

US EPA ARCHIVE DOCUMENT

(4-27-95)

DP Barcode : D205500
PC Code No : 110301
EEB Out :

To: Kathryn Davis
Chemical Review Manager 52
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 # : 110301-033068
Chemical Name : Erioglaucine
Type Product : Herbicide
Product Name : Aquashade
Company Name : Aquashade Inc.
Purpose : Submission of acute aquatic toxicity data in support of reregistration of Case No. 4010.

Action Code : 627 Date Due : 10/13/94
Scientist : C. Laird Date In : 07/25/94

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)	432975-03	Y	72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			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)	432975-02	Y	72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)	432975-01	Y				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

DP BARCODE: D205500

REREG CASE # 4010

CASE: 816361
SUBMISSION: S469956

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/15/94
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 CORE DATA
CHEMICALS: 110301 Erioglaucine

100.00 %

ID#: 110301-033068

COMPANY:

PRODUCT MANAGER: 52 KATHRYN DAVIS

703-308-8156 ROOM: CS1 3F3

PM TEAM REVIEWER: BONNIE ADLER

703-308-8523 ROOM: CS1 4N4

RECEIVED DATE: 07/08/94 DUE OUT DATE: 10/06/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 205500 EXPEDITE: N DATE SENT: 07/15/94 DATE RET.: / /

CHEMICAL: 110301 Erioglaucine

DP TYPE: 999 Miscellaneous Data Package

CSF: N

LABEL: N

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 10/13/94

DIV : EFED

07/25/94

/ /

NEGOT DATE: / /

BRAN: EEB

07/25/94

/ /

PROJ DATE: / /

SECT:

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/ /

REVR :

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CONTR:

/ /

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* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following data for the chemical Aquashade
(includes acid blue 9 and acid yellow 23);

GDLN 72-1d; Acute Tox in Rainbow Trout; MRID 43297501

GLDN 72-1b; Acute Tox in Bluegill; MRID 43297502

GDLN 72-2b; Acute Tox in Daphnia; MRID 43297503

Please review this information and see if these studies
fulfill data requirements.

* * * 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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2

100.0 Pesticide Name: Erioglaucine (aquashade)

100.3 Submission Purpose: Submission of three acute freshwater studies

101.0 Chemical and Physical Properties

101.1 Chemical Name:

Erioglaucine

101.2 Common Name:

Aquashade

1.3.0 Toxicological Properties:

96-hour LC_{50} for rainbow trout;
96-hour LC_{50} for bluegill sunfish; and
48-hour LC_{50} for Daphnia magna.

105.0 Conclusions:

A. Rainbow Trout (432975-01)

This study is scientifically sound and meets the guideline requirements for a formulated product using the rainbow trout. The 96-hour LC_{50} was >96 mg/L based on mean measured concentration which classifies aquashade as practically nontoxic to coldwater fish. The NOEC was 96 mg/L.

B. Bluegill Sunfish (432975-02)

This study is scientifically sound and meets the guideline requirements using a formulated product for bluegill sunfish. The 96-hour LC_{50} was >96 mg/L based on mean measured concentration which classifies aquashade as practically nontoxic to bluegill sunfish. The NOEC was 96 mg/L.

C. Daphnia magna (432975-03)

This study is scientifically sound and meets the guideline requirements using a formulated product for Daphnia magna. The 48-hour LC_{50} was >97 mg/L based on mean measured concentration which classifies aquashade as practically nontoxic to Daphnia magna. The NOEC was 97 mg/L.

The above data fulfill the guideline requirements for 72-1(b), 72-1(d), and 72-2(b) in support of reregistration of erioglaucine.

Curtis E. Laird 4-25-95
Curtis E. Laird, Fishery Biologist

Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Norman J. Cook 04-25-95
Norman J. Cook, Head-Section #2

Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Anthony F. Macri 4/27/95
Anthony F. Macri, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

DATA EVALUATION RECORD

1. **CHEMICAL:** Erioglaucine, Chemical Code: 110301, MRID No. 432975-01.
2. **TEST MATERIAL:** Aquashade; Acid Blue 9--23.63%, Acid Yellow 23--2.39%; Inerts 73.98% (a purity of 13.9% Azure blue dye).
3. **STUDY TYPE:** 96-Hour LC₅₀ for freshwater fish

Species Tested: Rainbow Trout
(Oncorhynchus mykiss)

4. **CITATION:** Graves, W.C. and Swigert, J.P. (1994) - Aquashade: 96-Hour Static Acute Toxicity Test With Rainbow Trout (Oncorhynchus mykiss) Project No. 196A-107A. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Applied Biochemists, Inc., 6120 West Douglas Avenue, Milwaukee, Wisconsin 53218, MRID No. 432975-01.

