DATA EVALUATION RECORD
HONEY BEE - FIELD TESTING FOR POLLINATORS, §141-5

1. **CHEMICAL:** Clothianidin, TI-435 — PC Code No.: 044309

2. **TEST MATERIAL:** TI-435 — Purity: 607.2 g/L (test substance); 26.9 g a.i./50,000 seeds (seed coating)

3. **CITATION:**

Author:	Ch. Maus and R. Schöning
Title:	Residue Levels of TI-435 FS 600 and its Relevant Metabolites in Pollen of Maize Plants from Dressed Seeds (Test Location: Farmland "Laacher Hof")
Study Completion Date:	January 19, 2001
Laboratory:	Bayer AG, Crop Protection-Development, Leverkusen-Bayerwerk, Germany
Sponsor:	Bayer AG, Crop Protection-Development, Leverkusen-Bayerwerk, Germany
Laboratory Report ID:	1100023
DP Barcode:	D278110
MRID No.:	45422438

4. **REVIEWED BY:** Rebecca Bryan, Staff Scientist, Dynamac Corporation.

Signature: Rebecca Bryan **Date:** 2/24/03

APPROVED BY: Teri Myers, Ph.D., Staff Scientist, Dynamac Corporation

Signature: Teri Myers **Date:** 2/24/03

5. **APPROVED BY:** Gabe Patrick, Biologist, EPA/EFED/ERB5

Signature: Gabe Patrick **Date:** 3/4/03

6. **APPROVED BY:** Hemendra Mulye, PhD, Senior Evaluation Officer, Health Canada, Pest Management Regulatory Agency, Environmental Assessment Division, Environmental Fate and Effects

Signature: **Date:** March 19/03

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: Maize (*Zea mays*)
Definitive Study Duration: 15 days

7. **CONCLUSIONS:** This toxicity study aimed to determine the residue levels of TI-435 and its relevant metabolites (TZMU and TZNG) in pollen from corn plants grown from treated seed. This study is not scientifically sound because residues of TI-435 were detected in the control pollen samples (1.7 and 1.1 µg/kg) and the source of the contamination could not be traced. The treatment pollen samples contained TI-435 residue levels of 5.4 and 3.3 µg/kg. Residues for the metabolites were below the limit of detection for both the control and treatment groups. This study is classified as INVALID.

8. **ADEQUACY OF THE STUDY:**

A. Classification: Invalid

B. Rationale: Residue levels of TI-435 were detected in the control pollen samples which were from plants grown from untreated seed and the source of this contamination could not be identified.

C. Repairability: None. Measures should have been taken to ensure a contamination-free control group.

9. **GUIDELINE DEVIATIONS:**

The distance between the control and treatment plot was not provided and TI-435 residues were detected in control pollen samples. The study authors reported that the source of the pollen contamination could not be unambiguously traced; however, the reviewer suspects that contamination may have resulted from the close proximity of control and treatment plots. This study was conducted without a prior agreed upon protocol between the registrant and the Agency - gp.

10. **SUBMISSION PURPOSE:** This study was submitted to evaluate the residue levels of TI-435 and its relevant metabolites in pollen samples from corn grown from treated seed.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera*, *Megachile rotundata*, or *Nomia melanderi*)	*Zea mays* (Maize) Bee performance was not evaluated in this study.
Age at beginning of test:	N/A
Supplier	N/A
All bees from the same source?	N/A

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	N/A
Lighting:	N/A
Temperature:	Month of July- minimum air temp: 10.0-15.6°C, maximum air temp: 16.3-27.4°C, soil temperature: 13.9-20.6°C Month of August- minimum air temp: 11.3-17.9°C, maximum air temp: 20.2-31.1°C, soil temperature: 16.4-22.4°C
Relative humidity:	Not reported
Precipitation:	A total of 145.7 mm of rain was recorded during the month of July and 77.1 mm during the month of August (p. 8).

Guideline Criteria	Reported Information
Site Characterization:	• The trial site was located at Bayer AG's experimental farmland "Laacher Hof", approximately 3 km south of Monheim (Germany, NRW 41 m above sea level) • The control plot was in field number 711 and the treatment plot was in field number 717. The exact location is documented in the raw data (not included in the study report).

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No
Reference toxicant tested?	No, a reference compound was not specified for this type of material and use pattern (p. 6).
Study Plots:	• There was one treatment and one control plot planted on the trial site. • Each plot was 9.6 x 55 m^2, with a between-row distance of 80 cm and a 12.5 cm in-row drilling distance. • Test plots were adjacent to similar test plots which were cultivated with either sunflower or rape plants. • Test plots were not treated with TI-435 before the study.

Guideline Criteria	Reported Information
Method of administration:	• Maize seeds (variety: "Santiago") were dressed at the Bayer Agricultural Research Centre at Monheim on 4/12/00 with TI-435 FS 600 at a rate of 26.9 g a.i./50,000 seeds (nominal 41.7 mL product/50,000 seeds); treatment rate = 53.8 g a.i./ha.. Seed from the treatment and control groups were also treated with a standard fungicide (Tutan FS 500 @ 400 mL/100 kg seed). • The control plot was drilled with untreated maize seed and the treatment plot was drilled with seeds dressed with test substance at a drilling rate of 100,000 seeds/ha on 5/2/00.
Definitive Test Sufficient number of time periods to yield statistically sound data.	Maize pollen sampled from July 20-August 3, 2000.
Controls: Negative control and/or diluent/solvent control	There was a negative control plot.
Number of colonies per group:	N/A
Solvent: Distilled water or the following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	N/A
Feeding:	N/A
Observation period:	Pollen samples collected from July 20-August 3, 2000 and residues were analyzed for TI-435 and relevant metabolites from September 6-28, 2000.

Guideline Criteria	Reported Information
Sampling Procedures:	
Plants: Pollen	Maize panicles cut, transferred to paper bags, and dried in laboratory. Pollen shaken from panicles and sieved.
Storage conditions:	Pollen samples were frozen at -20°C until residue analysis.
Same procedure for all treatment groups:	Yes

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control performance:	Control pollen samples were contaminated with TI-435 and the study authors reported that the source of contamination could not be traced (p. 9).
Raw data included?	A summary of the analytical results were provided (p. 10).
Signs of toxicity (if any) were described?	N/A

Residue Analysis of Pollen(µg/kg)[a]

Group	Type of Residue		
	TI-435	TZMU	TZNG
Control Pollen A	1.7 1.1[b] <LOQ[b]	n.d. n.d.[b] <LOQ[b]	n.d. n.d.[b] n.d.[b]
53.8 g a.i./ha Pollen A	5.4 3.3[b]	n.d. n.d.[b]	n.d. n.d.[b]

[a] Limit of quantitation (LOQ): 1 µg/kg; Limit of detection: 0.3 µg/kg
n.d.=Amount below limit of detection.
[b] Repetition of first analysis

Reported Statistical Results: Statistical analyses were not required.

13. VERIFICATION OF STATISTICAL RESULTS: N/A

14. REVIEWER'S COMMENTS:

The distance between the control and treatment plot was not provided and TI-435 residues were detected in control pollen samples. The study authors reported that the source of the pollen contamination could not be unambiguously traced; however, the reviewer suspects that contamination may have resulted from the close proximity of control and treatment plots. Given that residues of TI-435 were detected in the control pollen samples, this study is classified as INVALID.