Application dated Aug 9, 1977

EEB BRANCH REVIEW

DATE: IN 9/6/77 OUT 4/13/78 IN ____ OUT ____ IN ____ OUT ____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 3125-00GRO

PETITION OR EXP. PERMIT NO. ____

DATE DIV. RECEIVED ____

DATE OF SUBMISSION ____

DATE SUBMISSION ACCEPTED ____

TYPE PRODUCTS(S): I, D, H, (F) N, R, S ____

DATA ACCESSION NO(S). 231311

PRODUCT MGR. NO. Wilson (21)

PRODUCT NAME(S) BAYLETON

COMPANY NAME Mobay Chemical Corporation

SUBMISSION PURPOSE Registration (Manufacturing Use)

CHEMICAL & FORMULATION 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1,1-1,2,4-triazol-1-yl)-2-butanone

100.0 Pesticidal Use

For use in the manufacture of economic poisons only.

101.0 Chemical and Physical Properties

101.1 Chemical Name

1-(4-chlorophenoxy)-3,3-dimethyl-1-1(1H-1,2,4-triazol-1-yl)-2-butanone

101.2 Common Name

BAYLETON ™ (formerly BAT MEB 6447)

102.0 Behavior in the Environment

According to Ron Ney, no data are available on environmental chemistry.

103.0 Toxicological Properties

See attached sheets.

104.0 Hazard Assessment

104.1 Discussion

Due to a lack of data, only a cursory review and discussion will be made at this time.

As is the case with most "manufacturing only" use patterns, the greatest hazards to the environment comes either as a result of effluents being discharged directly or indirectly into waterways or by disposal of solid wastes in landfills where translocation (i.e., leaching, erosion, etc.) is likely to cause contamination far from the manufacturing site. The hazards associated with such common manufacturing practices can be both acute or chronic depending upon the physical and/or toxicological properties of the chemical. Based on the available toxicity data, it would appear that acute hazards to non-target organisms, with the possible exception of aquatic invertebrates, are minimal. Until such time as additional toxicological

and environmental chemistry data are available the issue of chronic toxicity cannot be addressed.

105.0 Conclusions

1. The Environmental Safety Section has found the following studies to be inadequate to support registration:

   a. "Acute oral toxicity of Bayleton to Adult Mallard Ducks."

      This study was found inadequate because such parameters as, temperature, housing, food consumption and body weights were not reported. If this information is provided, the study will be adequate to support registration.

   b. "Acute oral toxicity of Bayleton to the Canary."

      This study was found inadequate in that the canary is not a representative wildlife species.

   c. In the report entitled, "Acute toxicity of Bayleton technical to Bluegill, Channel Catfish and Rainbow Trout" the rainbow trout study was found to be inadequate in that there was an error in the reported mortality figures. Mr. D. Lamb of Chemagro was notified about this and will submit correction. Upon receipt of data this study will be adequate to support registration.

2. There are insufficient data, both for toxicity and environmental chemistry, to make a comprehensive hazard evaluation at this time.

3. Depending upon results of Environmental Chemistry studies, additional Environmental Safety studies may be required.

4. Final label statements and/or precautions will not be made until all outstanding data have been submitted and reviewed.

W. Welthousen
ril 13, 1978
vironmental Safety Section
:SB

DATA REVIEW NUMBER: ES-VII C.1

TEST: Acute Oral LD_{50}

SPECIES: Mallard Duck

RESULTS: Male > 4000 mg/kg
Female > 4000 mg/kg

CHEMICAL: Bayleton technical Batch No. 5030047

TITLE: Acute oral toxicity of Bayleton technical to Adult Mallard Ducks

ACCESSION NO: 231311

STUDY DATE: May 11, 1977

RESEARCHER: D.W. Lamb & M.A. Burke - Chemagro Agricultural Div.

REGISTRANT: MOBAY Chemical Corporation

VALIDATION CATEGORY: Invalid Data

CATEGORY REPAIRABILITY: Core Data

ABSTRACT: The acute oral LD_{50} of Bayleton technical to both adult male and female mallard ducks was determined to be greater than 4000 ppm.

