

8-9-95



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

AUG - 9 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Reconsideration for Guideline Acceptance of the Shell Deposition Study with Eastern Oyster (43212701) (D215275) and the Bobwhite Quail (43178501) and Mallard (43178502) Duck Reproduction Studies (D217123)

FROM: Anthony Maciorowski, Chief *W/Cwk for 08/09/95*
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

TO: Jude Andreasen, Team Reviewer,
Team 71
Special Review and Reregistration Division (7508W)

The submission from Elf Atochem is in response to the failure of the subject studies to fulfill guideline requirements. The information and explanation provided in connection with the avian reproduction studies were sufficient. Both the bobwhite and mallard studies will be upgraded to CORE or fulfills guideline requirements. (see attached addenda)

The acute exposure ^{WITH} eastern oyster is the most sensitive of all the aquatic species tested. The following is a list of the most sensitive aquatic acute tests and their results:

Table TPTH's of Most Sensitive Aquatic Acute Tests			
Species	Percent A.I.	Exposure (hour)	Results
Estuarine/Marine Species			
Eastern oyster	97.23	96	0.36 µg/L
Mysid	Technical	96	3.7 µg/L
Spot	100	48	46 µg/L
Freshwater Species			
Water flea	97.3	48	10 µg/L
Fathead minnow	Formulation	96	23.5 µg/L

Rainbow trout	'97	96	22 µg/L
Rainbow trout	Formulation	96	14.5 µg/L
Freshwater mussel	47.5	96	4.2 mg/L

Because tests with this species produce an EC₅₀ an order of magnitude less than the other studies, it is critical to the TPTH aquatic risk assessment. Therefore, a test unencumbered by poor control performance is considered necessary for an unambiguous risk assessment. The oyster study must be repeated.

Please contact Dennis McLane of EEB if any further information is needed (305-5096).

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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

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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.: 48178502

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 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

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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.

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