

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. **CHEMICAL:** Prometon.
Shaughnessey No. 080804.
2. **TEST MATERIAL:** Prometon technical; ID No. FL-872050, ACS-8114; Batch Code 73152-ML-5664; 98.5% active ingredient, a white powder.
3. **STUDY TYPE:** Acute Contact LD₅₀ Test.
Species Tested: Honey Bee
(Apis mellifera).
4. **CITATION:** Hoxter, K.A. and G.J. Smith. 1990. Prometon: An Acute Contact Study With The Honey Bee. Laboratory Report No. 108-323. Conducted by Wildlife International Ltd., Easton, MD. Submitted by Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 416091-15.

5. **REVIEWED BY:**

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

Signature: *Mark A. Mossler*

Date: *4/17/91*

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *P. Kosalwat*

Date: *4/17/91*

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: *Cynthia Mossler 12.3.94
Henry T. Craven*

Date: *4/23/91*

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute contact LD₅₀ test using honey bees. With a 48-hour LD₅₀ value of 36 µg ai/bee, prometon technical is considered relatively nontoxic to Apis mellifera, when administered as a solution. The no-effect concentration for this study was <13 µg ai/bee.
8. **RECOMMENDATIONS:** N/A.

9. BACKGROUND: N/A.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Two frames of honey bee (Apis mellifera) pupae were placed in an incubator for 8 days to allow pupae to emerge as adults. All test bees were 1 to 8 days old at the initiation of the test and were apparently healthy.
- B. Test System: Bees were contained in one pint rolled paper containers (87 mm in diameter and 85 mm high). Each container was covered with a plastic petri plate in which a 20-ml glass vial containing 50% sugar/water was inserted. This food source was available ad libitum throughout the test. A sponge affixed to the test chamber was misted daily to increase the humidity within the test chamber.
- C. Dosage: The appropriate amount of test material was dissolved in acetone. Five treatment levels representing 13, 22, 36, 60 and 101 μg active ingredient (ai)/bee were tested along with a solvent control and a negative control.
- D. Design: The test consisted of 5 treatment levels, a control, and a solvent control. Two replicates of 25 bees each were used for the treatment and controls. Twenty-five randomly selected bees were immobilized with nitrogen and laid out on paper. The bees were dosed individually on the thorax and/or abdomen with 2 μl of the appropriate test solution. Negative control bees were handled identically to treated bees, but were not dosed with any material. Solvent control bees received only acetone. Observations were recorded at 0, 24, and 48 hours. The test chamber received 8 hours of light per day. Temperature ranged between 22°C to 23°C with a mean relative humidity of 78%.
- E. Statistics: An LD_{50} value and 95% confidence limits were calculated by probit analysis. The LD_{50} value was used to classify the test substance according to toxicity categories. The categories were: highly toxic (less than 2 μg /bee), moderately toxic (greater than or

equal to 2 $\mu\text{g}/\text{bee}$ but less than 11 $\mu\text{g}/\text{bee}$), and relatively nontoxic (greater than or equal to 11 μg bee).

12. **REPORTED RESULTS:** Cumulative mortalities of the test bees during the 48-hour exposure period are presented in Table 1 (attached). At test termination, negative control and solvent control mortalities were 6% and 2%, respectively. Mortality at the 13, 22, 36, 60 and 101 μg ai/bee doses were 16%, 30%, 56%, 70% and 80%, respectively. These treatments were apparently dose responsive.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** In conclusion, prometon was classified as relatively nontoxic according to the toxicity categories. The honey bee acute contact LD_{50} value for prometon was determined to be approximately 36 μg ai/bee, with 95% confidence limits of 30 to 43 μg ai/bee. The no observed effect level was <13 μg ai/bee, based on treatment related mortality and signs of toxicity at that dose. The slope of the response curve was 2.1.

The study director confirms that to the best of their knowledge this study was conducted in compliance with Good Laboratory Practice Standards. A statement of compliance to Quality Assurance was included in the report.