5. **REVIEWED BY:**

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-25-95

6. **APPROVED BY:**

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 04-25-95

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a formulated product using the rainbow trout. The 96-hour LC₅₀ was >96 mg a.i./l based on mean measured concentration which classifies Aquashade as practically non-toxic to rainbow trout. The NOEC was 96 mg a.i./l.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:** This study was submitted in support of Aquashade reregistration.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Juvenile rainbow trout (Oncorhynchus mykiss) were obtained from Aquatic Research Organisms, Hampton, NH 03842. Food was withheld for 48 hours prior to testing. During the 30-day period prior to test initiation, fish were acclimated to test conditions for 50 hours. During the 14-day holding prior to testing, temperature ranged from 12.2 to 15.0 °C. During acclimation, the fish appeared healthy with no signs of disease or stress and no mortality occurred.

All fish used in the test were from the same year class. The average length of 10 control fish at the end of the test was 40 mm with an average weight of 0.87 g.

- B. Test System: Fish were tested in a 21-L glass aquaria with 15 L of test solution, temperature was 12±1°C, pH was 7.9, D.O. was 8.0 mg/L, photoperiod was 16L/8D with a 30 minutes transition period. Light intensity at the test solution surface was approximately 764 lux.
- C. Dosage: One dosage level (96 mg/L) with three replicates of ten fish per replicate and a dilution water control with three replicates of ten fish per replicate were tested.

- D. Design: Loading during the test was 0.58 g/L.

Observations of mortality and treatment-related effects were made at 5, 24, 48, 72, and 96 hours. The dissolved oxygen concentration (DO) and pH were measured in alternating replicates at the beginning of the test and at each 24-hour intervals. The temperature of one of the control chambers was monitored continuously and measured in each replicate vessel at the beginning and end of the test.

- E. Statistics: The 96-hour LC₅₀ value was visually determined since there was no mortality during the test.

12. REPORTED RESULTS: The mean measured concentration was 96 mg/L. No mortality or sublethal effects were noted in any test chamber during the study. The 96-hour LC₅₀

value for rainbow trout was >96 mg a.i./L. The no mortality concentration was 96 mg a.i./L.

During the test, the DO ranged from 9.0 to 10.2 mg/l (>60% of saturation). The pH was 7.9 based on individual measurements, and the temperature was 12± 1°C.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards set forth in 40 CFR Part 160. The dates and types of quality assurance audits were reported.

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

- A. Test Procedure: The test procedures were generally in accordance with the SEP, except for the following:

The test was conducted using a formulated product; technical grade is required.

NOTE: Measured concentrations represent Aquashade determined from measured concentrations of azure blue dye [REDACTED]

- B. Statistical Analysis: Due to no mortality, the LC₅₀ value was > 96 mg/L. The no-observed-effect concentration (NOEC) was 96 mg a.i./l.
- C. Discussion/Results: This study is scientifically sound and meets the guideline requirements for freshwater fish acute toxicity test using rainbow trout. The 96-hour LC₅₀ was >96 mg a.i./l based on mean measured concentration which classifies aquashade as practically non-toxic to rainbow trout. The NOEC was 96 mg a.i./l.
- D. Adequacy of the Study:
- (1) Classification: Core for a formulated product.
 - (2) Rationale: A formulated product was used consisting of 2 active ingredients: Acid Blue 9--23.63% and Acid Yellow 23--2.39% = 26.02% a.i.
 - (3) Repairability: Not repairable to core for technical grade material.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 01-05-93.

DATA EVALUATION RECORD

1. **CHEMICAL:** Erioglaucine, Chemical Code: 110301, MRID No. 432975-02
2. **TEST MATERIAL:** Aquashade; Acid Blue 9--23.63%, Acid Yellow 23--2.39%; Inerts 73.98% (a purity of 13.9% a.i. Azure blue dye).
3. **STUDY TYPE:** 96-Hour LC₅₀ For warmwater fish

Species Tested: Bluegill Sunfish
Lepomis macrochirus)
4. **CITATION:** Graves, W.C. and Swigert, J.P. (1994).
Aquashade: 96-Hour Static Acute Toxicity Test With Bluegill Sunfish (Lepomis macrochirus) Project No. 196A-108.
Prepared by Wildlife International Ltd., Easton, MD.
Submitted by Applied Biochemists, Inc., 6120 West Douglas Avenue, Milwaukee, Wisconsin 53218; MRID No. 432975-02.
5. **REVIEWED BY:**

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-25-95
6. **APPROVED BY:**

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman Cook
Date: 04.25.95
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements using a formulated product for bluegill sunfish. The 96-hour LC₅₀ was >96 mg a.i./l mean measured concentration which classifies Aquashade as practically non-toxic to bluegill sunfish. The NOEC was 96 mg a.i./l.
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:** This study was submitted in support of Aquashade reregistration.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Juvenile bluegill sunfish (Lepomis macrochirus) were obtained from Northeastern Biologists, Inc. P.O. Box 162, Rhinebeck, New York 12572. Food was withheld for 48 hours prior to testing. During the 14-day holding prior to testing, temperature ranged from 20.0 to 21.3 °C. During acclimation, the fish appeared healthy with no signs of disease or stress and no mortality occurred.

