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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

22/APR/1999
MEMORANDUM

Subject: EPA Reg. No.: 1812-UEE Griffin Propanil Technical
DP Barcode: D253646
Case No: 064332
PC Code: 028201

From: Eugenia McAndrew, Biologist EM
Technical Review Branch JCR
Registration Division (7505C)

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

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

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
028201	Propanil, N-(3,4-dichlorophenyl) propionamide	97.0
	Inert Ingredient(s):	3.0
	Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data and label for EPA Reg. No. 1812-UEE, a product known as Griffin Propanil Technical.

(1)

BACKGROUND: Griffin L.L.C has submitted a 6-pack of acute toxicity studies in support of EPA Reg. No. 1812-UEE , a product known as Griffin Propanil Technical. MRID # are 447515-02 to-05 and 446859-01 and -02. The studies were performed at Product Safety Labs, East Brunswick, NJ. An Agency contractor summarized the studies and then they were reviewed and revised by TRB.

RECOMMENDATIONS: The six studies were reviewed and are classified as acceptable.

The acute toxicity profile for EPA Reg. No. 1812-UEE 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	IV	acceptable
dermal sensitization	No	acceptable

This product is a technical. PM should contact the appropriate person in HED and send a copy of this memo.

LABELING: The precautionary and first aid statements below are required according to the Label Review System. The proposed label submitted does not contain all of the required statements and uses different language or only parts of required statements. The precautionary statement "Causes moderate eye irritation" is missing. The registrant has chosen to use category III precautionary statements for acute inhalation which is acceptable but used only used some of the category III statements for dermal toxicity. For the first aid statements for oral exposure, the registrant has not used the exact language below.

Date: 04/22/99 LABEL REVIEW SYSTEM

ID #: 001812-00422 Griffin Propanil Technical

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing.

2

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 person is unconscious, do not give anything by mouth and do not induce vomiting.

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

USER SAFETY RECOMMENDATIONS:

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

DATA EVALUATION REPORT

PROPANIL TECHNICAL

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: S Chang
Date: 4-16-99

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: H.T Borges
Date: APR 16 1999

Robert H. Ross, M.S., Group Leader
Signature: Robert H Ross
Date: APR 16 1999

Quality Assurance:
Eric Lewis, M.S.
Signature: Eric B. Lewis
Date: APR 16 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.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1, 870.1100)

Product Manager: 25
MRID No.: 44751502

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6319

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid

Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight: Males: 200-256 g; Females: 166-222 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: = 779 mg/kg (95% C.L. 291-1444 mg/kg)
   Females: = 907 mg/kg (95% C.L. cannot be calculated)
   Combined: = 841 mg/kg (95% C.L. 531-1198 mg/kg)
2. **The estimated LD_{50} is** 779 mg/kg
3. **Tox. Category:** III **Classification:** Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
500	1/5	1/5	2/10
1250	4/5	3/5	7/10
2500	5/5	5/5	10/10
5000	5/5	5/5	10/10

Observations: Two males and one female in the high-dose group died on the day (day 0) of test material administration. Two males and three females in the high-dose group and three females in the 2500 mg/kg group died on day 1. One male and one female in the high-dose group, three males and two females in the 2500 mg/kg group, four males and three females in the 1250 mg/kg group, and one male in the low-dose group died on day 2. Two males in the 2500 mg/kg group died on day 3. One female in the low-dose group died on day 4. Hypoactivity, hunched posture, and/or piloerection were noted on all surviving rats with recovery by day 2 or 3. The decedents also showed irregular respiration and were prone. In addition, the female decedent in the 500 mg/kg group had clear oral discharge, reduced food consumption, and reduced fecal volume. All surviving rats had normal body weight gains.

5

Gross Necropsy: All decedents had slightly to moderately red lungs, discolored liver, and/or red/black gastrointestinal tract. The urinary bladder of one decedent male in the high-dose group was filled with pink fluid. No gross abnormalities were found in the surviving rats.

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

Product Manager: 25
MRID No.: 44685901

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6320

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid

Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight: Males: 266-300 g; Females: 215-242 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)[a]	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

[a] The test material was applied as an 80% w/w mixture in distilled water.

Observations: No animals died during the study. No clinical abnormalities were observed. All animals had normal body weight gains with the exception of one female that lost weight (1 gram)during the second week.

Gross Necropsy: No gross abnormalities was noted.

