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181328
RECORD NO.

006315
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 06/18/87 OUT 7-17-87

FILE OR REG. NO. 3377-EG, 3377-EE, 3377-EU
PETITION OR EXP. NO. _____
DATE OF SUBMISSION 09/23/86
DATE RECEIVED BY HED 06/17/87
RD REQUESTED COMPLETION DATE 07/17/87
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RD ACTION CODE/TYPE OF REVIEW 160

TYPE PRODUCT(S) : I, D, H, F, N, R, S Disinfectant, Sanitizer, etc.

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. J. Kempter (32)

PRODUCT NAME(S) BCDMH 96

COMPANY NAME Ethyl Corporation

SUBMISSION PURPOSE Data Review for Technical

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
<u>006315</u>	<u>1-Bromo-3-chloro-5,5-dimethyl-</u>	<u>96.0</u>
	<u>hydantoin</u>	
	<u>Inert Ingredients</u>	<u>4.0</u>

100.0 Pesticide Name

BCDMH (1-Bromo-3-chloro-5,5-dimethylhydantoin)

100.1 Submission Purpose

Submission of fish and wildlife data for review.

101.0 Chemical and Physical Properties

101.1 Chemical Name

1-Bromo-3-chloro-5,5-dimethylhydantoin

102.0 Toxicological Properties

Avian Acute Oral LD₅₀ for Bobwhite Quail (\$71-1);
Avian Dietary LC₅₀ for Bobwhite Quail (\$71-2);
Avian Dietary LC₅₀ for Mallard Duck (\$71-2);
96-Hour LC₅₀ for Bluegill Sunfish (\$72-1);
96-Hour LC₅₀ for Fathead Minnow (\$72-1);
96-Hour LC₅₀ for Rainbow Trout (\$72-1); and
48-Hour LC₅₀ for Daphnia Magna (\$72-2).

103.0 Conclusions

A. Acute Oral LD₅₀ (Bobwhite Quail)

This study indicates BCDMH is slightly toxic to bobwhite quail with an LD₅₀ of 1839 mg/kg. This study does fulfill the requirement in support of registration for an avian acute oral LD₅₀ study.

B. Avian Dietary LC₅₀ (Bobwhite Quail)

This study indicates BCDMH is practically nontoxic to bobwhite quail with an LC₅₀ greater than 5620 ppm. This study does fulfill the requirement in support of registration for an avian dietary LC₅₀ study.

C. Avian Dietary LC₅₀ (Mallard Duck)

This study indicates BCDMH is practically nontoxic to mallard duck with an LC₅₀ greater than 5620 ppm. This study does not fulfill the requirement in support of registration.

D. Fish 96-Hour LC₅₀ (Bluegill Sunfish and Fathead Minnow)

This study indicates total residual chlorine (TRC) and free residual chlorine (FRC) ranged from 2.48

to 2.35 ppm for bluegill sunfish and 0.44 to 1.21 ppm for juvenile fathead minnow (96-hour peak ppm). This study showed the 96-hour LC₅₀ to range from highly to moderately toxic for juvenile fathead minnow and moderately toxic to bluegill sunfish. This study does not fulfill the requirement in support of registration for a warmwater fish study because there were no mortality data to verify LC₅₀ values, fish were fed during testing, and source of fish, symptoms of toxicity, and the percent of active ingredient are unknown. This study is not reparable.

E. Fish 96-Hour LC₅₀ (Rainbow Trout)

This study indicates BCDMH is highly toxic to rainbow trout with an LC₅₀ of 0.17 (0.13 to 0.20) ppm. This study does fulfill the requirement in support of registration for a coldwater fish study.

F. 48-Hour LC₅₀ Invertebrate (Daphnia magna)

This study indicates BCDMH is highly toxic to Daphnia magna with an LC₅₀ of 0.10 ppm. This study does fulfill the requirement in support of registration for an aquatic invertebrate study.

103.1 Data Inadequacy

<u>Species</u>	<u>LC₅₀(ppm)</u>		<u>Status</u>	<u>% ai</u>
	<u>TRC</u>	<u>FRC</u>		
Bluegill sunfish	2.48	2.35	Supplemental	96.0%
Fathead minnow	0.44	1.21	Supplemental	96.0%

103.2 Adequacy of Toxicity Data

<u>Species</u>	<u>LC/LD₅₀</u>	<u>Status</u>	<u>% ai</u>
Bobwhite quail	1839 mg/kg	Core	96.0
Bobwhite quail	> 5620 ppm	Core	96.0
Mallard duck	> 5620 ppm	Core	96.0
Rainbow trout	0.17 ppm	Core	96.0
<u>Daphnia magna</u>	0.10 ppm	Core	96.0

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DATA EVALUATION RECORD

1. Chemical: - BCDMH (1-Bromo-3-chloro-5,5-dimethylhydantoin)
2. Test Material: 96% (Technical ai)
3. Study Type: Avian Acute Oral LD50
Species Tested: Bobwhite Quail
(Colinus virginianus)
4. Study ID: Grimes, J. (1986). An Avian Oral Toxicity Study with the Bobwhite; Project No. 219-103; Prepared by Wildlife International, Ltd., for Ethyl Corporation, P.O. Box 14799, Baton Rouge, LA 70898.
5. Reviewed By: Curtis E. Laird
Fishery Biologist
EEB/HED
Signature: *Curtis E. Laird*
Date: 7-17-87
6. Approved By: Allen Vaughan
Supervisory Biologist
EEB/HED
Signature: *Allen W. Vaughan*
Date: 7.17.87
7. Conclusions:

This study indicates BCDMH is slightly toxic to bobwhite quail with an LD50 of 1839 mg/kg. This study does fulfill the requirement in support of registration for an avian acute oral LD50 study.
8. Recommendation: N/A.
9. Background:

This study was submitted for review in support of BCDMH 96 technical.
10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were 18-week-old bobwhite quail (Colinus virginianus) from Fritt's Ouail Farm.
- b. Test System - Birds were tested in 78 x 51 x 20 cm pens: temperature was 82 + 6 °F; humidity was 49 percent and photoperiod was 8 hours of light and 16 hours of darkness.
- c. Dose - Nominal doses were used based on mg/kg of body weight.
- d. Design - Ten birds per dose; 5 dose levels plus corn oil control (corn oil, 292, 486, 810, 1350, and 2250 mg/kg).
- e. Statistics - Stephan's computer program.

12. Reported Results:

The study author found the acute oral LD₅₀ to be 1839 mg/kg. The no-observed-effect level was 810 mg/kg.

13. Study Author's Conclusions:

The acute oral LD₅₀ was 1839 mg/kg.

This study was examined for conformance with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs (FEDERAL REGISTER, Volume 48, Number 230, November 29, 1983, pages 53946-53969). The final report was determined to be an accurate reflection of the data obtained. The dates of all audits and the results of those audits were reported to the Study Director/Laboratory Management.

14. Reviewer's Discussion and Interpretation of the Study:

- a. Test Procedure - The test procedure complied with the recommended EPA Protocol of October 1982 (Part 158).
- b. Statistical Analysis - The statistics were verified with Stephan's computer program.
- c. Discussion/Results - With the acute oral LD₅₀ of 1839 mg/kg indicates BCDMH is slightly toxic to bobwhite quail.

d. Adequacy of Study

- 1) Category - Core.
- 2) Rationale - N/A.
- 3) Reparability - N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1350	10	0	0	1.074217
1750	10	0	0	9.765625E-02
2150	10	0	0	7.765625E-02
2550	10	0	0	9.765625E-02
2950	10	0	0	7.765625E-02

THE BINOMIAL TEST SHOWS THAT 1750 AND 2250 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS. BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 1839.307

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

DATA EVALUATION RECORD

1. Chemical: BCDMH
2. Test Material: 96.0% (Technical ai), A White Powder
3. Study Type: Eight-Day Dietary LC₅₀

Species Tested: Bobwhite Quail
(Colinus virginianus)

4. Study ID: Grimes, J. (1986) A Dietary LC₅₀ Study with the Bobwhite; Project No. 219-101; Prepared by Wildlife International, Ltd., for Ethyl Corporation, P.O. Box 14799; Baton Rouge, LA 70898.

5. Reviewed By: Curtis E. Laird
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Signature: *Curtis E. Laird*
Date: 7-17-87

6. Approved By: Allen Vaughan
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EEB/HED

Signature: *Allen W. Vaughan*
Date: 7-17-87

7. Conclusions:

This study indicates BCDMH is practically nontoxic to bobwhite quail with an LC₅₀ > 5620 ppm. This study does fulfill the requirement in support of registration for an avian dietary LC₅₀ study.

8. Recommendation: N/A.

9. Background:

This study was submitted for review in support of BCDMH 96 technical.

10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were bobwhite quail from Sand Prairie Quail Farm in Maquoketa, Iowa; Age = 10 days.
- b. Test System - Birds were tested in brooder pens; size = 72 x 90 x 23 cm; temperature was 30 + 2 °C; humidity was 70 percent; photoperiod was 17-hour light and 7-hour darkness.
- c. Dose - Nominal dietary concentrations; corn oil was used as a carrier.
- d. Design - Ten birds per dose level; 5 dose levels plus control (corn oil, 562, 1000, 1780, 3160, and 5620 ppm).
- e. Statistics - No statistics were performed due to lack of mortality.

12. Reported Results:

The study author found the 8-day dietary LC₅₀ to be > 5620 ppm. The no-observed-effect level was 3160 ppm.

13. Study Author's Conclusions:

The 8-day dietary LC₅₀ were > 5620 ppm.

This study was examined for conformance with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs (FEDERAL REGISTER, Volume 48, Number 230, November 29, 1983, pages 53946-53969). The final report was determined to be an accurate reflection of the data obtained. The dates of all audits and the dates that results of those audits were reported to the Study Director/Laboratory Management.

14. Reviewer's Discussion and Interpretation of the Study:

- a. Test Procedure - The test procedure complied with the recommended EPA Protocol of October 1982 (Part 158).
- b. Statistical Analysis - No statistics were performed due to lack of mortality.
- c. Discussion/Results - BCDMH is practically nontoxic to bobwhite quail with an LC₅₀ > 5620 ppm.

d. Adequacy of Study

- 1) Category - Core.
- 2) Rationale - N/A.
- 3) Reparability - N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: BCDMH
2. Test Material: 96.0% (Technical ai), A White Powder
3. Study Type: Eight-Day Dietary LC₅₀
Species Tested: Mallard Duck
(Anas platyrhynchos)
4. Study ID: Grimes, J. (1986) A Dietary LC₅₀ Study with the Mallard Duck; Project No. 219-102; Prepared by Wildlife International, Ltd., for Ethyl Corporation, P.O. Box 14799; Baton Rouge, LA 70898.
5. Reviewed By: Curtis E. Laird
Fishery Biologist
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Signature: *Curtis E. Laird*
Date: 7-17-87
6. Approved By: Allen Vaughan
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Signature: *Allen W. Vaughan*
Date: 7.17.87
7. Conclusions:

This study indicates BCDMH is practically nontoxic to mallard duck with an LC₅₀ > 5620 ppm. This study does fulfill the requirement in support of registration for an avian dietary LC₅₀ study.
8. Recommendation: N/A.
9. Background:

This study was submitted for review in support of BCDMH 96.0% technical.
10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were mallard ducks (Anas platyrhynchos) from Whistling Wings, Hanover, IL 61041; Age = 9 days.
- b. Test System - Birds were tested in brooder pens; size = 72 x 90 x 24 cm; temperature was 82 + 3 °F; humidity was 72 percent; photoperiod was 17 hours of light and 7 hours of darkness.
- c. Dose - Nominal dietary concentration; corn oil was used as a carrier.
- d. Design - Ten birds per dose level; 5 dose levels plus corn oil control (corn oil, 562, 1000, 1780, 3160, and 5620 ppm).
- e. Statistics - No statistics were performed due to lack of mortality.

12. Reported Results:

The study author found the 8-day dietary LC₅₀ to be > 5620 ppm. The no-observed-effect concentration was 3160 ppm based on a possible reduction in body weight gain and feed consumption at 5620 ppm.

13. Study Author's Conclusions:

The 8-day dietary LC₅₀ was > 5620 ppm.

This study was examined for conformance with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs (FEDERAL REGISTER, Volume 48, Number 230, November 29, 1983, pages 53946-53969). The final report was determined to be an accurate reflection of the data obtained. The dates of all audits and the dates that results of those audits were reported to the Study Director/Laboratory Management.

14. Reviewer's Discussion and Interpretation of the Study:

- a. Test Procedure - The test procedure complied with the recommended EPA Protocol of October 1982 (Part 158).
- b. Statistical Analysis - No statistics were performed due to lack of mortality.
- c. Discussion/Results - BCDMH is practically nontoxic to mallard duck with an LC₅₀ > 5620 ppm.

d. Adequacy of Study

1) Category - Core.

2) Rationale - N/A.

3) Reparability - N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: BCDMH

2. Test Material:

3. Study Type: 96-Hour LC₅₀

Species Tested: Bluegill Sunfish and
Fathead Minnow

4. Study ID: Wilde, E.W.; et al. (1983) Acute Toxicity of Chlorine and Bromine to Fathead Minnows and Bluegills; No Study No.; Prepared by Savannah River Laboratory, E.I. du Pont de Nemours & Co., and submitted by Ethyl Corporation, P.O. Box 14799, Baton Rouge, LA 70898.

5. Reviewed By: Curtis E. Laird
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Signature: *Curtis E. Laird*

Date: 7-17-87

6. Approved By: Allen Vaughan
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Signature: *Allen W. Vaughan*

Date: 7-17-87

7. Conclusions:

This study indicates total residual chlorine (TRC) and free residual chlorine (FRC) ranged from 0.44 to 1.21 ppm for juvenile fathead minnow and 2.48 to 2.35 ppm for bluegill sunfish (96-hour peak mg/L). This shows the 96-hour LC₅₀ to range from highly to moderately toxic for juvenile fathead minnow and moderately toxic to bluegill sunfish. This study does not fulfill the requirement in support of registration because there were no mortality data to verify LC₅₀ values, fish were fed during testing, source of fish, symptoms of toxicity, and percent of ai are unknown.

8. Recommendation:

The registrant should conduct another 96-hour LC₅₀ for both bluegill sunfish and fathead minnow using technical grade material, fish weight should range from 0.5 to 5 grams, do not feed fish during testing, give source of fish, and include mortality data per dose level.

9. Background:

This study was submitted in support of BCDMH 96 technical.

10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were juvenile (fathead minnow) 6-weeks-old young of the year bluegill sunfish.
- b. Test System - Fish were tested in 15 L glass chambers; temperature was 21.1 °C, flow-through system with a 2-hour/day delivery.
- c. Dose - Nominal doses were used; no solvent used.
- d. Design - Ten fish per dose level; 3 dose level plus control.
- e. Statistics - No statistics were performed due to lack of mortality.

12. Reported Results:

The study author found the 96-hour LC₅₀ to be 0.44 ppm (TRC) and 1.21 ppm (TRB) for juvenile fathead minnow and 2.48 ppm (TRC) and 2.35 ppm (TRB) for bluegill sunfish.

13. Study Author's Conclusions:

The 96-hour LC₅₀ ranged from 0.44 to 1.21 ppm for juvenile fathead minnow and 2.35 to 2.48 ppm for bluegill sunfish. The information contained in this article was developed during the course of work under Contract No. DE-AC09-76SR00001 with the U.S. Department of Energy.

