

8-9-95

DP Barcode : D217123  
PC Code No : 083601  
EEB Out : 8/9/95

To: Lisa Engstrom  
Product Manager 62  
Special Review and Reregistration Division (7508W)

From: Anthony F. Maciorowski, Chief  
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 0099  
Chemical Name : Fentin hydroxide  
Type Product : fungicide  
Product Name : Du-ter  
Company Name :  
Purpose : Review additional data required for avian studies.

Action Code: 811  
Reviewer: Dennis McLane

Date Due: 9/9/95

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

| GDLN NO  | MRID NO  | CAT | GDLN NO  | MRID NO | CAT | GDLN NO   | MRID NO | CAT |
|----------|----------|-----|----------|---------|-----|-----------|---------|-----|
| 71-1 (A) |          |     | 72-2 (A) |         |     | 72-7 (A)  |         |     |
| 71-1 (B) |          |     | 72-2 (B) |         |     | 72-7 (B)  |         |     |
| 71-2 (A) |          |     | 72-3 (A) |         |     | 122-1 (A) |         |     |
| 71-2 (B) |          |     | 72-3 (B) |         |     | 122-1 (B) |         |     |
| 71-3     | 43178501 | Y   | 72-3 (C) |         |     | 122-2     |         |     |
| 71-4 (A) | 43178502 | Y   | 72-3 (D) |         |     | 123-1 (A) |         |     |
| 71-4 (B) |          |     | 72-3 (E) |         |     | 123-1 (B) |         |     |
| 71-5 (A) |          |     | 72-3 (F) |         |     | 123-2     |         |     |
| 71-5 (B) |          |     | 72-4 (A) |         |     | 124-1     |         |     |
| 72-1 (A) |          |     | 72-4 (B) |         |     | 124-2     |         |     |
| 72-1 (B) |          |     | 72-5     |         |     | 141-1     |         |     |
| 72-1 (C) |          |     | 72-6     |         |     | 141-2     |         |     |
| 72-1 (D) |          |     |          |         |     | 141-5     |         |     |

Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur

1/14

DP BARCODE: D217123

CASE: 838877  
SUBMISSION: S490048

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 07/11/95  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: SPECIAL REVIEW ACTION: 811 RISKASSESSMENT

CHEMICALS: 083601 Fentin hydroxide

100.00 %

ID#: 083601

COMPANY:

PRODUCT MANAGER: 62 LISA ENGSTROM *JUDE* 703-308-8031 ROOM: CS1 2N6

PM TEAM REVIEWER: ~~NILOUFAR NAZMI~~ *ANDREASEN* 703-308-~~8028~~ ROOM: CS1 2C5

RECEIVED DATE: 07/06/95 DUE OUT DATE: 09/04/95 *8016*

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 217123 EXPEDITE: N DATE SENT: 07/11/95 DATE RET.: / /

CHEMICAL: 083601 Fentin hydroxide

DP TYPE: 001 Submission Related Data Package

CSF: N

LABEL: N

| ASSIGNED TO | DATE IN        | DATE OUT       | ADMIN DUE DATE: 09/09/95 |
|-------------|----------------|----------------|--------------------------|
| DIV : EFED  | <i>7/11/95</i> | <i>/ /</i>     | NEGOT DATE: <i>/ /</i>   |
| BRAN: EEB   | <i>7/12/95</i> | <i>8/14/95</i> | PROJ DATE: <i>/ /</i>    |
| SECT: IO    | <i>/ /</i>     | <i>/ /</i>     |                          |
| REVR :      | <i>/ /</i>     | <i>/ /</i>     |                          |
| CONTR:      | <i>/ /</i>     | <i>/ /</i>     |                          |

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review this additional data which we required on avian studies with TPTH, as per review by Dennis McLane dated 9/14/94 of MRID 43178501 and 43178502. Please determine if these studies now satisfy guidelines 71-4(a) and (b). Respond to Jude Andreasen of SRB, not to the reviewers listed above.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|-------|----------------|----------|----------|-----|-----|-------|
|-------|----------------|----------|----------|-----|-----|-------|

