

US EPA ARCHIVE DOCUMENT

EEB files

109901
SHAUGHNESSY NO.

45
REVIEW NO.

EEB REVIEW

DATE: IN 7-16-85 OUT SEP 6 1985

FILE OR REG. NO 3125-320
PETITION OR EXP. NO. _____
DATE OF SUBMISSION 5-8-85
DATE RECEIVED BY HED 7-15-85
RD REQUESTED COMPLETION DATE 11-4-85
EEB ESTIMATED COMPLETION DATE 10-28-85
RD ACTION CODE/TYPE OF REVIEW 400/Data

TYPE PRODUCT(S) : I, D, H, F, N, R, S Fungicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Bayleton

COMPANY NAME Mobay Chemical Corporation

SUBMISSION PURPOSE Submission of further data to support registration. Data are relative to triazolylalanine, a plant metabolite.

SHAUGHNESSY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>109901</u>	<u>1-(4-chlorophenoxy)-3, 3-dimethyl-1-</u>	
	<u>(1H-1,2,4-triazol-1-yl)-2-butanone</u>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 6 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Bayleton Metabolite, Triazolylalanine,
Submission of Bobwhite and Mallard LC₅₀

THRU: Raymond W. Matheny, Head-Section 1 *Raymond W. Matheny*
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Michael W. Slimak, Chief *MSlimak*
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

TO: Henry Jacoby, Product Manager (21)
Registration Division (TS-767-C)

Both the voluntarily submitted avian studies follow the Pesticide Assessment Guidelines. This metabolite has not previously been reported to the Ecological Effects Branch. Also, no persistence, bioaccumulation or other environmental fate information is available. Therefore, the Ecological Effects Branch will defer a request for further studies (acute aquatic tests) until the environmental fate data are available.

Dennis J. McLane

Dennis J. McLane, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

Mobay



Eq MO #
3125-320

D. McClane
557 7560

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Mobay
Chemical Corporation

Agricultural
Chemicals Division

P.O. Box 4913
Hawthorn Road
Kansas City, MO 64120
Cable: Kemagro Kansas City
Telephone: 816/242-2000

May 8, 1985

Mr. Henry M. Jacoby
Product Manager (21)
Environmental Protection Agency
Registration Division (TS-767C)
Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Metabolite of Bayleton

Subject: Human Safety and Wildlife Data on Triazolylalanine

Dear Mr. Jacoby:

As we have mentioned in previous correspondence on this subject, Bayer AG, Ciba-Geigy AG, Imperial Chemical Industries PLC and a new participant, Rohm & Haas Company have developed a number of triazole fungicides. In the course of the work on the metabolism of these active ingredients it was found that triazolylalanine can occur as a metabolite in plants.

On the other hand this metabolite could not be found in animals. Therefore it became necessary to specifically evaluate the toxicological aspect of triazolylalanine in order to estimate the relevance of residues to warm-blooded animals and in particular to humans.

The above mentioned companies have jointly carried out the necessary studies or had them carried out by contract institutions and are now providing the reports as well as a summarizing assessment.

We are enclosing a document entitled: "Human Safety and Wildlife Data on Triazolylalanine (TA)" dated April 1985, which contains additional information on Triazolylalanine. Many of the studies mentioned in the list of references under Tab A in this document have been sent to you previously, therefore, they are not duplicated in this submission.

A two-generation reproduction study in rats is in progress and a final report is expected by December 1985. It will be sent to you immediately after receipt.

Bayleton and Baytan
metabolite

DATA EVALUATION RECORD

1. CHEMICAL: Triazolylalanine (600011)
2. TEST MATERIAL: Triazolylalanine (TRA) Batch No. TLB 1207,
Purity 97.5%
3. STUDY TYPE: Bobwhite Quail - Dietary LC50
4. STUDY ID: Beavers, J.B. and Jaber, M. (1983). A Dietary LC50
in the Bobwhite with CGA-131013, Final Report,
Project NO.:108-221, Wildlife International Ltd.,
Submitted by Ciba Geigy Corp., for file No., 3125-320
on 5-15-85. Acc # 257997.
5. REVIEWED BY:
Dennis J. McLane
Wildlife Biologist
EEB/HED
Signature: Dennis J. McLane
Date: 9-6-85
6. APPROVED BY:
Raymond W. Matheny
Supervisory Biologist
EEB/HED
Signature: Raymond W. Matheny
Date: 9-6-85
7. CONCLUSION:
This study is scientifically sound and meets guideline requirements. The LC50 of >5000 ppm indicates that this pesticide is practically nontoxic (Brooks, et al. 1973) to bobwhite quail.
8. RECOMMENDATIONS: N/A
9. BACKGROUND: Received on 5-15-85, this submission dated 5-8-85 was validated 8-30-85 by D. McLane. The company identified and submitted data on this metabolite voluntarily.
10. DISCUSSION OF INDIVIDUAL TEST: N/A
11. MATERIALS AND METHODS:
 - A. Species: Bobwhite Quail
Source: Sand Prairie Quail farm, Maquoketa, Iowa
Weight: 21 grams at day 0
Age: 12 days
 - B. Design: Ten animals per levels; 1 dose levels of 5000 ppm plus 5 control level each containing 10 birds.
 - C. Statistics: N/A

12. REPORTED RESULTS: (Excerpted from Citation)

Controls - There were no mortalities in the negative control group (see Table 1). A few birds in one levels were observed with lesions of nostril picking on Day 5 and one additional bird in a different level was noted with lesions of this form of cannibalism on Day 8. All other birds were normal in appearance and behavior throughout the test period.

