file

DER's Included
Avian Repro ND and BWQ
RT - Embryo larvae

109901
SHAUGHNESSEY NO.

27
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 8/18/82 OUT OCT 5 1982

FILE OR REG. NO. 3125-318; 3125-320

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 8/17/82

DATE RECEIVED BY HED 8/18/82

RD REQUESTED COMPLETION DATE 10/18/82

EEB ESTIMATED COMPLETION DATE 10/11/82

RD ACTION CODE/TYPE OF REVIEW 575-Conditional Registration Follow-up

TYPE PRODUCT(S): I, D, H, (F,) N, R, S Fungicide

DATA ACCESSION NO(S). 248117

PRODUCT MANAGER NO. 21-Jacoby

PRODUCT NAME(S) Bayletron 25% Wettable Powder - use on Turf

Bayletron 50% Wettable Powder - use on grasses grown for seed

COMPANY NAME Mobay

SUBMISSION PURPOSE Review submitted data in support of the two confitional registrations, and also in support of pending new uses: pine seedlings, apples, grapes, wheat and barley.

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
109901	Triadimefon	

Bayleton®

100 Pesticide Label Information

100.1 Pesticide Use

Fungicide

100.2 Formulation Information

Triadimefon is the active ingredient

103 Toxicological Information

Four studies were submitted:

1. An avian reproduction study with Bobwhite Quail using technical triadimefon.
2. An avian reproduction study with Mallard Ducks using technical triadimefon.
3. An embryo-larvae study with Rainbow Trout with technical triadimefon.
4. A life-cycle study with Daphnia magna (with technical ~~triadimefon~~ triadimenol (Baytan).

(The Daphnia magna study report #228 had been previously validated as core by Richard Lee (see 4/16/82 review).

103.3.1 Avian Reproduction Studies Bobwhite Quail

This study followed acceptable protocol and fulfills guideline requirements for an avian reproduction study. The no effect level was determined to be 20 ppm.

Mallard Duck

The study does not meet the guideline requirements because of the poor reproductive success in the control. It does however provide some useful supplemental information. The no effect level, at least up until the viable 3-week embryos were counted, was greater than 500 ppm.

103.4.2 Embryo-larvae Life Cycle Studies

This test did not follow accepted protocol for a fish embryo-larvae study because it only lasted 17 days instead of the suggested 60 days. It does not fulfill guideline requirements but does provide supplemental information. The 17-day LC_{50} was reported as 1270 ppb (885 to 2001 ppb 95% C.L.).

107 Conclusions

107.4 Data Adequacy

The following is a list of studies which were requested by EEB:

1. An avian reproduction study with Bobwhite Quail using technical triadimefon.
2. An avian reproduction study with Mallard Ducks using technical triadimefon.
3. A fish embryo-larvae study using technical triadimefon.
4. Two life cycle studies with Daphnia magna.

   a. one using technical triadimefon - this one is not necessary see 4/16/82

   b. another using the primary degradate (KWG-0519)

With this submission, the reviewer considers that the registrant has fulfilled numbers 1, 2, and 4a.

Note that even though one of the avian reproduction studies was categorized as core, it is felt that the chronic toxicity of triadimefon to birds is adequately characterized by these two studies and no more avian studies are needed.

107.5 Data Requests

Two following two studies still remain to be submitted to fulfill conditions of past registration actions.

1. A fish embryo-larvae study (the one submitted did not meet guideline requirements)

2. An aquatic invertebrate life-cycle study with the primary metabolite KWG-0519. The test material would be obtained by aging technical triadimefon long enough to insure a high concentration of KWG-0519.

this requirement has been fulfilled see #127201 Bayton Review dated 6/27/83

107.7 Recommendations

EEB recommends that Mobay Chemical Corporation be notified about the remaining data requirements.

Daniel Rieder 10/4/82
Daniel Rieder
Wildlife Biologist

Norman Cook 10.5.82
Norm Cook, Section Head
Section 2, EEB

Clayton Bushong 10/5/82
Clayton Bushong, Branch Chief
Ecological Effects Branch, HED

1. Chemical: Triadimefon (109901)

2. Formulation: 93% 1-(4-Chlorophenoxy)-3,3-dimethyl-1 - (1H -1,2, 4-ytriazo(-1-yl)-2-butanone

3. Citation: Lamb, D.W. and M.A. Carsel. 1982. Triadimefon (Bayleton®) Reproduction Study with Bobwhite Quail. Received 8/17/82. Study #81-675-03, Report #291. An unpublished report prepared by the Environmental Health Research Institute of the Mobay Chemical Corporation. Acc# 248117.

