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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

14/MAY/ 1999

MEMORANDUM

Subject: EPA Reg. No: 1812-UER Griffin Propanil 4E
DP Barcodes: D253641
Case No: 064333
PC Code: 028201

From: Masih Hashim, Toxicologist
Technical Review Branch
Registration Division (7505C)

To: Lisa Jones, PM Team 25
Herbicide Branch
Registration Division (7505C)

Applicant: Griffin, L.L.C.
P.O.Box 1847
Valdosta, GA 31603-1847

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Propanil	43.5
Inert Ingredients	56.5
Total:	100.0

BACKGROUND: Griffin L.L.C has submitted a set of six acute toxicity studies in support of its product Griffin Propanil 4E, # 1812 -UER. The MRID numbers for the animal studies are 446832-02, 446832-03 and 447459-01 through 447459-04. These studies were conducted at Product Safety Laboratories, East Brunswick, NJ. An Agency contractor summarized all the studies, then they were revised and evaluated by TRB.

RECOMMENDATIONS: Each of the six studies is acceptable in accordance with the Sub-Division F guidelines. The toxicology profile for the File Symbol # 1812-UER is as follows:

acute oral toxicity	III	acceptable
acute dermal toxicity	IV	acceptable
acute inhalation toxicity	IV	acceptable
primary eye irritation	III	acceptable
primary skin irritation	III	acceptable
dermal sensitization	negative	acceptable

LABELING:

ID #: 001812-00421 Griffin Propanil 4E

AGRICULTURAL USE REQUIREMENTS:

DIRECTIONS FOR USE:

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear and chemical resistant gloves (such as Nitrile, Butyl, Neoprene, and/or Barrier Laminate).

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes and chemical resistant gloves (such as Nitrile, Butyl, Neoprene, and/or Barrier Laminate). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

.3

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If the person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention, if irritation persists.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

NOTE TO PHYSICIAN:

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." 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.

DATA EVALUATION REPORT

PROPANIL EC

STUDY TYPES: ACUTE ORAL TOXICITY - RAT (81-1)
ACUTE DERMAL TOXICITY - RAT (81-2)
ACUTE INHALATION TOXICITY - RAT (81-3)
PRIMARY EYE IRRITATION - RABBIT (81-4)
PRIMARY DERMAL IRRITATION - RABBIT (81-5)
DERMAL SENSITIZATION - GUINEA PIG (81-6)

SUMMARY: ACUTE TOXICITY ONE-LINERS (81-1 through 81-6)

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831

Primary Reviewer:
Susan Chang, M.S.

Signature: SSChang
Date: 4-28-99

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T Borges
Date: APR 28 1999

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 28 1999

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 28 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

5

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100)

Product Manager: 25
MRID No.: 44745901

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6325

Testing Facility: Product Safety Labs
Author: Moore, G.E.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid

Species: Rats; Albino, Sprague-Dawley
Age: Young adult
Weight: Males: 194-254 g; Females: 167-207 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: > 1500 mg/kg and < 2500 mg/kg
   Females: = 1314 mg/kg (95% C.L. 988-1834 mg/kg)[a]
   Combined: = 1563 mg/kg (95% C.L. 1206-1908 mg/kg)[a]
2. **The estimated LD_{50} is** 1314 mg/kg
3. **Tox. Category:** III **Classification:** Acceptable

[a] LD_{50} calculated by Moving Angle Average Method [Thompson, W.R. and Weil, C.S., Biometrics 8(1) 52-54, 1952]

Procedure (Deviations): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
500	0/5	0/5	0/10
1500	0/5	4/5	4/10
2500	5/5	5/5	10/10
5000	5/5	5/5	10/10

Observations: Three females in the 1500 mg/kg group, four males and four females in the 2500 mg/kg group, and four males and five females in the high-dose group died on the day (day 0) of test material administration. One male in the high-dose group died on day 1. One female in the 1500 mg/kg group and one male in the 2500 mg/kg group died on day 2. One female in the 2500 mg/kg group died on day

3. Hypoactivity, hunched posture, and/or piloerection were noted on all surviving rats with recovery by day 3 or 4. The decedents also showed irregular respiration and were prone prior to death. In addition, two surviving females in the 500 mg/kg group had reduced fecal volume on days 2-3. All surviving rats had normal body weight gains.