CGA-131013 - There was one mortality at the 5000 ppm concentration (see Table 2). This bird was found dead on Day 3 with extensive lesions of the toe and nostril picking. This mortality was attributed to cannibalism and was not considered to be treatment related. All other birds appeared normal throughout the test period, and no effect was observed on body weight or feed consumption (see Tables 3 and 4). The LC₅₀ value of CGA-131013 was determined by inspection to be greater than 5000 ppm.

13. STUDY AUTHOR'S CONCLUSIONS/QA MEASURES:

Six separate audits were made: procedures, procedure, protocol, data, draft, and final report. Also this was signed by Lee F. Daggett, the Quality Assurance Officer.

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

A. TEST PROCEDURES: The study followed the guideline protocols.

B. STATISTICAL ANALYSIS:

The one dosage level negated the use of statistics.

C. DISCUSSION/RESULTS:

The study is sufficient for the purposes of registration.

D. ADEQUACY OF STUDY:

1. Category: Core

2. Rationale: The guidelines intent has been met.

3. Repair: N/A

15. COMPLETION OF ONE-LINER: Completion 8-29-85

16. CBI APPENDIX: N/A

RIN 5710-93

TRIADMEFON EFB REVIEW

Page ___ is not included in this copy.

Pages 6 through 7 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Bayle ton and Baylan
metabolite

DATA EVALUATION RECORD

- 1. CHEMICAL: Triazolynanine (600011 / Summary = "metabolite" of triazole comp)
- 2. TEST MATERIAL: Triazolylalanine (TRA) Batch No. TLB 1207
Purity 97.5%
- 3. STUDY TYPE: Mallard Duck - Dietary LC50 study
- 4. STUDY ID: Beavers, J.B. and Jaber, M. (1983). A Dietary LC50 in the Mallard with CGA-131013, Final Report, Project NO.: 08-222, Wildlife International Ltd., Submitted by Ciba Geigy Corp., for file No., 3125-320 on 5-15-85. Acc # 257997.

5. REVIEWED BY:

Dennis J. McLane
Wildlife Biologist
EEB/HED

Signature: Dennis J. McLane
Date: 9-6-85

6. APPROVED BY:

Raymond W. Matheny
Supervisory Biologist
EEB/HED

Signature: Raymond W. Matheny
Date: 9-6-85

7. CONCLUSION:

This study is scientifically sound and meets guideline requirements. The LC50 of >5000 ppm indicates that this pesticide is practically nontoxic (Brooks, et al. 1973) to mallard duck.

8. RECOMMENDATIONS: N/A

9. BACKGROUND: Received on 5-15-85, this submission dated 5-8-85 was validated 8-30-85, by D. McLane. The company identified and submitted data on this metabolite voluntarily.

10. DISCUSSION OF INDIVIDUAL TEST: N/A

11. MATERIALS AND METHODS

- A. SPECIES: Anas platyrhynchos SOURCE: Whistling Wings
WEIGHT: 125 Grams at Day 0 AGE: 10 days
- B. DESIGN: 10 animals per level; 1 dose levels of 5000 ppm and 5 control levels of 10 birds each.
- C. STATISTICS: N/A

12. REPORTED RESULTS: (Excerpted from Citation)

Controls - There were no mortalities in the negative control group (see Table 1). All birds were in appearance and behavior throughout the test period.

CGA-131013 - CGA-131013 did not cause mortality, overt symptoms of toxicity or behavioral abnormalities at 5000 ppm, the only concentration tested (see Table 2). Thus, the LC₅₀ value of CGA-131013 was determined by inspection to be greater than 5000 ppm. No effect on body weight or feed consumption was noted at that level (see Tables 3 and 4).

13. STUDY AUTHOR'S CONCLUSIONS:

The following audits were performed: Procedure, Protocol, Data, Data, Draft, and Final Report. This schedule of audits was signed by Lee F. Daggett, on 8-2-85.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY

A. TEST PROCEDURES: The study followed the guideline protocol.

B. STATISTICAL ANALYSIS:

Only one level (5000 ppm) was tested negating the need for the statistical interpretation of the data.

C. DISCUSSION/RESULTS:

The study is adequate for meeting the guideline requirements.

D. ADEQUACY OF STUDY:

1. Category: Core

2. Rationale: The procedure required by the guidelines were followed.

3. Repair: N/A

15. COMPLETION OF ONE-LINER: Completion 8-29-85

16. CBI APPENDIX: N/A

RIN 5710-93

TRIADMEFON EFB REVIEW

Page is not included in this copy.

Pages 10 through 11 are not included.

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- Identity of product inert ingredients.
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