DP Barcode : D206684
PC Code No : 110301
EEB Out : 08-31-94

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 avian toxicity data in support of reregistration of Case No. 4010.

Action Code : 627 Date Due : 11/16/94
Scientist : K. Valente Date In : 08/22/94

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)	433367-01 433367-02	Y	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			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)			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

DP BARCODE: D206684

REREG CASE # 4010

CASE: 816361
SUBMISSION: S472012

DATA PACKAGE RECORD
BEAN SHEET

DATE: 08/19/94

* * * 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: 08/11/94 DUE OUT DATE: 11/09/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 206684 EXPEDITE: N DATE SENT: 08/18/94 DATE RET.: / /
CHEMICAL: 110301 Erioglaucine
DP TYPE: 999 Miscellaneous Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	08/22/94	/ /
BRAN: EEB	08/22/94	/ /
SECT:	/ /	/ /
REVR :	/ /	08/31/94
CONTR:	/ /	/ /

ADMIN DUE DATE: 11/16/94
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following avian oral toxicity study for the chemical aquashade-blue;

GDLN 71-1(b) Acute Oral Toxicity for Quail; MRID 43336701
GDLN 71-1(b) Acute Oral Toxicity for Ducks; MRID 43336702

* * * 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

2

DP BARCODE: D206685 REREG CASE # 4010

CASE: 816362 DATA PACKAGE RECORD DATE: 08/19/94
SUBMISSION: S472014 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 CORE DATA
CHEMICALS: 110302 Tartrazine 100.00 %

ID#: 110302-033068
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: 08/15/94 DUE OUT DATE: 11/13/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 206685 EXPEDITE: N DATE SENT: 08/18/94 DATE RET.: / /
CHEMICAL: 110302 Tartrazine
DP TYPE: 999 Miscellaneous Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	08/22/94	/ /
BRAN: EEB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 11/16/94
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following Acute Avian Oral Tox study for the chemical aquashade-yellow;

GDLN 71-1(b) Acute Oral Toxicity-Quail; MRID 43336701
GDLN 71-1(b) Acute Oral Toxicity-Duck; MRID 43336702

* * * 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

3

Data Evaluation Record

1. **Chemical**: Aquashade (Erioglaucine & tartrazine)
   Shaughnessy No.:110301 and 110302

2. **Test Material**: Aquashade Formulated Product, 26.2% a.i. (23.83% erioglaucine, 2.39% tartrazine), a blue liquid.

3. **Study type**: Avian Single-Dose Oral LD_{50}

   Test Species: Mallard duck (*Anas platyrhynchos*)

4. **Study ID**: Campbell, Susan M. and Joanne B. Beavers. 1994. AQUASHADE: An Acute Oral Toxicity Study with the Mallard. Conducted by Wildlife International, 8598 Commerce Drive, Easton, MD 21601, for Applied Biochemists, Inc., 6120 West Douglas Avenue, Milwaukee, WI 53218. WIL Project # 196-104. **MRID 433367-02.**

5. **Reviewed by**: Kathryn Valente-Montague, M.S. Signature: Kathryn V. Montague
   Biologist Date: 8/31/94
   EEB/EFED

6. **Approved by**: Norman Cook Signature: Norman J. Cook
   Head, Section II Date: 09/07/94
   EEB/EFED

7. **Conclusions**: The study is scientifically sound and meets the requirements for an avian acute oral LD_{50} study. With an LD_{50} of >2250 mg/kg, the formulated product is considered to be practically non-toxic to mallards. The NOEL was 2250 mg/kg.

8. **Recommendations**: N/A

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

10. **Discussion of Individual Tests**: N/A

11. **Materials and Methods**:

a. Test animals: Mallards were obtained from Whistling Wings, Hanover, Illinois. At test initiation, the birds were 22 weeks of age. The birds were acclimated for 15 days prior to test initiation. The birds were maintained on a 8 hour light/16 hour dark photoperiod at a temperature of 24.8 ± 1.2° C and relative humidity of 61 ± 11% during the acclimation and test periods. The ducks were housed in 75 x 90 x 45 cm wire cages. The birds were fasted for 19 hours prior to test initiation, but were provided Wildlife International's gamebird feed *ad libitum* during the rest of the testing period. Tap water was provided *ad libitum* throughout the study.

