2-9-81
CASWELL FILE

000242

Memorandum

Date: February 9, 1981

Subject: EPA File Symbol: 4816-LIR A-PB GRAIN PROTECTION E.C.
Caswell #25, 670

From: B. T. Backus
IRB/TSS

To: Mr. Franklin Gee
Product Manager 17

Applicant: Fairfield American Corp.
3932 Salt Rd.
Medina, NY 14103

Active Ingredients:

Allethrin (Allyl homolog of Cinerin I)	15.00%
Related Compounds	1.67%
Piperonyl Butoxide, Technical	60.00%
Petroleum Distillate	6.00%
Inert Ingredients:	17.33%

Background:

Product is proposed for use in a 1:30 spray dilution with water, to be applied to grain (corn, barley, wheat, oats, rye and grain sorghum) which would be held in storage, at a rate of 5 gallons spray for every 1000 bushels grain.

Comments and Recommendations:

1. The acute oral LD50, acute dermal LD50, primary skin and eye irritation studies are adequate and acceptable.

2. The acute inhalation LC50 study has been classified as core supplementary data, as no actual concentration measurements of this product or its actives were made in the chamber while the study was in progress. However, use exposure would be to a considerably diluted (1:30) spray.

3. IRB/TSS would have no objections, on the basis of hazards to humans and domestic animals, to the conditional registration of this product under the cite-all method of support with the labeling revisions indicated below.

Labeling:

1. There should be a Statement of Practical Treatment (preferably under that heading) for the product, something like the following:

   If Swallowed: Drink a glass or two of water and induce vomiting by touching finger to back of throat. Do not induce vomiting or give anything by mouth to an unconscious person. Get medical attention.

2. The heading DIRECTIONS FOR USE, followed by: "It is a violation of Federal law..." should appear immediately above the use directions ("At a convenient time..."). The Storage and Disposal statement should follow the complete set of use directions.

Review:

The following studies were conducted on the product as proposed for registration by Cosmopolitan Safety Evaluation Inc., 76 Fourth St., Somerville NJ 08876. The studies were received at EPA 11-26-80 and are in Acc. 243906.

1. Acute Oral Toxicity Study in Rats. Dated Oct. 15, 1980; C.S.E. Study #0416A.

   Procedure: Groups of 5M, 5F 200-300 gm Sprague-Dawley derived rats were orally dosed at levels of 2.6, 3.2, 3.6, 4.0 and 5.0 g/kg, with 14-day observation, survivor sacrifice and gross necropsies.

   Results:

Dosage Level g/kg	Mortalities/Dosed M	F
2.6	1/5	1/5
3.2	0/5	1/5
3.6	1/5	2/5
4.0	2/5	4/5
5.0	3/5	5/5

   Symptoms: Lethargy, tremors, diarrhea, chromorhinorrhea. twitching, shivering, piloerection, clonic convulsions, rales, chromodacryorrhea, lacrimation, oral discharge, abdominal staining, increased startle reflex. At necropsy, most of mortalities had fluid or air in G.I. tract. Oral LD50 (M) = 4.50 (3.41-5.94) g/kg; (F) = 3.66 (3.08-4.36) g/kg. Most survivors gained weight.

   Study Classification: Core Guidelines Data

   Product Classification: Tox. Cat. III

2. Acute Dermal Toxicity Study Rabbit LD50. Dated October 13, 1980; C.S.E. #0416B.

   Procedure: 5M, 5F NZ white rabbits with abraded skin received a 24-hr occluded

dermal exposure to a dosage level of 2 g/kg, with subsequent 14-day observation, survivor sacrifice and gross necropsy.

Results: No mortalities. Some skin irritation. Most subjects lost some weight or remained the same. Nothing remarkable found in necropsies.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Acute Inhalation Toxicity Study in Rats; dated October 13, 1980; study #0416C.

Procedure: 5M, 5F rats were exposed for 4 hours to a nominal concentration of 5.21 mg/liter. Animals were subsequently observed 14 days. Mass median diameter was determined to be 2.74 microns, apparently by using a 4-stage cascade impactor for two 10-minute samplings.

Results: No mortalities. Symptomology included clear nasal and oral discharge during exposure; five hrs. following exposure 8 subjects were lethargic, 4 had piloerection, 4 had brown staining around nasal area, 1 had diarrhea; 2 subjects appeared normal. All rats were normal at 24 hrs and subsequently.

Study Classification: Core Supplementary Data (no actual measurements were made as to test material concentration).

4. Primary Eye Irritation Study in Rabbits; dated Oct. 13, 1980; study no. #0416D.

Procedure: 0.1 ml was instilled in one eye of each of 9 rabbits; 6 eyes remained unwashed, other 3 were flushed for one minute with water, starting no sooner than 20 seconds after instillation.

Results: No irritation. All scores zero at 24 hrs and subsequently.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. IV

5. Primary Dermal Irritation Study in Rabbits; dated Oct. 22, 1980; study no. #0416E.

Procedure: 0.5 ml test material was applied to 2 intact, 2 abraded sites on each of 6 rabbits, with 24-hr occluded dermal exposure.

Results: Some erythema (scores 1-2) at all sites at 24 and 72 hrs; no edema (all scores zero). PDIS = 1.75.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. IV

Bryant T Baker
2/10/81

Page_____ is not included in this copy.

Pages 4 through 6 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

X A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA Accession No.	Results	TOX Category	CORE Grade
Acute Oral LD50 - Rat Cosmopolitan Safety Evaluation 76 Fourth St. Somerville, NJ 08876 C.S.E. Study #0416A Oct. 15, 1980	Allethrin..... .....15.00% Related Com- pounds..1.67% Piperonyl Butoxide..... .....60.00%	243906	Oral LD50(M)=4.50(3.41-5.94) g/kg Oral LD50(F)=3.66(3.08-4.36) g/kg	III	Guidelines 000242
Acute Dermal LD50 - Rabbit Cosmopolitan Safety Evaluation 76 Fourth St. Somerville, NJ 08876 C.S.E. Study #0416B Oct. 13, 1980	Petroleum Distillate... .....6.00% Inerts..17.33%	243906	No mortalities at 2 g/kg. Dermal LD50 above 2 g/kg.	III	Minimum 000242
Acute Inhalation LC50 - Rat Cosmopolitan Safety Evaluation 76 Fourth St. Somerville, NJ 08876 C.S.E. Study #0416C Oct. 13, 1980		243906	No mortalities in 5M, 5F rats exposed for 4 hrs to a nominal concentration of 5.21 mg/l.	N.A.	Supplementary 000242
Primary Eye Irritation - Rabbit Cosmopolitan Safety Evaluation 76 Fourth St. Somerville, NJ 08876 C.S.E. Study #0416D Oct. 13, 1980		243906	All scores zero at 24 hrs and subsequently.	IV	Guidelines 000242
Primary Dermal Irritation-Rabbit Cosmopolitan Safety Evaluation 76 Fourth St. Somerville, NJ 08876 C.S.E. Study #0416E Oct. 22, 1980		243906	PIS = ~~PDIS~~ = 1.75. No edema observed.	IV	Guidelines 000242