All fish used in the test were from the same year class. The average length of 10 control fish at the end of the test was 21 mm with an average weight of 0.26 g.

- B. Test System: Fish were tested in a 21-L glass aquaria with 15 L of test solution, temperature was 22±1°C, pH was 8.4, D.O. was 7.4 mg/L, photoperiod was 16L/8D with a 30 minutes transition period. Light intensity at the test solution surface was approximately 658 lux.

- C. Dosage: One dosage level (96 mg/L) with three replicates of ten fish/replicate and a dilution water control with three replicates of ten fish/replicate were tested.

- D. Design: Loading during the test was 0.17 g/L.

Observations of mortality and treatment-related effects were made at 5, 24, 48, 72, and 96 hours. The dissolved oxygen concentration (DO) and pH were measured in alternating replicates at the beginning of the test and at each 24-hour observation. The temperature in one of the control chambers was monitored continuously and measured in each replicate vessel at the beginning and end of the test.

- E. Statistics: The 96-hour LC₅₀ value was visually determined since there was no mortality during the test. Stephan's computer program was not used due to lack of mortality

12. REPORTED RESULTS: The mean measured concentration was 96 mg/L. No mortality or sublethal effects were noted in any test chamber during the study. The 96-hour LC₅₀ value for bluegill sunfish was 96 mg/L.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards set forth in 40 CFR Part 160. The dates and types of quality assurance audits were reported. The substance characterization and stability were not conducted in conformance with Good Laboratory Practice Standards.

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

- A. Test Procedure: The test procedures were generally in accordance with the SEP, except for the following:

The test was conducted using a formulated product. Technical grade is required.

NOTE: Measured concentrations represent Aquashade determined from measured concentrations of Azure Blue dye [REDACTED]

- B. Statistical Analysis: Due to no mortality, the LC_{50} value was > 96 mg/L. The no-observed-effect concentration (NOEC) was 96 mg a.i./l.
- C. Discussion/Results: This study is scientifically sound and meets the guideline requirements for freshwater fish acute toxicity test using bluegill sunfish. The 96-hour LC_{50} was >96 mg a.i./l based on mean measured concentration which classifies aquashade as practically non-toxic to bluegill sunfish. The NOEC was 96 mg a.i./l.
- D. Adequacy of the Study:
- (1) Classification: Core for a formulated product.
 - (2) Rationale: A formulated product was used consisting of 2 active ingredients: Acid Blue 9--23.63% and Acid Yellow 23--2.39% = 26.02% a.i. or 13.9% a.i. of Azure Blue Dye.
 - (3) Repairability: Not repairable to core for technical grade material.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 01-05-93.

DATA EVALUATION RECORD

1. **CHEMICAL:** Erioglaucine, Chemical Code: 110301; MRID No. 432975-03.
2. **TEST MATERIAL:** Aquashade; Acid Blue 9--23.63%, Acid Yellow 23--2.39%; Inerts 73.98% (a purity of 13.9% a.i. Azure blue dye).
3. **STUDY TYPE:** 48-Hour LC₅₀ For aquatic freshwater invertebrate.
Species Tested: Cladoceran (Daphnia magna)
4. **CITATION:** Graves, W.C. and Swigert, J.P. (1994) - Aquashade: 48-Hour Static Acute Toxicity Test With The Cladoceran (Daphnia magna); Project No. 196A-109. Prepared by Wildlife International Ltd., Easton, MD And Submitted by Applied Biochemists, Inc., 6120 West Douglas Avenue, Milwaukee, Wisconsin 53218; MRID No. 432975-03.
5. **REVIEWED BY:**

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-25-95
6. **APPROVED BY:**

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 04-25-95
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements using a formulated product for Daphnia magna. The 48-hour LC₅₀ was >97 mg a.i./l based on mean measured concentration which classifies Aquashade as practically non-toxic to Daphnia magna. The NOEC was 97 mg a.i./l.
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:** This study was submitted in support of Aquashade reregistration.
10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: First instar Daphnia magna from laboratory culture were used. Daphnids were not fed during testing.
- B. Test System: Daphnids were tested in 300-ml glass beakers; temperature was $20 \pm 1^\circ\text{C}$, pH was 8.3; D.O. was 8.2 mg/L; photoperiod was 16L/8D with a 30 minutes transition period. Light intensity at the test solution surface was approximately 696 lux at the water surface.
- C. Dosage: One dosage level (96 mg/L) with three replicates and a dilution water control with three replicates were tested.
- D. Design: Loading ten daphnids per test chamber.