Toxicological symptoms included regurgitation and diarrhea. Symptoms became apparent within 5 minutes of administration.

COMMENT SHEET FS VII C.1

A. Additional Test Data

1. Intent of study - To satisfy regulatory requirements under Section 3.

2. Methodology/Protocol

a. Test Animals: Mallard Duck (Male & Female)

b. Age: Adult

c. Test Conditions: Unknown

d. Treatment

1. Concentrations - 500, 1000, 2000, 4000 mg/kg.

2. Fasting - Birds were fasted 20 hrs. prior to treatment.

3. Method of Treatment - The compound was suspended in polyethylene glycol 400 and administered with a syringe and catheter.

4. Observation Period - Birds were observed for 14 days after treatment for signs of toxicity and mortality.

5. Statistical Analysis - On performed (not necessary)

3. Additional Test Results

1. No deaths were reported at any dosage level.

2. No signs of diarrhea noted at 500 level.

B. Validation Category

Invalid - This study was classified as "Invalid" to support registration under section 3 for the following:

1. Test conditions (i.e., temperature, lighting, housing) were not reported.

2. Food consumption and body weight data were not reported.

C. Category Repairability

Provided those comments made in section B are adequately addressed this study may be reclassified as "Core Data" and can be used to support registration.

DATA REVIEW NUMBER: ES VII C.2

TEST: Acute Oral LD_{50}

SPECIES: Canary (Seninus canarius)

RESULTS: Estimated LD_{50} >1000 mg/kg

CHEMICAL: MEB 6447 (Bayleton) 93.4% pure

TITLE:

ACCESSION NO: 231311

STUDY DATE: August 1, 1973

RESEARCHER: Institute for Tierische Schadlinge

REGISTRANT: Chemagro (MOBAY Chem. Corp.)

VALIDATION CATEGORY: Invalid

CATEGORY REPAIRABILITY: No

ABSTRACT: The estimated LD_{50} of Bayleton to the canary was greater than 1000 mg/kg.

COMMENT SHEET ES VII C.2

A. Additional Test Data

1. Intent of study - To satisfy regulatory requirements.

2. Methodology/Protocol

a. Test material: Bayleton 93.4% (MEB 6447)

b. Test animals:

Age:
Sex:
Size:
Condition:
Number: 12

c. Test conditions: Unknown

d. Treatment:

1. Concentrations tested: 250, 500, 1000 mg/kg.

2. Period without food prior to application 1-hr.

3. Method of application: Probang

4. Observation period: 7 days

e. Statistical Analysis: None

3. Additional Test Results

a. Table

Dose	Results (dead/tested)	Comments
1000	0/2	Vomiting
500	0/4	Vomiting
250	0/6	Vomiting

B. Validation Category

Invalid - This study has been classified as "Invalid Data" in that it fails to satisfy the intent of the guidelines.

C. Category Rapairability

N/A

D. Additional Data Required

N/A

E. Comments:

This study fails to satisfy the intent of the guidelines in the following areas:

1. # of dosage levels tested.
2. # of birds tested/dosage level.
3. Species tested
4. Failure to determine LC_{50} value.
5. No statistical analysis performed.
6. Failure to report complete details of methods and materials.

DATA REVIEW NUMBER: ES VII D.1

TEST: Eight-day dietary LC_{50}

SPECIES: Bobwhite quail (Colinus virginianus)

RESULTS: The acute LC_{50} of Bayleton to Bobwhite quail is estimated to be greater than 4640 ppm.

CHEMICAL: Bayleton (93% a.i.)

TITLE: Eight-Day dietary LC_{50} -Bobwhite quail, Bayleton Technical Final Report.

ACCESSION NO: 231311

STUDY DATE: April 25, 1977

RESEARCHER: Wildlife International LTD.

REGISTRANT: Mobay Chemical Corp.

