

ECOLOGICAL EFFECTS BRANCH

Chemical: Profenofos

100.0 Purpose of Submission

Identification of all applicable data requirements for reregistration and review of guideline requirement 123-1 (b) Tier 2 Vegetative Vigor Nontarget Phytotoxicity Study (MRID # 416273-05).

101.0 Data Adequacy

The EEB has completed a DER for the 123-1(b) guideline requirement and has found the study to be scientifically sound (See attached DER). The NOEC value for all species for all parameters was 1.0 lb ai/A. No EC values were determined due to a lack of significant rate or true dose response. The study has been classified as "Core".

102.0 Data Summary

The following additional data must be submitted under FIFRA 3(C)(2)(B) to satisfy all reregistration data requirements:

<u>GDLN</u>	<u>Study Type</u>
71-2(a)	- Acute avian dietary, Quail
71-2(b)	- Acute avian dietary, mallard
71-5(b)	- Actual Terr. field study
72-7(b)	- Actual Aquatic field study

See attached table for complete review of data requirements.

103.0 Conclusions

The EEB has completed a review of a Tier 2 Nontarget Plant Study and has found the study to be scientifically sound. The study has been classified as "Core" data and satisfies the 123-1 guideline requirement.

The EEB has identified 4 studies that must be submitted to satisfy the reregistration data requirements. They are: 71-2(a), 71-2(b), 71-5(b) and 72-7(b).

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Reviewer: Richard Felthousen

1-C20-02

419191

MRID No. 416273-05

D165978

Section 2

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Profenofos.
Shaughnessey No. 111401.
- 2. **TEST MATERIAL:** Profenofos (Curacron); 0-(4-bromo-2-chlorophenyl)-0-ethyl-s-propyl phosphorothioate; CAS No. 108-90-7; 90.4% purity; an amber oily liquid.
- 3. **STUDY TYPE:** Non-Target Plants: Vegetative Vigor Nontarget Phytotoxicity Study - Tier 2. Species Tested: Ryegrass, Corn, Oat, Onion, Soybean, Lettuce, Carrot, Tomato, Cucumber, Cabbage.
- 4. **CITATION:** Chetram, R.S. 1990. Tier 2 Vegetative Vigor Nontarget Phytotoxicity Study Using Profenofos Technical (Curacron). Laboratory Project No. LR 90-408. Conducted by Pan-Agricultural Laboratories, Inc., Madera, CA. Submitted by Ciba-Giegy Corporation, Greensboro, NC. EPA MRID No. 416273-05.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Agronomist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Mark Mossler*

Date: *10/15/92*
Ken Sigmund
10/29/92

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
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Signature: *Neumaryd H. Mora*
Date: *10/19/92* for PK

Henry T. Craven, M.S.
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Signature: *Henry T. Craven*
Date: *11/3/92*

7. CONCLUSIONS:

Vegetative Vigor: The NOEC value for all species for all measured parameters (i.e., phytotoxicity, plant height, plant weight) is 1.0 lb ai/A. No EC values were determined due to a lack of significant rate or true dose response. This study is scientifically sound and meets the requirements for a Tier 2 vegetative vigor test using non-target plants.

8. RECOMMENDATIONS: N/A.

9. BACKGROUND: N/A.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Plants: Monocotyledon plants were represented by four species from two families (i.e., ryegrass, oat, corn, and onion). Dicotyledon plants were represented by six species from six families (i.e., soybean, lettuce, carrot, cabbage, tomato, and cucumber). Cultivars, seed sources, lot numbers, and germination ratings were provided in the report.

B. Test System:

Seedling Establishment: Seeds of each crop were planted in plastic pots (7.5 x 7.5 x 6.0 cm) and filled with a sterilized soil mix. A plexiglass template was used to create planting holes in the soil, thus allowing for uniform planting depth and seed distribution. Oat, soybean, cucumber, and corn were planted at a depth of 2.5 cm, while the remaining six species were planted at a depth of 2.3 cm. An analysis of the soil was provided in the report. After emergence, each pot was thinned to five plants/pot. The four plant species were allowed to grow for 7-17 days before treatment to allow each species to attain the 1-3 true leaf stage. Each treatment replicate was placed on an aluminum tray (6.125 x 31.125 cm). The spray plot was 3.21 x 1.67 ft (i.e., 5.36 ft²).

All applications were performed with a belt sprayer equipped with a single nozzle. A nozzle height of 12 inches and a nozzle pressure of 45-50 psi were used. The test spray solutions were prepared by dissolving profenofos technical in deionized water and acetone. The plants were sprayed at the equivalent of 468 l/ha (50 gpa) of water.

The pots were watered three times a day and a total of 53 ml of water was used to irrigate each pot per day.

- C. **Dosage:** Profenofos was applied at a rate of 1.0, 0.333, 0.111, 0.037, 0.0123, and 0 lb ai/A to all plant species.
- D. **Design:** Each crop/treatment combination was replicated three times (i.e., 5 plants/pot, 3 pots/treatment level). After treatment, the pots were randomized within crops and among treatments and placed in an on-site greenhouse.

Plant height was measured by extending the seedling to its maximum height and recording the height to the nearest millimeter. The mean plant height was calculated at 0 and 21 days after application.

Plant phytotoxicity was monitored at 7, 14, and 21 days after treatment. The phytotoxicity ratings evaluated five observable toxic effects: 0-indicates no effect; 1-indicates slight plant effect; 2-indicates a moderate effect (e.g., mild stunting or chlorosis); 3-indicates a severe effect; and 4-indicates a total effect or plant death.

Twenty-one days after treatment, the plants within treatment replicates (pots) were cut at the soil level and dried in a pre-weighed paper bag at 70°C for a minimum of 48 hours. After drying, the dry weight of the plant material was recorded.

Temperature, relative humidity, photoperiod, and illuminance during the period of growth were provided in the report.

- E. **Statistics:** All data were entered into a Lotus 1-2-3 spreadsheet. The spreadsheet calculated replicate means, treatment means, standard deviations, and analysis of variance tables. Treatment means were used to calculate the percent effect resulting from the

treatment. The percent effect was calculated using the following equation:

$$\% \text{ effect} = \frac{(\text{treatment mean} - \text{control mean})}{\text{control mean}} \times 100$$

Plant heights taken prior to treatment were used as a baseline to calculate the percent effect on growth at the 21 day observation period. The percent increase in height from the 0 day reading was calculated using the following equation:

$$\% \text{ increase} = \frac{(21 \text{ day mean} - 0 \text{ day mean})}{0 \text{ day mean}} \times 100$$

The percent effect on growth was calculated for each treatment using the following equation:

$$\% \text{ effect} = \frac{(\text{treat. \% increase} - \text{cont. \% increase})}{\text{control \% increase}} \times 100$$

An analysis of variance table was constructed using the Lotus 1-2-3 raw data spreadsheet. A one-way analysis of variance (ANOVA) model for data with equal sub-samples was used to analyze the data. The F-value from the analysis of variance table and an F table were used to determine if the treatment means were significantly different ($p < 0.05$). Treatment mean separation was achieved using either SAS or the LOTUS 1-2-3 spreadsheet.

Due to lack of significant rate effects and a lack of true dose response on each of the parameters measured, a probit analysis was neither conducted nor EC values computed.

12. REPORTED RESULTS:

Phytotoxicity rating: Statistical analysis of the 21 day phytotoxicity ratings showed no significant ($p < 0.05$) difference between the controls and any species. The resulting NOEC value for the ten species is 1.0 lb ai/A.

Plant height: Statistical analysis of the 21 day plant height data showed no significant difference between the controls and any species. However, lettuce showed a -38% effect on plant height at the 1.0 lb ai/A rate and cucumber demonstrated a -34%, -35%, and -33% effect at the 0.0123, 0.037, and 0.333 lb ai/A rates, respectively. The percent

difference in plant height ranged between -19% for lettuce treated with 1.0 lb ai/A to 15% for oat treated with 0.037 lb ai/A. The subsequent NOEC value for all tested species is 1.0 lb ai/A.

Plant dry weight: Statistical analysis of the plant dry weight data showed no significant difference between the controls and any species. Lettuce did demonstrate a 29% reduction in dry weight at the 0.111 lb ai/A treatment rate, however, it was not significant. Cabbage, oat, and corn demonstrated an increase in dry weight at all rates tested. The subsequent NOEC value for all tested species is 1.0 lb ai/A.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

"A no-effect concentration of 1.0 lb ai/A was reached on all measurement parameters, phytotoxicity rating, plant height, and plant dry weight for soybean, lettuce, carrot, tomato, cucumber, cabbage, oat, ryegrass, corn, and onion.

Due to the lack of significant rate differences, and the lack of a true dose response, EC₂₅ and EC₅₀ values could not be determined for any of the ten species."

The Quality Assurance Unit of Pan-Agricultural Laboratories, Inc., was responsible for the assurance of compliance with Good Laboratory Practice (GLP) Standards. Statements of compliance to GLP and QA were enclosed in the report.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures followed the SEP and Subdivision J guidelines, except for the following:

All plants in each replicate were weighed together, then the total weight was divided by the total number of plants to obtain each replicate mean value. The plants should have been individually weighed so the variation among plants within each replicate could be accounted for in the statistical analysis of the data.

Although stated in the protocol (attached as Appendix VIII to the study report), the report did not restate if the control plants were treated with the appropriate amount of acetone and water.

B. Statistical Analysis: Statistical analyses were conducted on lettuce (the most sensitive species) data for plant height (attached). The results are in agreement with the author's.

C. Discussion/Results:

This study is scientifically sound and meets the requirements for Tier 2 vegetative vigor test using non-target plants.

The NOEC value for all species for all parameters tested was 1.0 lb ai/A. No EC values were determined due to a lack of significant rate or true dose response.

D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A.
- (3) Repairability: N/A.

15. COMPLETION OF ONE LINER: N/A.

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Date:
Case No:
Chemical No:

PHASE IV
DATA REQUIREMENTS FOR PROFFENOFOS
ECOLOGICAL EFFECTS BRANCH

Data Requirement	Composition ¹	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail Duck	TGAI	All Outdoor	Yes	# 416273-01	No
71-1(b) Acute Avian Oral, Quail Duck (TEP)	TGAI	All Outdoor	No	MEID# 41627303	Yes
71-2(a) Acute Avian Diet, Quail	TGAI	All Outdoor	No	MEID# 41627302	Yes
71-2(b) Acute Avian Diet, Duck	TGAI	All Outdoor	No		Yes
71-3 Wild Mammal Toxicity					
71-4(a) Avian Reproduction Quail	TGAI	All Outdoor	Yes	Acc# 92148-005; 004	No
71-4(b) Avian Reproduction Duck	TGAI	All Outdoor	Yes	Acc# 92148-006	No
71-5(a) Simulated Terrestrial Field Study	TGAI	All Outdoor	Yes	Acc# 92148-007	No
71-5(b) Actual Terrestrial Field Study	TEP	All Outdoor	No		Yes
72-1(a) Acute Fish Toxicity Bluegill	TGAI	All Outdoor	Yes	Acc# 92148-008	No
72-1(b) Acute Fish Toxicity Bluegill (TEP)					
72-1(c) Acute Fish Toxicity Rainbow Trout	TGAI	All Outdoor	Yes	Acc# 92148-009	No
72-1(d) Acute Fish Toxicity Rainbow Trout (TEP)					
72-2(a) Acute Aquatic Invertebrate Toxicity					
72-2(b) Acute Aquatic Invertebrate Toxicity (TEP)	TGAI	All Outdoor	Yes	MEID# 416273-04	No
72-3(a) Acute Estuarine Tox Fish	TGAI	All Outdoor	Yes	Acc# 92148-010	No
72-3(b) Acute Estuarine Tox Mollusk	TGAI	All Outdoor	Yes	Acc# 92148-011	No
72-3(c) Acute Estuarine Tox Shrimp	TGAI	All Outdoor	Yes	Acc# 92148-012 92148-060	No

¹In Bibliographic Citation column indicates study may be upgraded.

1. Composition: TGA1 = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product

2. Use Patterns: A = Terrestrial Food Crop; B = Terrestrial Feed Crop; C = Terrestrial Non-Food Crop; D = Aquatic Food Crop; E = Aquatic Non-Food Outdoor; F = Aquatic Non-Food Industrial; G = Aquatic Non-Food Residential; H = Greenhouse Food Crop; I = Greenhouse Non-Food Crop; J = Forestry; K = Outdoor Residential; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 00000

3. The registrant has requested a waiver for all ecological effects data requirements. The data is insufficient, and due to the likelihood of exposure to non target avian species, EEB can not concede to all of these waivers, therefore, 71-1(a), 72-2(a) and 72-2(b) are required at this time.

~~A.~~ Due to the limited exposure to aquatic species, EEB is agreeing to the waiver request at this time, therefore, these tests are not required.

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Data Requirement	Composition ¹	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
72-3(d) Aque EstuMarine Tox Fish (TEP)					
72-3(e) Aque EstuMarine Tox Mollusk (TEP)					
72-3(f) Aque EstuMarine Tox Shrimp (TEP)					
72-4(a) Early Life-Stage Fish	TGAI	ALL OUTDOOR	YES	MRID # 42135201	No
72-4(b) Life-Cycle Aque Invertebrate	TGAI	ALL OUTDOOR	YES	Que. # 92148-013	No
72-5 Life-Cycle Fish					
72-6 Aque Org. Accumulation					
72-7(a) Simulated Aque Field Study					
72-7(b) Actual Aque Field Study	TEP	ALL OUTDOOR	No	Que. # 92148-015	YES
122-1(a) Spod Germ/Seedling Emerg.	TGAI	ALL OUTDOOR	YES	MRID # 416273-07	No
122-1(b) Vegetative Vigor					
122-2 Aque Plant Growth					
123-1(a) Spod Germ/Seedling Emerg.	TGAI	ALL OUTDOOR	YES	MRID # 416273-06	No
123-1(b) Vegetative Vigor	TGAI	ALL OUTDOOR	YES	MRID # 416273-05	No
123-2 Aque Plant Growth					
124-1 Terrestrial Field					
124-2 Aque Field					
141-1 Honey Bee Aque Contact	TGAI	ALL OUTDOOR	YES	MRID # 416273-08	No
141-2 Honey Bee Residue on Foliage					
141-5 Field Test for Pollinators					

¹In Bibliographic Citation column indicates study may be upgradable.

FOOTNOTES:

Composition: TGM = Technical grade of the active ingredient; PAFRA = Puro active ingredient; (indicated); TEP = Typical end-use product.

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