b. Dosing regime: The test substance was presented alone via oral gavage in the following nominal concentrations: 0.0 (control), 292, 486, 810, 1350 and 2250 mg/kg body weight. The doses were calculated for each bird so that all received a constant volume of 4 mL/kg body weight.

c. Study design: Ten birds, five males and five females, were assigned to each treatment level, including the controls. Observations for mortality and sublethal effects were made twice a day for 14 days post dosing. Body weights were measured at test initiation, and on days 3, 7 and 14. Average estimated feed consumption was measured for each group for days 0-3, 4-7 and 8-14.

d. Statistics: Normally, the computer program developed by C.E. Stephan is used to calculated the LD_{50}. However, in this case, the data did not fit the requirements of the program, so the LD_{50} was determined by visual inspection of the data.

12. Reported Results: Mallards were exposed to six concentrations of Aquashade: 0, 292, 486, 810, 1350 and 2250 mg/kg. There were no mortalities in the control or in any treatment group. No clinical sings of toxicity were noted during the test in the control or treatment groups. There were no effects on feed consumption or body weight during the study.

13. Study Author's Conclusions/Quality Assurance Report: Based on the observed results, the LD_{50} was >2250 mg/kg. The NOEC was 2250 mg/kg.

Quality Assurance and Good Laboratory Practice statements were included in the report.

14. Reviewer's Discussion and Interpretation of the Results:
a. Test Procedure: The test design and procedure were in accordance with protocols recommended by the Guidelines.

b. Statistical Analysis: The LD_{50} calculation was verified by visual inspection. The results were in agreement with the reported results.

c. Discussion/Results: The study is scientifically sound and in accordance with the Guidelines. The study is classified as core. With an LD_{50} of >2250 mg/kg, Aquashade is considered to be practically non-toxic to mallards.

d. Adequacy of the study:
(1) Classification: Core
(2) Rationale: N/A
(3) Repairability: N/A

Data Evaluation Record

1. **Chemical**: Aquashade (Erioglaucine & tartrazine)
   Shaughnessy No.:110301 and 110302

2. **Test Material**: Aquashade Formulated Product, 26.2% a.i. (23.83% erioglaucine, 2.39% tartrazine), a blue liquid.

3. **Study type**: Avian Single-Dose Oral LD_{50}

   Test Species: Bobwhite quail (Colinus virginianus)

4. **Study ID**: Campbell, Susan M. and Joanne B. Beavers. 1994. AQUASHADE: An Acute Oral Toxicity Study with the Northern Bobwhite. Conducted by Wildlife International, 8598 Commerce Drive, Easton, MD 21601, for Applied Biochemists, Inc., 6120 West Douglas Avenue, Milwaukee, WI 53218. WIL Project # 196-103A. **MRID 433367-01.**

5. **Reviewed by**: Kathryn Valente-Montague, M.S. Signature: Kathryn V. Montague
   Biologist Date:
   EEB/EFED

6. **Approved by**: Norman Cook Signature: Norman J. Cook
   Head, Section II Date: 09/07/94
   EEB/EFED

7. **Conclusions**: The study is scientifically sound and meets the requirements for an avian acute oral LD_{50} study. With an LD_{50} of >2250 mg/kg, the formulated product is considered to be practically non-toxic to Northern bobwhite. The NOEL was 2250 mg/kg.

8. **Recommendations**: N/A

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

10. **Discussion of Individual Tests**: N/A

11. **Materials and Methods**:
    a. Test animals: Bobwhite were obtained from Top Flight Quail, Belvedere, New Jersey. At test initiation, the birds were 35 weeks of age. The birds were acclimated for 13 weeks prior to test initiation. The birds were maintained on a 8 hour light/16 hour dark photoperiod at a temperature of 22.2 ± 2.1° C and relative humidity of 39 ± 10% during the acclimation and test periods. The quail were housed in 78 x 51 cm galvanized steel mesh cages with solid steel side walls. The birds were fasted for 19 hours prior to test initiation, but were provided Wildlife International's gamebird feed *ad*

libitum during the rest of the testing period. Tap water was provided *ad libitum* throughout the study.

