APR 29 1996

DP Barcode: D222458

Case: 025978

MEMORANDUM

Subject: EPA File Symbol/EPA Reg. No.: 4816-688/PERMANONE® MULTI-PURPOSE 10% E.C.

From: Carol E. Glasgow, Ph.D., Toxicologist Carol
Precautionary Review Section
Registration Support Branch (7505W)
Registration Division (7505C)

To: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Applicant: AgrEvo™ Environmental Health
95 Chestnut Ridge Road
Montvale, NJ 07645

FORMULATION:

Active Ingredient (s):	% by weight
Permethrin: (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl) 2,2-dimethyl cyclopropanecarboxylate	10.0
Inert ingredient(s)	90.0

BACKGROUND: The manufacturer originally requested a study review on a dermal irritation study, reviewed both by EPA and given a III, and by the California Department of Pesticide Regulation (CDPR) and given a II, be reevaluated. Upon reevaluation PRS decided that the CDPR evaluation was correct. On 3/17/95 EPA down-graded to II by PRS.

The classification of the reevaluated recommendation was "...based on the incidence of grade 3 (moderate to severe) erythema and the duration of the overall irritancy response observed in the test animals."

After the reevaluation, AgrEvo™ submitted a repeat primary dermal irritation study on January 4, 1996, on PERMANONE® MULTI-PURPOSE 10% E.C. to change the labeling. Study performed by Stillmeadow Incorporated on MRID # 438950-01.

RECOMMENDATION: RSB/PRS findings are as follows:

The dermal irritancy study is Acceptable, but it will still be classified as II. Although the grade of 3 erythema is reduced in this study, the n value of the test animals is so small that a

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minor change may not be significant. In addition, the duration of irritancy , until day 10, is still indicative of problems.

TOXICITY PROFILES

Primary dermal irritation	II	Acceptable

LABELING: The signal word is "Warning." The following language should be included on the label:

> Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of practical language should include that listed below:

> *If on skin*: Wash with plenty of soap and water. Get medical attention.
>
> *If swallowed*: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

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

Product Manager:	13	**Reviewer:**	Carol Glasgow, Ph.D.
Report Date:	August 24, 1995	**Report No.:**	2272-95
MRID No.:	438950-01		
Testing Laboratory:	STILLMEADOW, Incorporated		
Author(s):	Janice O. Kuhn, Ph.D., D.A.B.T.		
Species:	New Zealand White rabbit		
Weight:	males: 2.350-2.400 kg, females: 2.250-2.650 kg		
Age:	young adult		
Sex:	3 male, 3 female		
Source:	Ray Nichols Rabbitry; Lumberton, Texas		
Test Material:	RUC #1031 (Permanone MP 10% E.C.), Lot No. 18382; clear liquid		
Quality Assurance (40 CFR §160.12):	Included, acceptable		

Summary:

1. **Toxicity Category:** II

2. **Classification:** Acceptable

Procedure (Deviation from §81.5): Animals quarantined 12 days before dosing. On the day prior to treatment, animals were prepared by clipping the dorsal areas of trunk free of hair to expose an area at least 8 x 8 cm. Only animals free of pre-existing skin irritation or defects were selected for testing. On day of treatment, 0.05 ml of undiluted test material was applied to skin and covered with a surgical gauze patch two layers thick and measuring 2.5 x 2.5 cm. Each patch secured in place with a strip of non-irritating adhesive tape and the entire trunk of animal loosely wrapped with orthopedic stockinette. After 4 hours, patches and wrappings removed, test sites gently washed with room temperature tap water and a clean wet cloth. Observations made on ½, 24, 48 and 72 hours and on days 7, 10 and 14. The scale utilized for scoring presented in report. Other effects were also recorded if noted.

Results: This product is definitely a moderate irritant, with rabbits exhibiting erythema and edema through day 10. At the first reading only 1 rabbit showed any effect, but by 48 hours the maximum reading in this study was observed, with 3/6 rabbits having grade 2 erythema and 2/6 grade 1. Five of six rabbits exhibited grade 1 edema. Atonia was seen in 2 males and all females starting at 48 hours and through day 10.