4. Reviewed By: Daniel Rieder
Section 2

5. Date Reviewed: 9/9/82

6. Test Type: Avian Reproduction Study

A. Species: Bobwhite quail (Colinus virginianus)

B. Test Material: 93% pure Triadimefon

7. Reported Results:

NEL was 20 ppm.

8. Reviewers Conclusion: This study followed acceptabble protocol and fulfills guideline requirements for an avian reproduction study.

Reported Methods

Bobwhite Quail were tested with triadimefon to evaluate its effects on avian reproduction. The birds were 34 weeks old and weighed 160-200 g at the beginning of the study. There were three test levels (20, 100 and 500 ppm) and a control. Each level had 24 cages with one female and one male per cage. Temperature was maintained at 69 to 74° F (20 to 23°C) and relative humidity was maintained at 35 to 60%. The photoperiod schedule was 7.5 hrs. light per day for the first 8 weeks and then increased to 17 hrs. light per day. Fresh diet was prepared each week and stored frozen until used.

Body weights were recorded at initiation, at weeks 2, 4, 6, 8 and at end of study. Food consumption was measured weekly. Eggs were collected for incubation twice daily from week 10 to week 25. On day 21 of incubation, the eggs were placed in hatcher. On day 26 hatchlings were removed from hatcher, weighed and then housed according to parental test group. Observation of ducks continued for 14 days post-hatch.

Egg shell thickness was measured from eggs taken from each laying female during week 1, 3, 5, 7 and 9 of egg laying.

Gross postmortem examinations were performed on birds that died during the study and on 20 randomly selected pairs from each test group.

Results

Five birds died during the study, these were not considered to be compound related.

Table 1. Summary of Reproductive Results

	Control	20 ppm	100 ppm	500 ppm
Eggs Laid	1437	1378	1422	1492
Eggs Cracked	63	101	184	205
Eggs Set	1261	1170	1126	1170
Fertile Eggs	1138	1042	973	941
Viable 3-week Embryos	1060	972	897	877
Hatchlings	635	724	570	488
14-Day Survivors	595	613	472	411

The above data were paired (control to 20 ppm, control to 100 ppm, and 20 ppm to 100 ppm) and analyzed using chisquare. Significant Statistical difference was found between the results at 20 ppm and those at 100 ppm.

The observed No Effect Level was 20 ppm.

Discussion

Statistical analysis was not performed on the 14-day survival results as the hatchlings were separated only by concentration and not by parental pen group. However the total number of survivors at 14 days show a dose-related trend which supports the chisquare statistical analysis.

Conclusion

1. Category: Core

1. Chemical: Triadimefon (109901)

2. Formulation: 93% 1-(4-chlorophenoxy)-3,3-dimethyl-(1H-1,2, 4-triazol-1-yl)-2-butanone

3. Citation: Carlisle, J.C. and M.A. Carsel. 1982. Triadimefon (®Bayleton) Reproduction study with Mallard Duck. Study No. 81-675-05, Tox. Report No. 290. Received 8/17/82. An unpublished report prepared by Mobay Chemical Corp. Accession # 248117

4. Reviewed By: Daniel Rieder
Wildlife Biologist

5. Date Reviewed: 9/13/82

6. Test Type: Avian Reproduction with Mallard Ducks.

Test Material: Technical Triadimefon, 93% pure

7. Results: NEL of 500 ppm

8. Conclusion: This study does not meet the guideline requirements because of the poor reproductive success in the control. It does, however, provide some useful information for a hazard assessment.

Reported Methods

The birds were 20 weeks old when the study started. The weight range was 957 to 1385 g for males and 906 to 1267 g for females. Three test levels (20, 100, and 500 ppm) and a control level were used. There were 14 pairs in seperate pens at each level. Temperature and humidity were maintained at 69 to 74°F (21° to 23°C) and 35 to 55% respectively. Light was on for 7 1/2 hrs per day for the first 8 weeks then increased to 17 hrs per day for the remaining 15 weeks.