7

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 25
MRID No.: 44683202

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6326

Testing Facility: Product Safety Labs
Author: Moore, G.E.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid

Species: Rats; Albino, Sprague-Dawley
Age: Young adult
Weight: Males: 250-275 g; Females: 203-224 g
Source: Ace Animals, Inc., Boyertown, PA

Dermal LD_{50} Testing:

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: > 5000 mg/kg
   Females: > 5000 mg/kg
   Combined: > 5000 mg/kg
2. **The estimated LD_{50} is** > 5000 mg/kg
3. **Tox. Category:** IV

Classification: Acceptable

Procedure (Deviations from §81-2): None

Results:

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

Observations: No animals died during the study. Irregular respiration and/or hunched posture were noted on five rats that recovered by day 2. Erythema/edema was noted on all dose sites on days 1-3. All animals had normal body weight gains.

Gross Necropsy: No gross abnormalities were noted.

7

6

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (870.1300)

Product Manager: 25
MRID No.: 44683203

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6327

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid

Species: Rats; Albino, Sprague-Dawley
Age: Young adult
Weight: Males: 252-285 g; Females: 202-232 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LC_{50} (mg/L):**
   Males: > 2.06 mg/L
   Females: > 2.06 mg/L
   Combined: > 2.06 mg/L
2. **The estimated LC_{50} is** > 2.06 mg/L
3. **Tox. Category:** IV

Classification: Acceptable

Procedure (Deviations): None

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.06	0/5	0/5	0/10

Clinical Observations: The clinical abnormalities during exposure included ocular and nasal discharge, irregular respiration, dyspnea, hypoactivity, and/or hunched posture. Upon removal from the chamber, nasal discharge, irregular respiration, dyspnea, hypoactivity, and/or hunched posture were noted in all rats. One female developed facial staining. All rats recovered by day 2 and had normal body weight gains with the exception of one female that lost weight during the second week.

Gross Necropsy Findings: No gross abnormalities were noted .

Chamber Atmosphere		
Grav. Conc.	MMAD	GSD
2.06 mg/L	2.8 μm	1.63

Other Information: Approximately 86% of particles had an aerodynamic diameter ≤3.3 μm.

Chamber Environment [a]	
Chamber Volume	150 L
Airflow	45.5 LPM
Temperature	70°F
Relative Humidity	58-62%

[a] Whole body

Gross Necropsy: All decedents had slightly to moderately red lungs, discolored livers, and/or yellow/red gastrointestinal tracts. No gross abnormalities were found in the surviving rats.

L0

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400)

Product Manager: 25
MRID No.: 44745902

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6328

Testing Facility: Product Safety Labs
Author: Moore, G.E.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid
Dosage: 0.1 mL

Species: Rabbits; Albino, New Zealand White
Age: Adult
Weight: Not reported
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** III (Moderate irritant)
2. **Classification**: Acceptable

Procedure (Deviations): None

Observations	Number "positive"/number tested					
	Hours				Days	
	1	24	48	72	4	7
	Unwashed eyes					
Corneal Opacity	0/6	6/6	6/6	6/6	4/6	0/6
Iritis	3/6	6/6	5/6	4/6	0/6	0/6
Conjunctivae:						
Redness	6/6	6/6	4/6	3/6	1/6	0/6
Chemosis	4/6	4/6	4/6	1/6	0/6	0/6
Discharge	6/6	2/6	0/6	0/6	0/6	0/6

Summary: Corneal opacity was noted on 6/6 rabbits 24 hours after test material instillation that persisted through 72 hours with resolution on two rabbits by day 4 and on four rabbits by day 7. Iritis was noted on 3/6, 6/6, 5/6, and 4/6 rabbits by 1, 24, 48, and 72 hours with resolution by day 4. Conjunctivitis was noted on all rabbits by one hour with resolution by day 7. The highest average ocular irritation index was 34.2 recorded 24 hours after instillation. This classifies the test material as a moderate irritant.

