

FILE 3/9/87

D.P.

Shaughnessy #: 118401

Due Date: 10/9/84

Init: 24 OCT 1984

SK

To: George LaRocca
Product Manager #15
Registration Division (TS-767)

From: Joseph C. Reinert, Ph.D., Chief
Review Section # 4
Environmental Fate Branch
Hazard Evaluation Division (TS-769c)

Attached please find the EFB review of...

Reg./File No.: 241-260

Chemical: Amdro

Type Product: I

Product Name: Amdro

Company Name: American Cyanamid

Submission Purpose: Applicator Exposure Assessment

ZBB Code: 3(c)(5)

ACTION CODE: 336

Date In: 8/6/84

EAB # 4497

Date Completed: 9/14/84

TAIS (level II) Days

764

5

Deferrals To:

 Ecological Effects Branch

 Residue Chemistry Branch

 Toxicology Branch

Review of Exposure Study and Exposure Assessment
for Amdro (Fire Ant Bait)

1. Chemical: Common and Trade Name: Amdro
Chemical Name: Tetrahydro-5,5-dimethyl-2(1-H)-pyrimidinone (3-[4-(trifluoromethyl) phenyl]-1-(2-[4-(trifluoromethyl) phenyl] ethenyl)-2-propenylidene) hydrazone

2. Citation: Theoretical Hazard of Amdro Fire Ant Bait Insecticide to Applicators, submitted by Robert L. Linkfield, American Cyanamid Company, Agricultural Research Division, P.O. Box 400, Princeton, NJ 08540, July 31, 1984.

3. Type of Application: Aerial
INERT INGREDIENT INFORMATION IS NOT INCLUDED

4. Type of Formulation: MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED
0.88% AI [REDACTED]

5. Application Rate of Formulation: 1-1.5 lbs./acre

6. Reviewed by:

Harold R. Day Chemist Hazard Evaluation Division	Signature: <u>Harold R. Day</u> Date: <u>Oct 24, 1984</u>
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7. Approved by:

Joe C. Reinert Section Chief Hazard Evaluation Division	Signature: _____ Date: _____
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8. Topic: Loader, Flagger, and Scout Exposure
(note: pilot exposure was not measured)

9. Conclusions:

This study is not valid for the following reasons:

1. There is no measurement of pilot exposure.
2. The flagger was in an enclosed vehicle which is not a real measure of actual situations. Also, only one person was used and exposure was measured for only 15 minutes.



4. The air samples taken were too small to give an adequate sampling compared to normal human respiration. It should be noted that in a previous Counter 15G exposure study, there was a respiratory exposure value.
5. The concentration factor (one to fifteen) is large and would multiply any error by 15.
6. Higher than normal body weight figures (78 kg) were used.
7. The report format is very confusing and hard to follow.
8. Only one loader was monitored and only for a five minute period. This is an insufficient sample size.
9. Exposures were calculated on a whole body basis and it is difficult to separate out the exposed body values.
10. The data table in the appendix listing analytical results does not properly identify the samples.
11. The registrant did not submit a protocol for this study for review by EAB. If this had been done, the protocol would have been rejected.

Finally, this report is poorly organized, hard to follow, and contains too much extraneous information. The actual exposure values (weight of pesticide per unit time) are practically impossible to extract in some cases, and impossible in other cases, because they are so buried in the report calculations or are missing altogether. Without this basic information, no reliable exposure assessment can be made.

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10. Methods and Materials:

A. Introduction

Amdro is a 0.88% AI formulated bait. Amdro is [redacted] to make a low-dust flowable formulation for use against fire ants. It can be applied in three different ways though this submission only addresses aerial.

1. 4-5 teaspoons per mound.
2. Applied uniformly on land by disc applicator.
3. Aerially.

Amdro acts as a slow poison to the queen ant. Worker ants pick up the bait and transport it back to the queen, which dies, resulting in the demise of the ant colony.

B. Surrogate Study

American Cyanamid has submitted a study on a surrogate pesticide called COUNTER-15G which is a 15% AI formulated product of the organophosphate "terbufos" [redacted]. It is a granular product intended for aerial application on corn. American Cyanamid claims the exposure study they submitted on this pesticide can be used to estimate exposure from the use of Amdro. This surrogate study is applicable only to aerial application. The protocol for this study was not reviewed by EPA

Related exposure reviews completed by EPA are:

1. Counter Terbufos (CL 92,100/15G): Farmer Exposure Study with Counter 15G American Cyanamid Report No. C-2085. November 1, 1982.
2. Reg/File No. 241-ETA, Human Exposure Assessment for Maxforce Roach Bait Paste dated 22 May 1984.
3. Reg./File No. 2F2627, Human Exposure Analysis for Mound Treatment with Amdro, dated 18 March 1983.

Summary of Above Studies:

For No. 1, the study was conducted with 11 farmers and 5 controls. The application was by ground boom equipment. The pesticide counter was applied as a dry granular material to corn. The final assessment of exposure without protective was clothing was

Respiratory	11.3 ug/hr
Dermal	87.0 ug/hr
Total	<u>98.3 ug/hr</u>

For No. 2, the bait containing Amdro would have negligible exposure for stated uses in cracks and crevices.

For No. 3, the maximum estimated exposure for bait use on ant mounds would be 0.015 mg/kg/day. This represents a worst case situation for a child rolling on grass containing the granules.

C. Evaluation of Counter 15G Study

Personnel Used

A total of five persons were used in the study. The personnel were assigned the following tasks:

<u>Function</u>	<u>Number</u>	<u>Time Exposed Minutes</u>
1. Flagger	1	15
2. Loader	1	5
3. Scout	3	30 (entered field 3 and 7 days post treatment)

Monitoring Methods-Dermal

Dermal Patches

Each person wore 12 patches-six inside and six outside (not overlapping) at the following locations: chest, back, on leg calf, one thigh, one forearm, and one upper arm. Following exposure, the patches were frozen and sent to American Cyanamid laboratory in New Jersey for analyses. The patch size was 40.3 cm square.

Monitoring Methods-Inhalation

Each worker was monitored for respiratory exposure by pulling air in the worker's breathing zone through a resin-filled trapping tube with the aid of an air monitoring pump. The samples (tubes) were frozen, later extracted and analyzed at American Cyanamid laboratories in New Jersey.

Urine Sampling

The persons exposed were monitored for Counter residues in their urine which was collected periodically and also analyzed for creatinine which gives a good indicator of urine balance in the individuals tested.

Blood Collection

Worker's blood was monitored for Counter and its metabolites in periodic blood samples

Hand Washes

Upon completion of application activities, all the persons hands were washed in ethanol (200 ml each hand).

Wind Drift and Distribution

Suspended pads (in a potential drift area), ground pans in the crop area, and corn leaf samples were placed in the application area to measure aerial drift and distribution.

Analytical Methods

The residues on the pads and other samples were analyzed by gas chromatography using a flame photometric detector. The sensitivity of the method used is in the nanogram range.

11. Results:

1. Ground pans placed between the rows of the treated corn field yielded about 13 ug/square cm.
2. Pads placed 50 ft. from the crop edge yielded 0.05 ug/square cm.
3. All the resin-filled collection tubes showed no detectible pesticide indicating negligible respiratory exposure.
4. The registrant claims total average exposure values for the persons tested is:
Flagger -- 0
Loader -- 331 ug/hr
Scout
3 days -- 381 ug/hr
7 days -- 250 ug/hr
5. Since Amdro is about 1/15 of the concentration of in Counter 15G, the above exposure values should be multiplied by the fraction of 0.88/15.