The test compound was mixed with acetone and corn oil before being added to the feed mix. The control birds were given a diet with 1% corn oil.

The study was initiated November 16, 1981 and terminated June 8, 1982.

Results

No ducks died during the study and no compound-related lesions were seen in sacrificed ducks. There were no statistically significant differences in any of the reproductive indices. Egg laying began at week 9 and lasted until week 23.

ANALYSIS OF REPRODUCTIVE SUCCESS

	Control	20 ppm	100 ppm	500 ppm
Total Eggs Lai d	571	499	694	632
Eggs laid per female	40.8	33.3	49.6	45.1
Eggs Cracked	23	12	17	30
Eggs Set	485	436	619	546
Fertile Eggs	315	323	504	412
Viable 3 Week Embryo's	236	224	315	265
Hatchlings	91	94	70	75
14-Day Survivors	84	93	67	71

Discussion

There does not appear to be any effect on reproduction at the highest test level . . . at least up to the point where viable 3 week embryos were counted. Compared to other studies (34 per female), the number of eggs laid per female in this test were high enough. (See Feb 2, 1982 letter from R. Balcomb to Mark Jaber, Table 1.) So the NEL would be greater than 500 ppm. However there was a very low number of hatchlings and consequently few 14-day survivors compared to the number of eggs laid and viable 3-week

embryos. The survivoral rate in this test for the control was only 16% compared to 57% in other studies. (See previously referenced letter.) So while the number of hatchlings and 14-day survivors seem to suggest a dose related "trend", no statistical significance can be attached to it and furthermore the poor survival rates at all levels, including the control, negate any effects that the study might have shown.

Conclusion

Category: Supplemental

Rationale: Poor hatchling survival rate in the control

Repairability: Not reparable to core.

1. Chemical: Triadimefon (109901)

2. Formulation: 93% 1-(4-chlorophenoxy)-3,3-dimethyl-1-
-(1H-1,2,4-triazol-1-y 1)-2-butanone

3. Citation: Carlisle, J.C. 1982. Rainbow Trout
Embryo-larvae study triadimefon (Bayleton®).
study No. 81-666-01, Report #250. Data Acc. No. 248117

4. Reviewed By: Daniel Rieder
Wildlife Biologist

5. Date Reviewed: Sept 16, 1982

6. Test Type: Fish Early Life stage chronic toxicity
Rainbow Trout

7. Results: 17 day LC_{50} = 1270 ppb (885-2001 ppb 95% C.L.)

8. Conclusions: This test did not follow accepted protocol for fish embryo-larvae study, therefore it does not fulfill the guideline requirements. It does, however, show that triadimefon is highly toxic to trout in the early life stages.

11 not endorsed

Reported Methods

From 230 to 243 trout embryos were tested at each of 5 test levels (50, 150, 450, 1350, and 4050 ppb) and in a control. The embryos at each level were divided into 2 groups and tested in seperate 5 gallon containers. The containers were aerated. Temperature was measured twice a day. Flow rate was 75 liters per vessel per day. The concentrations were verified by chemical analysis periodically. Photo period was 16 hrs light and 8 hrs dark. The embryos were exposed from 3 to 9 days before they hatched.

Results

Temperature ranged from 9.9°C to 12.8°C.
The measured concentrations ranged from 90.6% (at higher levels) to 133.8% (at lower levels) of the nominal concentrations.

Mortality Table

Concentration (ppb)	% Mortality at day 17
Control	8.23
50	19.57
150	29.66
450	43.33
1350	56.85
4050	65.83

The 17 day LC_{50} = 1270 ppb (885-2001 ppb 95% C.L.)

Reviewers Evaluation

The test protocol deviated from standard protocol (ASTM) in the following details:

1. The test containers were aerated and they should not be.
2. The temperature deviated more than 1°C.
3. The tast concentrations were too far apart, i.e. each lower concentration was much more than the accepted 50% less than the next higher.
4. The test lasted only 17 days as opposed to the recommended 60 days.

The first 3 deviation are not significant but the last one keeps the study from fulfilling guideline requirements.

Conclusion

Category: Supplemental

Rationale: The study was not long enough to fulfill the requirements for a fish "life-cycle" toxicity test.

Repairable: Not repairable.