VALIDATION CATEGORY: Core Data

CATEGORY REPAIRABILITY: N/A

ABSTRACT:

COMMENT SHEET ES VII D.1

A. Additional Test Data

1. Intent of study - Data to support registration.

2. Methodology/Protocol

a. Test Material: Bayleton 93% a.i.

b. Test Animals: Age-14 days, Sex-Male & Female, Condition-healthy, Number-10 birds/concentration.

c. Test Conditions: Environment: Battery brooden temperature was maintained at 99.0 F from the day of hatch through completion of study.

Photoperiod: Unknown

d. Treatment: The material was dissolved in corn oil in concentrations such that the addition of two parts (by weight) of each solution to 98 parts of ration resulted in the following geometric series of dosage levels: 464, 1000, 2150, 4640 and 10,000. For the purposes of diet preparation, one experimental material was assumed to be 100% active material. Birds on treated feed for 5-days.

e. Husbandry: Starter ration and water were available ad libitum throughout the study.

f. Statistical Analysis: Litchfield, J.T. and Wilcoxon, F.J.

g. References: J. Pharmocol. Exptl. Therop., 96, 99, 1949.

B. Validation Category (Rational)

This study has been classified as "Core Data" in that it satisfies the intent of the proposed guidelines.

C. Category Repairability (Rationale)

N/A

D. Additional Data Required

N/A

E. Comments:

The Litchfield-Wilcoxon method used to analyze the data in this study should only be used when two or more partial kills occur. Although this may be sufficient to invalidate the study (in addition, the actual plotting of the curve was never submitted), it was felt that because of the high values it was not that important in this case.

DATA REVIEW NUMBER: ES VII D.2

TEST: Eight-Day Dietary LC_{50}

SPECIES: Mallard Duck (Anas platyrhynchos)

RESULTS: The acute LC_{50} of Bayleton technical is estimated to be greater than 10,000 ppm.

CHEMICAL: Bayleton (93% a.i.)

TITLE: Eight-Day Dietary LC_{50} - Mallard Duck Final Report

ACCESSION NO: 231311

STUDY DATE: April 25, 1977

RESEARCHER: Wildlife International LTD.

REGISTRANT: Mobay Chemical Corporation

VALIDATION CATEGORY: Core Data

CATEGORY REPAIRABILITY: N/A

ABSTRACT: Throughout the duration of the test the birds showed no overt signs of toxicity. At the 10,000 ppm dose level there was a reduction in feed consumption and body weight gain.

COMMENT SHEET ES VII D.2

A. Additional Test Data

1. Intent of study - data to support registration.

2. Methodology/Protocol

a. Test Material: Bayleton 93% a.i.

b. Test Animals: Age-14 days, Sex-Male & Female, Condition-healthy, Number-10 birds/concentration.

c. Test Conditions: Environment: Battery brooder temperature was maintained at 99.0 F from the day of hatch through completion of study.

Photoperiod: Unknown

d. Treatment: The material was disdolved in corn oil in concentrations such that the addition of two parts (by weight) of each solution to 98 parts of ration resulted in the following logarithmic series of dosage levels: 464, 1000, 2150, 4640 and 10,000. For the purposes of diet preparation, the experimental material was assumed to be 100% active material. Birds on treated feed for 5-days.

e. Husbandry: Starter ration and water were available ad libitum throughout the study.

f. Statistical Analysis: Litchfield, J.T. and Wilcoxon, F.J.

g. References: J. Pharmocol. Exptl. Therop., 96, 99, 1949.

B. Validation Category (Rational)

This study has been classified as "Core Data,"

C. Category Repairability (Rationale)

N/A

D. Additional Data Required

N/A

E. Comments:

The Litchfield-Wilcoxon method used to analyze the data in this study should only be used when two or more partial kills occur. Although this may be sufficient to invalidate the study (in addition, the actual plotting of the curve was never submitted), it was felt that because of the high values it was not that important in this case.

DATA REVIEW NUMBER: ES VII F-1&2, G-1

TEST: 96-hr. Static Bioassay

SPECIES: Bluegill Sunfish, Channel Catfish, Rainbow Trout.

RESULTS: Bluegill 11(9.7-12) ppm
Channel Cat 15(13-17) ppm
Rainbow Trout 14(12-16) ppm

CHEMICAL: Bayleton (Technical - 93% a.i.)

TITLE: Acute toxicity of Bayleton technical to Bluegill, Channel Catfish and Rainbow Trout.

ACCESSION NO: 231311

STUDY DATE: May 3, 1977

RESEARCHER: D.W. Lamb and D.J. Roney

REGISTRANT: Mobay Chemical Corp.

VALIDATION CATEGORY: Core Data (Bluegill and Channel Cat.)

CATEGORY REPAIRABILITY: N/A

ABSTRACT: Bayleton technical was studied to determine the acute toxicity to a warm water and a cold water species of fish. Under standard static conditions, bluegill, channel catfish and rainbow trout were exposed to several concentrations of the technical for a 96-hr. period. Mortality data were recorded at 24-hr. intervals. The three species tolerated approximately the same level of the technical. The 96-hr. LC_{50} values and 95% confidence limits for bluegill, channel catfish and rainbow trout were 11 (9.7-12) ppm, 15 (13-17) ppm and 14 (12-16) ppm, respectively.

COMMENT SHEET ES VII F-1&2 and G-1

A. Additional Test Data

1. Intent of study - To gather fish toxicity data to support registration.

2. Methodology/Protocol

a. Test Material: Bayleton 93% active ingredient.

b. Test Animals: Size: ≈ 35 mn, weight 0.5-1.0 g, Number-10 fish/concentration, condition-healthy.

c. Test Conditions: Water-Each liter of deionized water was reconstituted with 30 mg of calcium sulfate, 30 mg of magnesium sulfate, 48 ma of sodium bicarbonate and 2 mg of potassium chloride.

pH 7.6

Container: 5 gal. widemouth jar containing 15 liters of bioassay water.

Temperature: By means of a water bath, temperature were maintained at 18°C for bluegill and channel catfish and 12°C for the rainbow trout.

d. Husbandry: Loading factor was less than one gram of fish per liter of water. Prior to introduction of the chemical and fish, the bioassay water was saturated with dissolved oxygen. During the 96-hr. experiment, the fish were not fed, the water was not aerated and mortality data were recorded at 24-hr. intervals.

e. Treatment:

Species	Concentrations Tested
Bluegill	4.7, 6.9, 10.1, 14.8, and 21.8 ppm
Channel Catfish	7.5, 10.5, 14.7, 20.6, and 28.9 ppm
Rainbow	3.2, 4.7, 6.9, 10.1, 14.8, and 21.8 ppm.

f. Statistical Analysis: Weil, C.S: Tables for convenient calculation of median-effective dose and instruction in their use. Biometrics, 8, 249, 1952.

3. Additional Test Results:

a. Mortality Table:

Species	Dose Level	No. of	Cumulative Mortality Hours				LC_{50} &95% Confidence
Bluegill	Control	10	0	0	0	0	
	4.7	0	0	0	0		
	6.9	10	0	0	0	11	
	14.8	10	2	2	3	(9.7-12)	
	21.8	10	10	10	10		
Channel	Control	10	0	0	0	0	
	7.5	10	0	0	0		
	10.5	10	1	2	2	15	
	14.7	10	0	2	3	(13-17)	
	20.6	10	10	10	10		
	28.9	10	10	10	10		
Rainbow Trout	Control	10	0	0	0	0	
	3.2	10	0	0	0	0	
	4.7	10	0	0	0	0	14
	6.9	10	0	1	1	1	(12-16)
	10.1	10	0	0	0	0	
	14.8	10	0	1	4	4	
	21.8	10	6	8	8	10	

B. Validation Category (Rationale)

This study has been classified as "Core Data" in that it is scientifically sound and satisfies the intent of the guidelines.

C. Additional Data Required/Discussion

Upon validation of statistical analysis for the rainbow trout study it was discovered that the LC_{50} value as presented was incorrect. (See comment section). A phone call was made to Mr. D. Lamb of Chemagro to determine source of error. After checking his raw data he found that the reported 96-hr. mortality for the 14.8 ppm concentration was 7 instead of the reported 4. Mr. Lamb will submit corrected data.

