

US EPA ARCHIVE DOCUMENT

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: ~~HELOUFAR 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	7/11/95	/ /	NEGOT DATE: / /
BRAN: EEB	7/12/95	8/14/95	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * 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
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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:

Dennis 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, Section Head *LTC* 8-8-95
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 14 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.

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