

US EPA ARCHIVE DOCUMENT



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

1/17/1992

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol

4816-696 / PERMANONE General Purpose Aqueous Insecticide  
& 4816-709 / PERMANONE General Purpose Aqueous Insecticide II

FROM: Ian Blackwell  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H7505C)

E 1/17/92

TO: George Larocca PM 13  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

APPLICANT: Fairfield American Corporation  
8th & Harrison Streets  
Frenchtown, NJ 08825

FORMULATION FROM LABEL:

	<u>% by wt.</u>	
<u>Active Ingredient(s):</u>	696	709
<u>Permethrin</u>	<u>0.5</u>	<u>0.5</u>
<u>Inert Ingredients:.....</u>	<u>99.5</u>	<u>99.5</u>
Total	100.0%	100.0%

BACKGROUND: The applicant, Fairfield American Corporation, has submitted acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization studies in support of the products "Permanone General Purpose Aqueous Insecticide" and "Permanone General Purpose Aqueous Insecticide II". The studies were conducted by Stillmeadow, Inc., using Permanone General Purpose Aqueous Insecticide. The MRID numbers are 418517-01 through 418517-06.

RECOMMENDATION: RSB/PRS findings are:

1. The formulas of the products "Permanone General Purpose Aqueous Insecticide" and "Permanone General Purpose Aqueous Insecticide II" are substantially similar, thus the studies may be used to support both of these products.
2. The acute oral toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization studies are graded core-guideline data and are acceptable to support the registration of the products "Permanone General Purpose Aqueous Insecticide" and "Permanone General Purpose Aqueous Insecticide II".
3. The acute dermal toxicity study is graded core-minimum data because the weights of the all of the test animals were over 3.0 kilograms. The weights should have between 2.0 and 3.0 kilograms (for rabbits).

LABELING:

1. The signal word is "CAUTION".
2. Because all of the toxicity/irritation studies are graded toxicity category IV and there was no dermal sensitization, precautionary statements and statements of practical treatment are not required. However, the signal word "CAUTION" and child hazard warning must appear on the front panel of the label.
3. The statements concerning the removal of pets and covering of aquariums should be placed under the Directions For Use.

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

Product Manager: (13). Report Date: 8/17/90  
Reviewer: Ian D. Blackwell Report No.: 7212-90

MRID No.: 418517-01

Testing Facility: Stillmeadow, Inc.  
Author(s): Janice O. Kuhn

Species: Sprague-Dawley rat  
Sex: 5 males + 5 females  
Age: young adult  
Weight: 183 to 243 g  
Source: Harlan Sprague Dawley, Inc.

Test Material: Permanone General Purpose Aqueous  
Insecticide; Codes 72055 72065 FNB90-1-26A 6/19/90

Observation Days (Post Exposure): (14); other ( )  
Quality Assurance (40 CFR §160.12): Included

Conclusion:

1. The estimated LD50 is > 5050 mg/kg.
2. Toxicity Category: IV  
Classification: core-guideline

Procedure (Deviations From §81-1):  
None

Results:

Reported Mortality

Dosage ( mg/kg)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
5050 mg/kg	0/5	0/5	0/10

Observations: All ten test animals displayed piloerection and an activity decrease which subsided by day 3. No abnormalities were observed upon gross necropsy.

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

Product Manager (PM): 13  
Reviewer: Ian D. Blackwell Report No.: 7213-90  
MRID No.: 418517-02 Report Date: 8/21/90

Testing Laboratory: Stillmeadow, Inc.  
Author(s): Janice O. Kuhn

Species : New Zealand White rabbit  
Age : young adult  
Sex : 5 males + 5 females . Wt.: 3.050 to 4.325 kg  
Source: Ray Nichols Rabbitry .

Test Material: PERMANONE General Purpose Aqueous Insecticide  
Codes 72055 72065 FNB90-1026A 6-19-90  
Dosage: 5050 mg/kg

Quality Assurance (40 CFR §160.12): Included

Summary:

LD50: > 5050 mg/kg  
Toxicity Category: IV  
Classification: core - minimum

Procedure (Deviations From §81-2):  
Animals overweight.

Results:

1. Reported Mortality

Dosage (mg/kg)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
5050 mg/kg	0/5	0/5	0/10

2. Observations: All test animals appeared normal throughout the study. One female was found to have its urinary bladder filled with a tan slurry upon gross necropsy.