D. Comments

Statistical Validation

Bluegill sunfish
0,3,10,10 f value (see table) = 0.2
R value = 1.47
d = log R=.1673
Log m Log Da + d (f+1) for K=3
Log m $\simeq$ Log 6.9 + .1673 (1.2)
Log m $\simeq$ Log .8388 + .2007
Antilog $\simeq$ 1.0395
= 10.95 ppm

Channel Catfish

2, 3, 10, 10 f value (see table) = 0
R value = 1.47 d=log R = .1673
Log m Log Da+d (f+1) for K=3
Log m $\simeq$ Log 10.5 + .1673 (1)
Log m $\simeq$ Log 1.0211 + .1673
Log m $\simeq$ Log = 1.1884
Antilog = 15.4 ppm

Rainbow-using 1,0,4,10 LC_{50} = 10.16. However 1,0,7,10 was mortality f value (see table) = .77778.

R value =1.47
d=log R=.1673 Log Da-Log 6.9=.8333
Log m log Da+d(f+1) for K=3
Log m $\simeq$ =.8388+.1673 (1.77778)
Log m $\simeq$ =.8388+.2974
Antilog $\simeq$ 13.68 ppm

DATA REVIEW NUMBER: ES VII H.1

TEST: 48-hr. Static Bioassay

SPECIES: Daphnia Magna

RESULTS: 48-hour LC_{50} = 1.6 ppm (1.2-2.1 95% C.I.)

CHEMICAL: Bayleton Technical (Batch No.-5030047)

TITLE: Acute toxicity of Bayleton ™ (formerly Bay MEB 6447) Technical to Daphnia magna

ACCESSION NO: 231311

STUDY DATE: March 14, 1977

RESEARCHER: D.W. Lamb and M.A. Burke of the Chemagro Agricultural Division - Res. and Development.

REGISTRANT: Mobay Chemical Corporation

VALIDATION CATEGORY: Invalid Data

CATEGORY REPAIRABILITY: Core Data

ABSTRACT: The 48-hr. LC_{50} of Bayleton (technical) to Daphnia magna was found to be 1.6 ppm (1.2-2.1 95% C.I.). Mortality was recorded when all movements ceased. Study was conducted under static conditions.

A. Additional Test Data

1. Intent of study - to gather aquatic invertebrate toxicity data to support registration under Section 3.

2. Methodology/Protocol

a. Test material: Bayleton Technical

b. Test animals: Species: Daphnia magna Size: 1 st and 2nd instars, number: 10/ concentrations - (6 concentrations)

c. Test Conditions: Containers: Pint jars containing 300 mls of filtered water.

Husbandry: The daphnia were rinsed once in filtered water.

d. Treatment: Concentrations tested. Control, 0.4, 0.6, 0.8, 1.1, 1.6, 2.2 ppm.

e. Statistical Analysis: Not reported.

3. Additional Test Results

a. Mortality Table

Species	Exp. Conc. (ppm)	No. of Daphnia	Cumulative Mortality/Symptoms Hours 24	Cumulative Mortality/Symptoms Hours 48	48-hr. LC_{50} & 95% Confidence Limits (ppm)
Daphnia magna	0	10	0/0	0/0	
	0.4	10	0/0	0/0	
	0.6	10	0/0	0/1	1.6
	0.8	10	0/0	2/1	(1.2 to 2.1)
	1.1	10	0/0	3/1	
	1.6	10	0/0	4/0	
	2.2	10	0/1	8/0	

B. Validation Category (Rationale)

This study has been determined to be inadequate to support registration under Section 3 for the following:

1. Test conditions such as water temperature, pH, dissolved oxygen and hardness were not reported.

2. The statistical method used to analyze the test was not reported.

C. Category Repairability (Rationale)

If those comments, addressed under Section B, are adequately addressed this study can be classified as "Core Data" and suitable to support registration under Section 3.