b. Dosing regime: The test substance was presented alone via oral gavage in the following nominal concentrations: 0.0 (control), 292, 486, 810, 1350 and 2250 mg/kg body weight. The doses were calculated for each bird so that all received a constant volume of 4 mL/kg body weight.

c. Study design: Ten birds, five males and five females, were assigned to each treatment level, including the controls. Observations for mortality and sublethal effects were made twice a day for 14 days post dosing. Body weights were measured at test initiation, and on days 3, 7 and 14. Average estimated feed consumption was measured for each group for days 0-3, 4-7 and 8-14.

d. Statistics: Normally, the computer program developed by C.E. Stephan is used to calculated the LD_{50}. However, in this case, the data did not fit the requirements of the program, so the LD_{50} was determined by visual inspection of the data.

12. **Reported Results**: Bobwhite were exposed to six concentrations of Aquashade: 0, 292, 486, 810, 1350 and 2250 mg/kg. There were no mortalities in the control group, and one incidental mortality at 1350 mg/kg due to aggression from cagemates. One control bird exhibited lethargy, ruffling and reduced reaction to external stimuli in conjunction with a bruised head on day 2, but appeared normal by the afternoon of day 3. Several birds exhibited lameness and ruffling, apparently due to having their toenails trimmed before test initiation. No clinical sings of toxicity associated with treatment with the test chemical were noted during the test. There were no effects on feed consumption or body weight during the study.

13. **Study Author's Conclusions/Quality Assurance Report**: Based on the observed results, the LD_{50} was >2250 mg/kg. The NOEC was 2250 mg/kg.

Quality Assurance and Good Laboratory Practice statements were included in the report.

14. **Reviewer's Discussion and Interpretation of the Results**:
a. Test Procedure: The test design and procedure were in accordance with protocols recommended by the Guidelines.

b. Statistical Analysis: The LD_{50} calculation was verified by visual inspection. The results were in agreement with the reported results.

c. Discussion/Results: The study is scientifically sound and in accordance with the Guidelines. The study is classified as

core. With an LD_{50} of >2250 mg/kg, Aquashade is considered to be practically non-toxic to northern bobwhite.

d. Adequacy of the study:
(1) Classification: Core
(2) Rationale: N/A
(3) Repairability: N/A

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

September 7, 1994

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Erioglaucine (AQUASHADE) Study Upgrades and Avian Acute Data Evaluation Records (D198333 and D206684)

TO: Kathryn Davis, PM 52
Special Review and Reregistration Division (7508W)

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Aquashade, Inc. has submitted information in support of upgrading two previously submitted studies, a mallard acute oral study and daphnid acute study (Acc. # 41995). This information was apparently submitted previously, and the studies in question were upgraded to core/acceptable on 7/15/80. However, a later memorandum, dated 1/7/93 (copy attached), states that all previously submitted studies for this chemical are invalid. Therefore, the information submitted in this package do not make the studies in question acceptable, and both must be repeated in order to fulfill Guidelines 71-1 and 72-2. Only TEP testing (AQUASHADE) is required, as the FIFRA registered product is registered for direct application to the aquatic sites.

Additionally, Applied Biochemists, Inc., has submitted 2 avian acute oral studies (MRID #433367-01 and 433367-02) in support of reregistration of Aquashade (erioglaucine and tartrazine). The studies have been reviewed and classified as core, fulfilling Guideline 71-1. The LD_{50} for both studies was >2250, indicating that Aquashade is practically non-toxic to gamebirds and waterfowl.

Only one acute oral study is usually required to fulfill Guideline 71-1, and two dietary studies are required to fulfill Guideline 71-2. However, since two acute oral studies were submitted, both of which show Aquashade to be practically non-toxic to birds, and neither species was more sensitive than the other, only one dietary test is required, preferably with a waterfowl (mallard) as it has the greater chance of exposure from the application of Aquashade.

9

The following data requirements are **outstanding** for Aquashade:
71-2: Avian dietary testing--waterfowl (TEP)
72-1b: Freshwater fish (warmwater) acute (TEP)
72-1d: Freshwater fish (coldwater) acute (TEP)
72-2: Freshwater invertebrate acute (TEP)

Chronic aquatic testing (72-4a and 72-4b) is reserved pending the results of the acute tests.

If you have any questions on the above, please contact Kathryn Valente-Montague (308-2804).