10

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500)

Product Manager: 25
MRID No.: 44745903

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6329

Testing Facility: Product Safety Labs
Author: Moore, G.E.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid
Dosage: 0.5 mL

Species: Rabbits; Albino, New Zealand White
Age: Adult
Weight: Not reported
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** III (Moderate irritant)
2. **Classification**: Acceptable

Procedure (Deviations): None

Results: PDIS = 3.7 (Moderate irritant). Very slight erythema and well defined erythema were noted on 4/6 and 2/6 rabbits at one hour after patch removal. By 24 hours, well defined erythema and moderate erythema were noted on 1/6 and 5/6 rabbits, respectively, that persisted through 72 hours. Five rabbits had very slight erythema and one rabbit had well defined erythema on day 7. Very slight edema was noted on all rabbits at one hour. Edema intensified on 5/6 rabbits by 24 hours through 72 hours. By day 7, two rabbits still had very slight edema. By day 10, no erythema or edema was noted on any rabbits. Desquamation was noted on 4/6 rabbits on day 7 and 2/6 rabbits on day 10. Shiny skin was noted on 2/6 rabbits on day 10.

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (870.2600)

Product Manager: 25
MRID No.: 44745904

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6330

Testing Facility: Product Safety Labs
Author: Moore, G.E.

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid
Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)

Species: Guinea pigs; Albino, Hartley
Age: Young adult
Weight: Males: 330-449 g
Source: Davidson's Mill Farm, South Brunswick, NJ

Method: Buehler

Conclusion:

1. **There is no indication that this product is a dermal sensitizer.**
2. **Classification**: Acceptable

Procedure (Deviations): None

Procedure: For the induction phase, 0.4 mL of undiluted test material was applied under occlusion for six hours once each week for three weeks. Twelve days after the third induction, the animals were challenged with 0.4 mL of 75% w/w test material in corn oil under occlusion at naive sites for 6 hours. A naive control group was treated with 0.4 mL of 75% test material in corn oil at challenge only. The positive control group animals were induced with 0.4 mL of 0.08% DNCB in 80% aqueous ethanol and challenged with 0.04% DNCB in acetone. A naive positive control group was challenged with 0.04% DNCB in acetone. Reactions were scored 24 and 48 hours post exposure.

Results: Very faint usually nonconfluent erythema and faint usually confluent erythema were noted on 7/10 and 1/10 animals, respectively, at 24 hours that persisted through 48 hours with the exception of the erythema on one animal that intensified to faint usually confluent after the first induction. Very faint usually nonconfluent erythema to severe erythema were noted on all animals after the second and the third inductions. Eschar was also present on five animals after the third induction. After challenge, no positive reaction was found on any test or naive control animal. The DNCB positive control and naive control animals responded appropriately.

L3

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D253641
2. **PC CODE:** 028201
3. **CURRENT DATE:** May6, 1999
4. **TEST MATERIAL:** Propanil EC (42.6% Propanil); Batch 377-67E; non-viscous black liquid

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity rat/Product Safety Labs, 6325/10-15-98	44745901	LD_{50} > 1500 mg/kg and < 2500 mg/kg (males) = 1314 mg/kg (females) = 1563 mg/kg (combined)	III	A
Acute dermal toxicity rat/Product Safety Labs, 6326/10-15-98	44683202	LD_{50} > 5000 mg/kg (males, females, combined)	IV	A
Acute inhalation toxicity rat/Product Safety Labs, 6327/10-15-98	44683203	LC_{50} > 2.06 mg/L (males, females, combined)	IV	A
Primary eye irritation rabbit/Product Safety Labs, 6328/10-15-98	44745902	Moderate irritant	III	A
Primary dermal irritation rabbit/Product Safety Labs, 6329/10-15-98	44745903	Moderate irritant	III	A
Dermal sensitization guinea pig/Product Safety Labs, 6330/10-15-98	44745904	Not a sensitizer	--	A

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