Observations of mortality and treatment-related effects were made at 6, 24, and 48 hours. The dissolved oxygen concentration (DO) exceeded 60 % of saturation throughout the test. Measurement of pH, D.O., and temperature were made every twenty-four hours.

- E. Statistics: The 48-hour LC_{50} value was visually determined since there was no mortality during the test. Stephan's computer program was not used due to lack of mortality
12. REPORTED RESULTS: The mean measured concentration was 96 mg/L. No mortality or sublethal effects were noted in any test chamber during the study. The 96-hour LC_{50} value for daphnid was $>97 \text{ mg a.i./l}$. The no mortality concentration was 96 mg a.i./L.

During the test, the D.O. was 8.2 mg/l ($>60\%$ of saturation). The pH value ranged from 8.2 to 8.3; temperature was $20 \pm 1^\circ\text{C}$.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards set forth in 40 CFR Part 160. The dates and types of quality assurance audits were reported.

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

- A. Test Procedure: The test procedures were generally in accordance with the SEP, except for the following:

The test was conducted using a formulated product (13.9% a.i. Azure Blue dye or 26.02% Aquashade); technical grade is required.

NOTE: Measured concentrations represent Aquashade determined from measured concentrations of Azure Blue Dye in water.

- B. Statistical Analysis: Due to no mortality, the LC_{50} value was > 97 mg/L. The no-observed-effect concentration (NOEC) was 97 mg a.i./l.
- C. Discussion/Results: This study is scientifically sound and meets the guideline requirements for freshwater invertebrate acute toxicity test using Daphnia magna. The 48-hour LC_{50} was >97 mg a.i./l based on mean measured concentration which classifies aquashade as practically non-toxic to Daphnia magna. The NOEC was 97 mg a.i./l.
- D. Adequacy of the Study:
- (1) Classification: Core for a formulated product.
 - (2) Rationale: A formulated product was used consisting of 2 active ingredients: Acid Blue 9--23.63% and Acid Yellow 23--2.39% = 26.02% a.i. or 13.9% a.i. of Azure Blue Dye.
 - (3) Repairability: Not repairable to core for technical grade material.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 08-04-94.

Shaughnessy No. 110311

Chemical Name

ERIOGLAUCINE (AQUASHADE)

Chemical Class

Page

1 of

8-4-94

Study/Species/Lab/

Chemical
S.I.

Results

Reviewer/
DateValidation
Status

14-Day Single Dose Oral LD50.

Species:

LD50 = mg/kg (95% C.L.) Contr. Mort. (%) =

Lab.:

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

Acc. #:

14-Day Dose Level mg/kg/(% Mortality) Sex =

Comments:

14-Day Single Dose Oral LD50.

Species:

LD50 = mg/kg (95% C.L.) Contr. Mort. (%) =

Lab.:

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

Acc. #:

14-Day Dose Level mg/kg/(% Mortality) Sex =

Comments:

8-Day Dietary LC50.

Species:

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

Lab.:

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

Acc. #:

8-Day Dose Level ppm/(% Mortality) Sex =

Comments:

8-Day Dietary LC50.

Species:

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

Lab.:

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

Acc. #:

8-Day Dose Level ppm/(% Mortality) Sex =

Comments:

96-hour LC50.

Species: BROWN TROUTLab: Wildlife Intl.13.9

Acc. #:

MRID # 432975-01LC50 = 96 PPM (95% C.L.) Contr. Mort. (%) = 0Slope = NA # Animals/Level = 30 Sol. Contr. Mort. (%) = N/A96-hour Dose Level ppm/(% Mortality) Temperature = 12±1°C 8-4-94 CoreComments: Core for formulated product

96-hour LC50.

Species: BluegillLab.: Wildlife Intl.13.9

Acc. #:

MRID # 432975-02LC50 = 96 PPM (95% C.L.) Contr. Mort. (%) = 0Slope = N/A # Animals/Level = 30 Sol. Contr. Mort. (%) = N/A96-hour Dose Level ppm/(% Mortality) Temp. = 21.8°C 8-4-94 CoreComments: Core for formulated product

48-hour Invertebrate.

Species: Daphnia magnaLab.: Wildlife Intl.13.9

Acc. #:

MRID # 432975-03LC50 = 97 PPM (95% C.L.) Contr. Mort. (%) = 0Slope = N/A # Animals/Level = 30 Sol. Contr. Mort. (%) = N/A96-hour Dose Level ppm/(% Mortality) Temp. = 21.8 8-4-94 CoreComments: Core for Formulated Product