7

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: 25
MRID No.: 44685902

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6321

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid

Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight: Males: 234-250 g; Females: 193-206 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LC_{50} (mg/L):**
   Males: > 2.13 mg/L
   Females: > 2.13 mg/L
   Combined: > 2.13 mg/L
2. **The estimated LC_{50} is** > 2.13 mg/L
3. **Tox. Category:** IV **Classification**: Acceptable

Procedure (Deviations from §81-3): None

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.13	0/5	0/5	0/10

Clinical Observations: The clinical abnormalities during exposure included ocular and nasal discharge, irregular respiration, hypoactivity, and/or hunched posture. Upon removal from the chamber, ocular discharge, nasal discharge, and/or facial staining were noted in all rats. All rats recovered by day 2 and had normal body weight gains.

Gross Necropsy Findings: No gross abnormalities were noted .

8

Chamber Atmosphere		
Grav. Conc.	MMAD	GSD
2.13 mg/L	3.6 μm	1.79

Chamber Environment [a]	
Chamber Volume	100 L
Airflow	50.7 LPM
Temperature	66-69°F
Relative Humidity	56-62%

[a] Whole body

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 25
MRID No.: 44751503

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6322

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid
Dosage: 0.1 mL (~ 0.09-0.1 g powder)

Species: Rabbits; Albino, New Zealand White
Age: Adult
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** III
2. **Classification**: Acceptable

Procedure (Deviations from §81-4): None

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

Summary: No corneal opacity or iritis was noted on any rabbits during the study. Four rabbits exhibited conjunctival redness one hour after test material instillation with resolution by 48 hours. This classifies the test material as a minimal irritant.

10

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 25
MRID No.: 44751504

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6323

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid
Dosage: 0.5 g ground to a powder and moistened with distilled water (80% w/w in distilled water)

Species: Rabbits; Albino, New Zealand White
Age: Adult
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** IV
2. **Classification**: Acceptable

Procedure (Deviations from §81-5): None

Results: PDIS = 0.0 (Non-irritant). No irritation was noted on any rabbits during the study.

Special Comments: None

11

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 25
MRID No.: 44751505

Reviewer: Susan Chang
Study Completion Date: October 15, 1998
Study No.: 6324

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

Quality Assurance (40 CFR §160.12): Included

Test Material: Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid
Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)

Species: Guinea pigs; Albino, Hartley
Age: Young adult
Weight: Males: 348-436 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 from §81-6): None

Procedure: For the induction phase, 0.4 g of an 80% w/w test material in distilled water was applied under occlusion for six hours once each week for three weeks. Guinea pigs were left untreated for twelve days before challenge. The animals were challenged with 0.4 g of an 80% w/w test material in distilled water under occlusion at naive sites for 6 hours. A naive control group was treated with 0.4 g of an 80% w/w test material in distilled water 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 0.4 mL of 0.04% DNCB in acetone at challenge. Reactions were scored 24 and 48 hours post exposure.

Results: One, two, and one animals had very faint usually nonconfluent erythema 24 hours after the first, second, and third inductions, respectively. By 48 hours, no irritation was noted on any animals. None of the test or naive control animals had any irritation after challenge. The DNCB positive control and naive control animals responded appropriately.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D253646
2. **PC CODE:** 028201
3. **CURRENT DATE:** April 22, 1999
4. **TEST MATERIAL:** Propanil Technical (97.5% Propanil); Lot 98-050; gray flaked solid

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity rat/Product Safety Labs, 6319/10-15-98	44751502	LD_{50} = 779 mg/kg (males) = 907 mg/kg (females) = 841 mg/kg (combined)	III	A
Acute dermal toxicity rat/Product Safety Labs, 6320/10-15-98	44685901	LD_{50} > 5000 mg/kg (males, females, combined)	IV	A
Acute inhalation toxicity rat/Product Safety Labs, 6321/10-15-98	44685902	LC_{50} > 2.13 mg/L (males, females, combined)	IV	A
Primary eye irritation rabbit/Product Safety Labs, 6322/10-15-98	44751503	Minimal irritant; no corneal opacity or iritis noted on any rabbits; all irritation cleared by 48 hours	III	A
Primary dermal irritation rabbit/Product Safety Labs, 6323/10-15-98	44751504	Non-irritant	IV	A
Dermal sensitization guinea pig/Product Safety Labs, 6324/10-15-98	44751505	Not a sensitizer	--	A

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

13