Addendum to  
DATA EVALUATION RECORD  
§ 71-4 Avian Reproduction Study  
Bobwhite Quail

1. CHEMICAL: TPTH
2. TEST MATERIAL: TPTH 97.9% (Batch No. GFRAM 911K; 97.9%; CAS No. 76-87-9) was a fine, white powder with a characteristic odor.
3. CITATION:

Author: Carol A. Pederson,  
Connie L. Lesar  
Title: Toxicity and Reproduction  
Study in Bobwhite Quail  
Date: January 24, 1994  
Laboratory Report #: BLAL No. 106-009-07  
Any Other Study #: N/A  
Sponsor: Elf Atochem North America,  
Inc., Philadelphia, PA  
Laboratory: Bio-life Associates, Ltd  
MRID No.: 43178501

4. REVIEWED BY:

*D. J. McLane* 8-3-95  
Dennis J. McLane, Wildlife Biologist  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507 C)

5. APPROVED BY:

*Les Touart* 8.8.95  
Les Touart, Section Head  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507 C)

6. CONCLUSION: This study is scientifically sound and fulfills the guideline requirements. The no-effect-level and the lowest effect level are 3 ppm and 30 ppm, respectively. A letter from Biolife adequately addressed the questions raised in the initial DER. Following is a list of those questions and attached is the portion of the letter which corresponds to those questions:

1. The report omitted the scientific explanation for removing the small eggs.
2. It was reported that the birds were treated with an antibiotic but the illness was not reported.
3. The dosage levels were separated by a factor of three rather than five.
4. The rationale for using more than 2% total vehicle was not included. The guidelines indicate only 2% total vehicle, in this study 2% corn oil was used and 1%

acetone or a total of 3%.

EEB found the rational and information supplied adequate.

---

TPTH

---

Page \_\_\_\_\_ is not included in this copy.

Pages 5 through 7 are not included in this copy.

---

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.

---

Addendum to  
DATA EVALUATION RECORD  
§ 71-4 Avian Reproduction Study  
Mallard

1. CHEMICAL: TPTH
2. TEST MATERIAL: TPTH (Batch No. GFRAM 911K; 97.9%; CAS No. 76-87-9) was a fine, white powder with a characteristic odor.

3. CITATION:

Author: Carol A. Pederson,  
Connie L. Lesar  
Title: Toxicity and Reproduction  
Study in Mallard Ducks  
Date: January 24, 1994  
Laboratory Report #: BLAL No. 106-010-08  
Any Other Study #: N/A  
Sponsor: Elf Atochem North America,  
Inc., Philadelphia, PA  
Laboratory: Bio-life Associates, Ltd  
MRID No.: 45178502

4. REVIEWED BY:

*[Signature]* 8-3-95  
Dennis J. McLane, Wildlife Biologist  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507 C)

5. APPROVED BY:

*[Signature]* 8-8-95  
Les Touart, Section Head  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507 C)

6. CONCLUSION: This study is scientifically sound and fulfills the guideline requirements TPTH at 30 and 90 ppm cause many reproductive effects. The no-effect-level and the lowest effect level are 3 ppm and 30 ppm, respectively. A letter from Biolife adequately addressed the questions raised in the initial DER. Following is a list of those questions and attached is the portion of the letter which corresponds to those questions:

1. The report omitted the scientific explanation for removing the small eggs.
2. It was reported that the birds were treated with an antibiotic but the illness was not reported.
3. The dosage levels were separated by a factor of three rather than five.
4. The rationale for using more than 2% total vehicle was not included. The guidelines indicate only 2% total vehicle, in this study 2% corn oil was used and 1% acetone or a total of 3%.

5. Food consumption weight per pen (replicate) was not submitted.

Attached is the letter with their responses. In addition the printout for the food consumption data using chicks.sas is also attached. This statistical analysis showed no differences between the control and any of the treatment levels. EEB found the rational and information supplied adequate.

---

TPTH

---

Page \_\_\_\_\_ is not included in this copy.

Pages 10 through 18 are not included in this copy.

---

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.

---