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

- A. **Test Procedure:** The test procedures generally follow the protocols recommended by the SEP.
- B. **Statistical Analysis:** Probit analysis was conducted on the data to determine the LD_{50} . Computer printouts are attached. The results for the LD_{50} value are in near agreement with the author's. The reviewer obtained an LD_{50} of 37 μg ai/bee with and 95% confidence interval of 31 to 45 μg ai/bee.
- C. **Discussion/Results:** With a 48-hour LD_{50} of 36 μg ai/bee, prometon technical is considered relatively nontoxic to honey bees (*Apis mellifera*). The no-effect concentration was determined to be <13 μg ai/bee.

D. Adequacy of the Study:

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

15. COMPLETION OF ONE-LINER: Yes, April 1, 1991.

TABLE 1
 CUMULATIVE MORTALITY OF HONEY BEES
 EXPOSED TO PROMETON FOR 48 HOURS BY REPLICATE*

Experimental Group	Concentration (μg a.i./bee)	Day 0		Day 1		Day 2		Replicates Combined	Mortality %		
		Observation		Replicate		Replicate					
		First Replicate	Second Replicate	A	B	A	B				
Negative Control	0	2	1	2	1	2	1	3/50	6%		
Solvent Control	0	1	0	1	0	1	0	1/50	2%		
Treatment											
	13	2	(3)	2	3	2	6	2	6	8/50	16%
	22	(2)	(2)	1(1)	1(1)	6	9	6	9	15/50	30%
	36	1(6)	(4)	2(5)	1(3)	17	11	17	11	28/50	56%
	60	(7)	1(6)	2(5)	3(4)	16	18	17	18	35/50	70%
	101	1(2)	(2)	4(2)	(2)	23	17	22	18	40/50	80%

*Each replicate contained 25 bees.

() Indicates bees found immobile.

The LD50 value was determined to be 36 μg a.i./bee with a 95% confidence interval of 30 to 43 μg a.i./bee.

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NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY, THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

MM Prometon Apis mellifera 04-17-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
101	49	39	79.5918	0
60	49	34	69.3877	0
36	49	27	55.102	0
22	49	14	28.5714	0
13	49	7	14.2857	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 32.8213

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	7.979203E-02	36.51715	29.92836	44.61869

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
3	7.004477E-02	1	.6922127

SLOPE = 2.194181
95 PERCENT CONFIDENCE LIMITS = 1.613469 AND 2.774892

LC50 = 37.11257
95 PERCENT CONFIDENCE LIMITS = 30.86875 AND 44.73379

LC10 = 9.788522
95 PERCENT CONFIDENCE LIMITS = 5.837257 AND 13.46315

Shaughnessey No. 080804

Chemical Name Paracetamol

Chemical Class _____

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Study/Species/Lab/
MRID # 48 hr Chemical
% a.i.

14-Day Single Oral LD₅₀ 98.5%

LD₅₀ = 36 $\frac{\mu\text{g}}{\text{kg}}$ (30-43 $\frac{\mu\text{g}}{\text{kg}}$) 95% C.L.
Probit Analysis
Subst. = 2%
Negative = 6%

Species Apis mellifera - honey bee

Slope = 2.1 # Animals/Level = 50 Age (Days) = 1-8
Sex = N/A. (F)

Lab Wildlife International, Ltd.

Reviewer/Date M. Posselt 4/16/91 Validation Status Core

MRID # 416091-15 14-Day Dose Level $\frac{\mu\text{g}}{\text{kg}}$ / (% Mortality)
(13), 16% (22), 30% (36), 56% (60), 70% (101) 80%

Comments: Acute Contact

8-Day Dietary LC₅₀

LC₅₀ = pp (95% C.L.) Contr. Mort. (%) =

Species

Slope = # Animals/Level = Age (Days) =

Lab

Sex =

MRID # 416091-15 8-Day Dose Level pp / (% Mortality)
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Comments: ✓