3
Discharge*	2/3	2/3	1/3	1/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3

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

A. Observations - Corneal opacity and conjunctivitis were noted in all three eyes at the one hour observation. By 24 hours, 2/3 eyes exhibited iritis. The corneal opacity persisted in one eye through day 24. The iritis persisted in the same eye through day 24. No positive scores were noted for conjunctivitis by day 14. The study report states that "additional signs of irritation included lachrymatory or Harderian discharge; erythema, edema, thickening and convolution of the eyelids; dried secretion around the periorbital skin, irregular corneal surface, hemorrhage of the conjunctiva and nictating membrane, hair loss around the eye and irregular corneal surface and neovascularisation. In two animals, all signs of irritation resolved within 17 days. In the third animal, convoluted eyelids and irregular corneal surface, together with ghost vessels in place of neovascularisation, were still apparent 28 days after instillation."

B. Reviewer's Conclusions: Agree with study author

Reviewer: Eugenia McAndrew
Product Manager (EPA): 22

April 21, 2004

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

TEST MATERIAL: Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

CITATION: Johnson, I.R. Propiconazole/Chlorothalonil SE (A-13817A: Skin Irritation Study in the Rabbit. Central Toxicology Laboratory, Cheshire, UK. Laboratory Report Number EB4991. April 8, 2003. MRID 46079707. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46079707), three young adult female New Zealand albino rabbits (Source: Charles River UK Limited, Margate, Kent, UK) were dermally exposed to 0.5 mL of Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid). The test substance was applied to a 6 cm² dose site on the left flank of each animal. Test sites were covered with a piece of gauze secured by surgical tape and covered with a piece of impermeable rubber sheeting for 4 hours. Animals were then observed at 1, 24, 48 and 72 hours and at intervals for up to 14 days after removal of the dressings. Irritation was scored by the method of Draize.

In this study, formulation is slight irritant. 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:

A. Observations - One hour after patch removal, very slight erythema and very slight edema were noted at 2/3 sites. By 24 hours, these two sites were free of dermal irritation but the third site developed very slight erythema and very slight edema. At 72 hours, the only irritation noted was very slight erythema at one site. All sites were free of dermal irritation by day 10. The study report states that desquamation was seen in one animal from days 7 to 14.

B. Results - PDII - 0.67

C. Reviewer's Conclusions - Agree with study author

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D299536
2. **PC CODES:** 122101, 081901
3. **CURRENT DATE:** 21/APR/2004
4. **TEST MATERIAL:** Propiconazole/chlorothalonil SE (Batch No. FL021750; Reference No. A13817A; 2.79% w/w Propiconazole (CGA64250) and 38.5% w/w Chlorothalonil (ASF41); off-white/grey liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Product Safety Labs 12966/1-29-03	46079703	LD ₅₀ = 3129 mg/kg (females)	III	A
Acute dermal toxicity/rat Central Toxicology Laboratory CR3601/4-9-03	46079704	LD ₅₀ > 5000 mg/kg (males females combined)	IV	A
Acute inhalation toxicity/rat Central Toxicology Laboratory HR2416/7-22-03	46079705	LC ₅₀ > 2.57 mg/L (males females combined)	IV	A
Primary eye irritation/rabbit Central Toxicology Laboratory FB5971/4-8-03	46079706	Corneal opacity and iritis persisting in one eye through day 21.	I	A
Primary dermal irritation/rabbit Central Toxicology Laboratory EB4991/4-8-03	46079707	PDII = 0.67 Slight irritation at 72 hours.	IV	A
Dermal sensitization	--	A sensitizer	-	W

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

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