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

Product Manager (PM): 13  
Reviewer: Ian D. Blackwell  
MRID No: 418517-03

Report No.: 7214-90  
Report Date: 9/10/90

Testing Laboratory: Stillmeadow, Inc.  
Author(s): Mark S. Holbert

Species: Sprague-Dawley rat  
Wt.: 209 to 278 grams Age: young adult  
Sex: 5 males + 5 females  
Source: Harlan Sprague Dawley

Test Material : PERMANONE General Purpose Aqueous Insecticide  
Codes 72055 72054 FNB 90-1-26A 6-19-90  
Conc. : 5.18 mg/L (analytical).

Quality Assurance (40 CFR §160.12): Included

Summary:

LC50: 5.18 mg/L  
Toxicity Category: IV  
Classification: core - guideline

Procedure (Deviations From §81-3):

Results:

1. Reported Mortality:

Concentration (mg/L)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
5.18 mg/L (analytical)	0/5	0/5	0/10

% particles  $\leq$  1.1 microns = 61.8  
MMAD = 0.518 um (1 hour)  
0.920 um (3 1/4 hours)

2. Observations: All test animals displayed piloerection and a decrease in activity at 4.5 hours after exposure. No signs of toxicity were noted during or after Day 1. No abnormalities were noted upon gross necropsy.

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

Product Manager: (PM) 13  
Reviewer: Ian D. Blackwell  
MRID No.: 418517-06 Report Date: 9/17/90  
Report No.: 7217-90  
Testing Laboratory: Stillmeadow, Inc.  
Author(s): Janice O. Kuhn

Species: Hartley albino guinea pig  
Sex : 20 males . Age : Not specified  
Weight: 295 to 365 g .  
Source: Harlan Sprague Dawley, Inc.

Test Material: Permanone General Purpose Aqueous Insecticide  
Codes 72055 72065 FNB-1-90-26A 6-19-90  
Dosage : 0.5 ml of undiluted test material  
Positive Control: 1-Chloro-2,4-dinitrobenzene

Quality Assurance (40 CFR §160.12): Included

Method: Modified Buehler Method .

Summary: This product is not a dermal sensitizer.  
Classification: core - guideline .

Procedure (Deviation From §81-6):

Results: No irritation was observed from the initial induction through Day 6 for any of the test animals. On Day 13, 5/10 animals displayed very slight erythema and no edema was displayed. Forty-eight hours after the final induction treatment ( Day 22), 7/10 test animals displayed very slight erythema and 1/10 displayed very slight edema. On the virgin test site, no erythema or edema was displayed at 24 or 48 hours after the challenge dose.

For the positive control, no irritation was noted through Day 3. On Day 15, 5/10 animals displayed moderate to severe erythema and 5/10 displayed well-defined erythema. Twenty-four hours after challenge, 1/10 animals displayed well-defined erythema and 9/10 animals displayed very slight erythema.

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Tox Chem No. 652BB

File Last Updated

Current Date 12/31/91

Study/Animal/Lab/Date	Material	EPA Accession Number	Results: LD50, LC50, etc.	Tox. Cat.	CORE Grade
Acute oral toxicity/ 7212-90/ rat/ Stillmeadow, Inc./ 8-17-90	Permethrin.....0.5%	418517-01	LD50 > 5050 mg/kg	IV	guideline
Acute dermal toxicity/ 7213-90/ rabbit/ Stillmeadow, Inc./ 8-21-90		418517-02	LD50 > 5050 mg/kg	IV	minimum
Acute inhalation tox./ 7214-90/ rat / Stillmeadow, Inc./ 9-10-90		418517-03	LC50 > 5.18 mg/L	IV	guideline
Primary eye irritation 7215-90 / rabbit / Stillmeadow, Inc./ 8-31-90		418517-04	1/6 displayed corneal redness at 1 hour. Corneal stippling in 4/6 on Day 1.	IV	guideline
Primary dermal irrit./ 7216-90 / rabbit / Stillmeadow, Inc./ 8-9-90		418517-05	No dermal irritation was exhibited.	IV	guideline
Dermal sensitization 7217-90 / guinea pig/ Stillmeadow, inc.		418517-06	Non-sensitizer	---	guideline

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