

US EPA ARCHIVE DOCUMENT



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

4816-688
↳ 432-1132

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES
January 24, 1990

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 4816-551 ; 4816-688 ; 4816-TEE

Permanone 10 HFG Conc. ; Permanone Multi Purpose 10% EC ;
Permanone 10% E.C.

FROM: Olga Odiott *Olga Odiott*
Precautionary Review Section E 1/29/90
Registration Support Branch
Registration Division (H75-05C)

TO: George La Rocca (PM 15)
Insecticide-Herbicide Branch
Registration Division (H75-05C)

APPLICANT: Fairfield American Corporation
809 Harrison Street
Frenchtown, NJ. 08825

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
<u>Permethrin (3-phenoxyphenyl)methyl (+/-) cis/trans</u>	<u>10.00%</u>
<u>3-(2,2-dichlorophenyl)-2,2-dimethylcyclopropane-</u> <u>carboxylate</u>	<u> </u>
<u>Inert Ingredient(s):</u>	<u>90.00%</u>
<u>Total</u>	<u>100.0%</u>

199201

BACKGROUND

The registrant is applying for: - amendments on EPA Reg. No. 4816-551 and 4816-688 ; - registration of 4816-TEE (4816-551, 4816-688 and 4816-TEE are identical products).

Reg. No. 4816-551 carries the signal word Warning and Reg. No. 4816-688 is mislabeled with the signal word Caution. The product was reformulated and a new eye irritation study submitted to justify downgrading of 4816-551 to Caution, and to retain the signal word for 4816-688 and it's split registration 4816-TEE. The study was conducted at Stillmeadow Inc. MRID No. 412178-02.

RECOMMENDATION

RSB/PRS finds the primary eye study acceptable to support the requested amendments/registrations. Nevertheless approval of the amendments/registration is not recommended until a new set of acute toxicity data is submitted on the reformulated product.

These products have been reformulated and changes in inert ingredients have been incorporated several times (12/17/79, 6/29/84, 6/23/88, 8/21/89) since first registered in November of 1979. Acute toxicity data, other than primary eye irritation studies; were not submitted in conjunction with the aforementioned changes in formulation. There are substantial differences between the current product formulation and the product that was originally tested and registered.

The following studies must be submitted on the new formulation: acute oral, acute dermal, acute inhalation, primary dermal irritation and dermal sensitization.

LABELING

The precautionary label review is pending submittance of outstanding data.

Note to PM:

A Memo by Dr. Stanley Gross in acute inhalation toxicity testing is included for registrant reference.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15) Reviewer: O. Odiott
 MRID No.: 412178-02 Report Date: June 23, 1989
 Testing Laboratory: Stillmeadow, Inc. Report No. 6196-89
 Author(s): Kuhn, Janice A.
 Species: Rabbit, New Zealand white
 Sex: 3 ♂, 3 ♀ Weight: not specified
 Source: Ray Nichols, Rabbitry, Lumberton, Texas
 Dosage: 0.1 ml
 Test Material: FE N45 - Permapone 10% E.C.
 Quality Assurance (40 CFR §160.12): attached.

Summary:

Tox. Category: III Classification: Guideline

Procedure (Deviation From §81-4):

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	0/6	0/6	0/6	0/6	0/6		
Iris	0/6	0/6	0/6	0/6	0/6	0/6		
Conjunctivae Redness	1/6	0/6	0/6	0/6	0/6	0/6		
Chemosis	2/6	2/6	0/6	0/6	0/6	0/6		
Discharge	4/6	0/6	0/6	0/6	0/6	0/6		

Comments: