

**DATA EVALUATION RECORD
SEEDLING EMERGENCE EC₂₅ TEST
§122-1(a&b) (TIER I)**

1. **CHEMICAL:** Prothioconazole formulation PC Code No.: 113961

2. **TEST MATERIAL:** JAU 6476 480SC Purity: 414 g a.i./L

Common name: Prothioconazole formulation
Active Ingredient: Prothioconazole
Chemical: IUPAC name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4,-triazole-3-thione
CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4,-triazole-3-thione
CAS No.: 178928-70-6
Synonyms: JAU6476

3. **CITATION:**

Author: Sabbert, T.J.

Title: Tier I Seedling Emergence and Vegetative Vigor Non-Target Phytotoxicity Study Using JAU 6476 480SC

Study Completion Date: March 16, 2004

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6. SECONDARY REVIEW BY:

Émilie Larivière, Evaluation Officer, HC/PMRA/EAD

Signature:

Date: 9/2/05

Christopher J. Salice, EPA/EFED/ERB-IV

Signature:

Date: 7/17/05

7. STUDY PARAMETERS:

Scientific Name of Test Organism: Dicots: *Fagopyrum sagittatum*, *Helianthus annua*,
Cucumis sativa, *Brassica rapa*, *Glycine max*,
Lycopersicon esculentum
Monocots: *Zea mays*, *Lolium perenne*, *Allium*
cepa, *Triticum aestivum*

Definitive Study Duration: 21 days

Type of Concentrations: Nominal

8. CONCLUSIONS:

Seedling emergence and vegetative vigor were studied on 10 plant species after application of Prothioconazole formulation at 305 g a.i./ha. Test species included buckwheat, corn, cucumber, soybean, sunflower, tomato, onion, ryegrass, turnip, and wheat. By 21 days, cucumber was the only test species in the seedling emergence test which experienced inhibition greater than 25%; shoot height and dry weight were reduced 26% and 31%. While inhibition did not exceed 25%, sunflower emergence, turnip height, and soybean dry weight exhibited significant reductions from control, as well. By 21 days, none of the test species in the vegetative vigor test experienced $\geq 25\%$ inhibition for any of the endpoints. However, there were significant reductions in cucumber height (22%) and tomato dry weight (11%). The phytotoxicity percentage rating ranged from 0-1.3%. Based on cucumber shoot height and dry weight, the EC_{25} was <305 g a.i./ha in the seedling emergence test; the NOAEC was <305 g a.i./ha for sunflower emergence, cucumber and turnip height, and cucumber and soybean weight, and was 305 g a.i./ha for all other species and endpoints. The EC_{25} for all test species in the vegetative vigor test was >305 g a.i./ha; the NOAEC for cucumber and tomato was <305 g a.i./ha and 305 g a.i./ha for all other species and endpoints.

This study is classified as ACCEPTABLE. This study is scientifically sound and fulfills the Tier I guideline requirements for a seedling emergence and vegetative vigor study (Subdivision J, §122-1a&b).

Seedling Emergence

Most sensitive monocot: None

Most sensitive parameter: None

NOAEC: 305 g a.i./ha

EC_{25} : >305 g a.i./ha 95% C.I.: N/A

Slope: N/A

Most sensitive dicot: Cucumber
Most sensitive parameter: Height and Dry weight (26 and 31% inhibition)
NOAEC: <305 g a.i./ha (cucumber, sunflower, turnip, and soybean); 305 g a.i./ha (remaining species)
EC₂₅: <305 g a.i./ha (cucumber) 95% C.I.: N/A
Slope: N/A

Vegetative Vigor

Most sensitive monocot: None
Most sensitive parameter: None
NOAEC: 305 g a.i./ha
EC₂₅: >305 g a.i./ha 95% C.I.: N/A
Slope: N/A

Most sensitive dicot: None
Most sensitive parameter: None
NOAEC: <305 g a.i./ha (cucumber and tomato); 305 g a.i./ha (remaining species)
EC₂₅: >305 g a.i./ha 95% C.I.: N/A
Slope: N/A

9. ADEQUACY OF THE STUDY:

A. Classification: ACCEPTABLE

B. Rationale: This study is scientifically sound and fulfills the guideline requirements for a Tier I seedling emergence and vegetative vigor study (Subdivision J, §122-1a&b).

C. Repairability: Not applicable

10. GUIDELINE DEVIATIONS:

None

11. SUBMISSION PURPOSE: This study was submitted to provide data on the phytotoxicity

of Prothioconazole to non-target crop species after pre-emergent (seedling emergence) and post-emergent (vegetative vigor) application for the purpose of chemical registration.

12. MATERIALS AND METHODS:

A. Test Organisms

| Guideline Criteria | Reported Information |
|---|--|
| <p>Species: 6 dicots in 4 families, including soybean and a rootcrop; 4 monocots in 2 families, including corn.</p> | <p><u>Dicots:</u> buckwheat, sunflower, cucumber, turnip, soybean, and tomato <u>Monocots:</u> corn, onion, ryegrass, and wheat</p> |
| <p>Number of plants per repetition:</p> | <p><u>Seedling Emergence:</u> Buckwheat, Corn, Cucumber, Soybean, Sunflower, and Tomato- 2 seeds/pot, 5 pots/rep, 4 reps/treatment level</p> <p>Onion, Ryegrass, Turnip, and Wheat- 5 seeds/pot, 2 pots/rep, 4 reps/treatment level</p> <p><u>Vegetative Vigor:</u> All species thinned prior to treatment to 10 plants/rep, 4 reps/treatment level, 40 plants total per species per treatment level</p> |
| <p>Source of seed and historical % germination of seed:</p> | <p>See p. 33, Appendix 2 for seed source information. Historical % germination is not reported.</p> |

B. Test System

| Guideline Criteria | Reported Information |
|------------------------|----------------------|
| <p>Solvent:</p> | <p>N/A</p> |

| Guideline Criteria | Reported Information |
|--|---|
| <p>Site of test:</p> | <p><u>Seedling Emergence:</u> Greenhouse at Bayer Research Park, Stilwell, Kansas.</p> <p><u>Vegetative Vigor:</u> Greenhouse at Bayer Research Park, Stilwell, Kansas.</p> |
| <p>Planting method/type of pot:</p> | <p><u>Turnip, Onion, Ryegrass, and Wheat-</u> Plastic pots with drainage holes (9 cm diameter by 8 cm tall)</p> <p><u>Buckwheat, Cucumber, Corn, Soybean, Sunflower, and Tomato-</u> Plastic pots with drainage holes (10.5 cm diameter by 12 cm tall)</p> <p>The growth medium was steam-pasteurized sandy loam with organic content of approximately 2.4% and an approximate pH of 5.8.</p> |
| <p>Method of application:</p> | <p>Test material applied using an Allen spray chamber equipped with an overhead nozzle.</p> <p><u>Seedling Emergence:</u> Spray solution was applied directly to the soil surface.</p> <p><u>Vegetative Vigor:</u> Spray solution applied to canopy height of plants at the two to four-true leaf stages.</p> |
| <p>Method of watering:</p> | <p><u>Seedling emergence/Vegetative Vigor:</u> After test application, pots were initially hand watered at the soil surface to establish the continuous water column, then the pots were subirrigated with capillary mats. Water was tap water supplied by Johnson County, Kansas Water District.</p> |

| Guideline Criteria | Reported Information |
|-------------------------------------|--|
| Growth stage at application: | <u>Seedling emergence:</u> Soil surface <u>Vegetative Vigor:</u> Two to four-leaf growth stage. |

C. Test Design

| Guideline Criteria | Reported Information |
|--|---|
| Dose range: 2x or 3x | <u>Seedling Emergence/Vegetative Vigor-</u> N/A (one test concentration) |
| Doses: At least 5 | <u>Seedling Emergence/Vegetative Vigor-</u> 305 g a.i./ha |
| Controls: Negative and solvent | <u>Seedling Emergence/Vegetative Vigor-</u> Negative control (not sprayed) and blank formulation |
| Replicates per dose: At least 3 | <u>Seedling Emergence/Vegetative Vigor-</u> 4 replicates |
| Test duration: 14 days | <u>Seedling Emergence/Vegetative Vigor-</u> 21 days |
| Were observations made at least weekly? | Yes |
| Maximum dosage rate: | <u>Seedling Emergence/Vegetative Vigor-</u> The maximum formulated product label use rate was equivalent to a field application rate of 305 g a.i./ha. |

13. REPORTED RESULTS:

| Guideline Criteria | Reported Information |
|---|--|
| Quality assurance and GLP compliance statements were included in the report? | Yes |
| Was a NOAEC observed for each species? | <p><u>Seedling Emergence</u>- A NOAEC could not be determined for cucumber, sunflower, turnip, and soybean.</p> <p><u>Vegetative Vigor</u>- A NOAEC could not be determined for cucumber and tomato.</p> |
| Phytotoxic observations: | <p><u>Seedling Emergence</u>- No significant phytotoxic effects ($\geq 25\%$ rating on Day 21) were observed in any of the ten species. Mean phytotoxicity ratings for the 305 g a.i./ha treatment groups ranged from 0-17.5%.</p> <p><u>Vegetative Vigor</u>- No significant phytotoxic effects ($\geq 25\%$ rating on Day 21) were observed in any of the ten species. Mean phytotoxicity ratings for the 305 g a.i./ha treatment groups ranged from 0-1.3%.</p> |
| Were initial chemical concentrations measured? (Optional) | Yes; see Appendix 4 (pp. 35-41) |
| Were adequate raw data included? | <p><u>Seedling Emergence</u>- Replicate emergence, survival, shoot height, dry weight, and phytotoxicity ratings were provided.</p> <p><u>Vegetative Vigor</u>- Replicate survival, shoot height, dry weight, and phytotoxicity ratings were provided.</p> |

Results for the most sensitive parameter of each species

Results Synopsis

Seedling Emergence

| Crop | Day 21 Emergence | | Shoot Length | | Dry Weight | | Survival | | Most sensitive parameter |
|-----------|------------------|------------------|--------------|------------------|------------|------------------|----------|------------------|--------------------------|
| | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | |
| Buckwheat | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Corn | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Cucumber | 305 | >305 | <305 | <305 | <305 | <305 | 305 | >305 | Dry Weight |
| Soybean | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Sunflower | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Tomato | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Onion | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Ryegrass | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Turnip | <305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Wheat | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |

ND = Not determined

* Units are g a.i./ha

Vegetative Vigor

| Crop | Shoot Length | | Dry Weight | | Survival | | Most sensitive parameter |
|-----------|--------------|------------------|------------|------------------|----------|------------------|--------------------------|
| | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | |
| Buckwheat | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Corn | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Cucumber | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Soybean | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Sunflower | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Tomato | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Onion | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Ryegrass | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Turnip | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Wheat | 305 | >305 | 305 | >305 | 305 | >305 | None |

ND = Not determined

* Units are g a.i./ha

Morphological Observations

Buckwheat

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 94%, 100%, 34.7 cm, and 5.066 g, respectively. Percent emergence and percent survival were compared using the pooled controls and shoot height and dry weight were compared using the blank formulation control. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 98%, 100%, 32.9 cm, and 4.009 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 72.0 cm, and 27.091 g, respectively. Percent survival and shoot height was compared using the pooled controls and dry weight was compared using the blank formulation control. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 73.0 cm, and 27.748 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Corn

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 100%, 100%, 74.3 cm, and 8.799 g, respectively. Percent emergence and percent survival were compared using the pooled controls and shoot height was compared using the blank formulation control. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 95%, 100%, 73.5 cm, and 8.384 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 99%, 109.6 cm, and 29.872 g, respectively. Percent survival and shoot height were compared using the pooled controls and dry weight was compared using the blank

formulation control. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 109.4 cm, and 28.017 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. The mean phytotoxicity rating (%) for the 305 g a.i./ha treatment group was 1.3.

Cucumber

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 93%, 99%, 74.3 cm, and 5.949 g, respectively. Percent emergence, percent survival, and dry weight were compared using the pooled controls and shoot height was compared using the blank formulation control. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 93%, 100%, 16.3 cm, and 4.099 g, respectively. Shoot height experienced a 26% inhibition and dry weight experienced a 31% inhibition when compared to the blank formulation control. The mean phytotoxicity rating (%) for the 305 g a.i./ha treatment group was 17.5.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 76.8 cm, and 51.226 g, respectively. Percent survival was compared using the pooled controls and shoot height and dry weight were compared using the blank formulation control. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 59.9 cm, and 45.945 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Soybean

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 99%, 100%, 26.2 cm, and 4.625 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 100%, 23.8 cm, and 4.111 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 56.0 cm, and 22.124 g, respectively. Percent survival was compared using the pooled controls and shoot height and dry weight were compared using the blank

formulation control. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 56.0 cm, and 20.671 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Sunflower

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 100%, 100%, 33.8 cm, and 6.675 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 93%, 100%, 33.2 cm, and 6.131 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 86.1 cm, and 44.066 g, respectively. All endpoints were compared using the pooled controls. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 87.3 cm, and 41.739 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Tomato

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 88%, 100%, 14.2 cm, and 0.857 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 95%, 100%, 12.4 cm, and 0.719 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. The mean phytotoxicity rating (%) for the 305 g a.i./ha treatment group was 6.3.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 53.9 cm, and 23.398 g, respectively. All endpoints were compared using the pooled controls. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 54.0 cm, and 20.771 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group.

No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Onion

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 95%, 97%, 15.5 cm, and 0.124 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 93%, 100%, 15.8 cm, and 0.124 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 30.1 cm, and 1.233 g, respectively. All endpoints were compared using the pooled controls. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 31.0 cm, and 1.294 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Ryegrass

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 88%, 99%, 17.9 cm, and 0.167 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 95%, 100%, 17.1 cm, and 0.180 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 24.4 cm, and 2.319 g, respectively. All endpoints were compared using the pooled controls. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 24.5 cm, and 2.538 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Turnip

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 95%, 100%, 14.9 cm, and 2.355 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 98%, 100%, 13.7 cm, and 2.187 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 24.4 cm, and 8.900 g, respectively. Mean shoot height compared using the blank formulation control and the mean percent survival and dry weight were compared using the pooled control. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 24.9 cm, and 8.472 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Wheat

Seedling Emergence:

By 21 days, the mean percent emergence, percent survival, shoot height and dry weight of the controls were 98%, 99%, 33.6 cm, and 1.586 g, respectively. All endpoints were compared using the pooled controls. The mean percent emergence, percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 100%, 31.9 cm, and 1.586 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Vegetative Vigor:

By 21 days, the mean percent survival, shoot height and dry weight of the controls were 100%, 36.8 cm, and 4.855 g, respectively. All endpoints were compared using the pooled controls. The mean percent survival, shoot height, and dry weight of the 305 g a.i./ha treatment group were 100%, 36.1 cm, and 4.506 g, respectively. No endpoint experienced a $\geq 25\%$ inhibition in either the controls or the 305 g a.i./ha treatment group. No phytotoxic effects were observed in the pooled control or the 305 g a.i./ha treatment group.

Statistical Results

Statistical Method: Comparison of the control groups was performed with SAS, ver 8.2. Control means were compared using a two-tailed planned comparison t-test. The results from this test determined whether or not to pool the control groups. If the test indicated that pooling the control groups was unacceptable, then the blank formulation control was used unless otherwise indicated. Excel (2000) spreadsheets were used to calculate the percent effect for seedling emergence, seedling survival, visual phytotoxicity, plant height, and dry weight, using pooled controls (except as noted).

Seedling Emergence

Most sensitive monocot: None

Most sensitive parameter: None

NOAEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

EC₅₀: >305 g a.i./ha 95% C.I.: N/A

Slope: Not reported

Most sensitive dicot: Cucumber (31% inhibition)

Most sensitive parameter: Dry weight

NOAEC: <305 g a.i./ha

EC₂₅: <305 g a.i./ha 95% C.I.: N/A

EC₅₀: NA 95% C.I.: N/A

Slope: Not reported

Vegetative Vigor

Most sensitive monocot: None

Most sensitive parameter: None

NOAEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

EC₅₀: >305 g a.i./ha 95% C.I.: N/A

Slope: Not reported

Most sensitive dicot: None

Most sensitive parameter: None

NOAEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

EC₅₀: >305 g a.i./ha 95% C.I.: N/A

Slope: Not reported

14. REVIEWER'S VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: For all species and endpoints exhibiting inhibition equal to or exceeding 5%, the control group was first compared to the blank formulation control to determine whether or not to pool the two control groups upon comparison to the treatment group via a t-test. In one case (cucumber seedling emergence height), there was a significant difference between the control groups, so the treatment group was compared to the blank formulation control. These analyses were conducted using Excel and spreadsheets accompany this DER as raw data files (e.g., 6049_122-1_height).

Results synopsis

Seedling Emergence

| Crop | Emergence* | | Survival | | Shoot Length | | Dry Weight | | Most Sensitive Parameter |
|-----------|-------------------|------------------|----------|------------------|-------------------|------------------|-------------------|------------------|--------------------------|
| | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | NOAEC | EC ₂₅ | |
| Buckwheat | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Corn | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Cucumber | 305 | >305 | 305 | >305 | <305 | <305 | <305 | <305 | Dry weight |
| Soybean | 305 | >305 | 305 | >305 | 305 | >305 | <305 ^a | >305 | None |
| Sunflower | <305 ^a | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Tomato | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Onion | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Ryegrass | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Turnip | 305 | >305 | 305 | >305 | <305 ^a | >305 | 305 | >305 | None |
| Wheat | 305 | >305 | 305 | >305 | 305 | >305 | 305 | >305 | None |

^a The reviewer's estimate was lower than the study authors'.

^b The reviewer's estimate was higher than the study authors'.

*units are g a.i./ha

Vegetative Vigor

| Crop | Survival | | Shoot Length | | Dry Weight | | Most Sensitive Parameter |
|-----------|----------|------------------|-------------------|------------------|-------------------|------------------|--------------------------|
| | NOAE C | EC ₂₅ | NOAE C | EC ₂₅ | NOAEC | EC ₂₅ | |
| Buckwheat | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Corn | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Cucumber | 305 | >305 | <305 ^a | >305 | 305 | >305 | None |
| Soybean | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Sunflower | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Tomato | 305 | >305 | 305 | >305 | <305 ^a | >305 | None |
| Onion | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Ryegrass | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Turnip | 305 | >305 | 305 | >305 | 305 | >305 | None |
| Wheat | 305 | >305 | 305 | >305 | 305 | >305 | None |

^a The reviewer's estimate was lower than the study authors'.

^b The reviewer's estimate was higher than the study authors'.

*units are g a.i./ha

Seedling Emergence

Most sensitive monocot: None

Most sensitive parameter: None

NOAEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

Slope: N/A

Most sensitive dicot: Cucumber
Most sensitive parameter: Height and Dry weight (26 and 31% inhibition)
NOAEC: <305 g a.i./ha (cucumber, sunflower, turnip, and soybean); 305 g a.i./ha (remaining species)
EC₂₅: <305 g a.i./ha (cucumber) 95% C.I.: N/A
Slope: N/A

Vegetative Vigor

Most sensitive monocot: None
Most sensitive parameter: None
NOAEC: 305 g a.i./ha
EC₂₅: >305 g a.i./ha 95% C.I.: N/A
Slope: N/A

Most sensitive dicot: None
Most sensitive parameter: None
NOAEC: <305 g a.i./ha (cucumber and tomato); 305 g a.i./ha (remaining species)
EC₂₅: >305 g a.i./ha 95% C.I.: N/A
Slope: N/A

15. REVIEWER'S COMMENTS:

The reviewer's conclusions regarding the most (and only) sensitive species in the seedling emergence test (cucumber, a dicot) was identical to the study author's. However, the reviewer's analysis also detected significant reductions in some endpoints for several species (i.e., sunflower, turnip, and soybean for seedling emergence and cucumber and tomato for vegetative vigor); while these reductions did not exceed 25%, a NOAEC could not be determined for these species.

The seedling emergence definitive study was conducted from January 16, 2001 to February 6, 2001. The vegetative vigor definitive study was conducted from January 10, 2001 to January 31, 2001. The average temperatures for the seedling emergence test ranged from 19 to 35°C and the relative humidity means ranged from 38 to 93%. The average temperatures for the vegetative vigor test ranged from 18 to 30°C and the relative humidity means ranged from 15 to 91%. The greenhouse photoperiod setting was 14 hour light/10 hour dark with supplemental light.

This study was conducted in accordance with USEPA Good Laboratory Practice Regulations (Title 40, Part 160) and included a Quality Assurance statement.

Based on the results of this test, a Tier II seedling emergence test with Prothioconazole is recommended for Cucumber.

16. REFERENCES:

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Kratkg, B. A and Warren, G. E., 1971, The Use of Three Simple, Rapid, Bioassays on Forty-Two Herbicides, Weed Research, 11, 257-262.

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Sebaugh, Jeanne. 1999. Sebaugh Information Services, Columbia, Missouri, USA.

USEPA, 1982. Pesticide Assessment Guidelines, Subdivision J- Hazard Evaluation: Non-Target Plants. EPA-540/9-82-020. Office of Pesticide Programs, Washington, D.C. 55pp.

USEPA, 1986. Standard Evaluation Procedure, Non-Target Plants: Seed Germination, Seedling Emergence, and Vegetative Vigor- Tier I. EPA-540/9-86-134. Office of Pesticide Programs, Washington, D.C.

USEPA, 1989. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR Part 160). Federal Register, Vol. 54, No. 158: 34067-34074.

APPENDIX I. OUTPUT FROM REVIEWER'S STATISTICAL VERIFICATION:

See Excel raw data files that accompany this DER (i.e., "6049_122-1_height") for results of t-tests.

Data Evaluation Report on the acute toxicity of Prothioconazole formulation to terrestrial vascular plants (seedling emergence and vegetative vigour)

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA

Date: September 2, 2005

PMRA Submission Number: 2004-0844

Study Type: Acute Toxicity to Non-Target Plants- Laboratory Studies with the End-Use Product

Sabbert, T.J. 2004. Tier 1 seedling emergence and vegetative vigor non-target phytotoxicity study using JAU 6476 480SC. Bayer CropScience, RTP, NC. Bayer Report 200951.

PMRA DATA CODE: 9.8.6

EPA DP Barcode: D303488

OECD Data Point: IIIA 10.8.1.1

EPA MRID: 46246049

EPA Guideline: 122-1 (a&b) Tier 1

Reviewing Agency: US EPA

EAD Executive Summary:

Seedling emergence and vegetative vigour were studied on 10 plant species after application of Prothioconazole formulation (JAU6476 480 SC; 414 g a.i./L) at 305 g a.i./ha. Test species included the dicot crops buckwheat (*Fagopyrum sagittatum*), sunflower (*Helianthus annua*), cucumber (*Cucumis sativa*), turnip (*Brassica rapa*), soybean (*Glycine max*) and tomato (*Lycopersicon esculentum*), and the monocot crops corn (*Zea mays*), onion (*Allium cepa*), ryegrass (*Lolium perenne*) and wheat (*Triticum aestivum*). The study was conducted according to U.S. EPA Guideline 122-1 and was in compliance with USEPA Good Laboratory Practice Regulations (Title 40, Part 160). By 21 days, cucumber was the only test species in the seedling emergence test which experienced inhibition greater than 25%; shoot height and dry weight were reduced 26% and 31%. While inhibition did not exceed 25%, sunflower emergence, turnip height, and soybean dry weight exhibited statistically significant reductions from control, at 7.5, 9 and 11%, respectively. The phytotoxicity percentage rating for seedling emergence ranged from 0-17.5%.

By 21 days, none of the test species in the vegetative vigour test experienced $\geq 25\%$ inhibition for

any of the endpoints. However, there were statistically significant reductions in cucumber height (22%) and tomato dry weight (11%). The phytotoxicity percentage rating for vegetative vigour ranged from 0-1.3%. Based on cucumber shoot height and dry weight, the EC₂₅ was <305 g a.i./ha in the seedling emergence test; the NOEC was <305 g a.i./ha for sunflower emergence, cucumber and turnip height, and cucumber and soybean weight, and was 305 g a.i./ha for all other species and endpoints. The EC₂₅ for all test species in the vegetative vigour test was >305 g a.i./ha; the NOEC for cucumber and tomato was <305 g a.i./ha and 305 g a.i./ha for all other species and endpoints. Based on the results of this test, a Tier II seedling emergence test with prothioconazole is recommended for cucumber.

Seedling Emergence

Most sensitive monocot: None

Most sensitive parameter: None

NOEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

Slope: N/A

Most sensitive dicot: Cucumber

Most sensitive parameter: height and dry weight (26 and 31% inhibition)

NOEC: <305 g a.i./ha (cucumber, sunflower, turnip, and soybean); 305 g a.i./ha (remaining species)

EC₂₅: <305 g a.i./ha (cucumber) 95% C.I.: N/A

Slope: N/A

Vegetative Vigour

Most sensitive monocot: None

Most sensitive parameter: None

NOEC: 305 g a.i./ha

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

Slope: N/A

Most sensitive dicot: None

Most sensitive parameter: None

NOEC: <305 g a.i./ha (cucumber and tomato); 305 g a.i./ha (remaining species)

EC₂₅: >305 g a.i./ha 95% C.I.: N/A

Slope: N/A

EAD Comments:

1. The appropriate PMRA information (PMRA Submission Number, PMRA Data Code, PMRA company code, PMRA active ingredient code, PMRA use site category, OECD data point) was added to the PMRA review portion of the DER. The PMRA Submission Number was added to the Header of the DER. Information on the chemical name (IUPAC name, CAS name and synonym) available from the study report, the PMRA Chemistry review and other sources of information was added at the beginning of the DER. The name of the EAD secondary reviewer was added to the front portion of the DER and sections were renumbered accordingly.

2. The scoring system for phytotoxic effects is the following:

0%: No injury/effect; 20%: slight plant effects or effect restricted to one area of the plant (e.g., a leaf); 40%: Moderate effect involving the whole plant - mild stunting, chlorosis; 60%: Severe effect with recovery possible; 80%: Total plant effect (very poor vigor); 100%: Moribund or plant death

3. The EAD reviewer calculated the percent inhibition for sunflower emergence, turnip height, and soybean dry weight at 7.5, 9 and 11%, respectively, compared to the pooled control.

4. After a cursory look at the data, the EAD evaluator did not feel that redoing the statistical analyses was warranted. The results obtained by the study author and the EPA reviewer are acceptable.

5. The EAD reviewer agrees with the conclusions of the EPA reviewer.

Study Acceptability: This study is classified as ACCEPTABLE. This study is scientifically sound and fulfills the data requirements for a Tier I seedling emergence and vegetative vigor study.