14. Reviewer's Discussion and Interpretation of the Study

- a. Test Procedure - The test procedure did not comply with the recommended EPA Protocol of October 1982 (Part 158). See section 8 above.
- b. Statistical Analysis - No statistics were performed due to lack of mortality.
- c. Discussion/Results - This study indicated TRC is highly toxic and TRB is moderately toxic to juvenile fathead minnow and both TRC and TRB are moderately toxic to bluegill sunfish.
- d. Adequacy of Study
 - 1) Category - Supplemental.
 - 2) Rationale - See section 8 above.
 - 3) Reparability - Not reparable.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: BCDMH
2. Test Material: 96.0% (Technical ai), A White Powder
3. Study Type: 96-Hour LC₅₀
Species Tested: Rainbow Trout
(Salmo gairdneri)
4. Study ID: Surprenant, D.C. (1986) Acute Toxicity of Bromo-Chloro-Dimethylhydantoin (BCDMH) to Rainbow Trout (Salmo gairdneri) under Flowthrough Conditions; Report No. BW-86-9-2138; Prepared by Springborn Bionomics, Inc., for Ethyl Corporation, Baton Rouge, LA 70898.
5. Reviewed By: Curtis E. Laird
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Signature: *Curtis E. Laird*
Date: 7-17-87
6. Approved By: Allen Vaughan
Supervisory Biologist
EEB/HED
Signature: *Allen W. Vaughan*
Date: 7-17-87
7. Conclusions:

This study indicates BCDMH is highly toxic to rainbow trout with an LC₅₀ of 0.17 (0.13 to 0.20) ppm. This study does fulfill the requirement in support of registration for a coldwater fish study.
8. Recommendation: N/A.
9. Background:

This study was submitted in support of BCDMH 96 technical.
10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were rainbow trout (Salmo gairdneri) from a commercial source in California; weight = 0.32 g; SL = 33 mm.
- b. Test System - Fish were tested in 11 L glass aquariums; temperature was 12 °C; photoperiod was 16 hours of light and 8 hours of darkness.
- c. Dose - Nominal concentrations were used; no solvent used.
- d. Design - Ten fish per dose level; 5 dose levels plus control (0, 0.054, 0.083, 0.13, 0.20, 0.30 ppm).
- e. Statistics - The statistics were verified with Stephan's computer program (Probit Methods).

12. Reported Results:

The study author found the 96-hour LC₅₀ to be 0.14 ppm. The no-observed-effect level was 0.045 ppm.

13. Study Author's Conclusions:

The 96-hour LC₅₀ was 0.14 (0.13 to 0.20) ppm.

The data contained in this report were audited by the Quality Assurance Unit to assure compliance with the Protocols, Standard Operating Procedures, and the pertinent EPA Laboratory Practice Regulations. It was the opinion of Quality Assurance Unit that these data accurately reflect the raw data generated during this study.

14. Reviewer's Discussion and Interpretation of the Study:

- a. Test Procedure - The test procedure complied with the recommended EPA Protocol of October 1982. The measured concentrations ranged from 80 to 90 percent of the nominal concentrations.
- b. Statistical Analysis - The statistics were verified with Stephan's computer program.
- c. Discussion/Results - BCDMH is highly toxic to rainbow trout with an LC₅₀ of 0.14 ppm.
- d. Adequacy of Study
 - 1) Category - Core.

2) Rationale - N/A.

3) Reparability - N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: BCDMH
2. Test Material: 96.0% (Technical ai)
3. Study Type: 48-Hour LC₅₀

Species Tested: Daphnia magna

4. Study ID: Hoberg, J.R. (1986) Acute Toxicity of Bromo-Chloro-Dimethylhydantoin (BCDMH) to Daphnia magna under Flow-through Conditions; Report No. RW-86-9-2140; Prepared by Springborn Bionomics for Ethyl Corporation, P.O. Box 14799, Baton Rouge, LA 70898.

5. Reviewed By: Curtis E. Laird
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EEB/HED

Signature: *Curtis E. Laird*

Date: 7-17-87

6. Approved By: Allen Vaughan
Supervisory Biologist
EEB/HED

Signature: *Allen W. Vaughan*

Date: 7-17-87

7. Conclusions:

This study indicates BCDMH is highly toxic to Daphnia magna with an LC₅₀ of 0.10 ppm. This study does fulfill the requirement in support of registration for an aquatic invertebrate study. The no-observed-effect level was 0.022 ppm.

8. Recommendation: N/A.

9. Background:

This study was submitted in support of BCDMH 96 technical.

10. Discussion of Individual Test: N/A.

11. Material and Methods:

- a. Test Animals - Test animals were Daphnia magna from laboratory stock.
- b. Test System - Test system was 1.8 L glass vessels; temperature was 20 °C.
- c. Dose - Nominal test concentration plus control. The measured concentration ranged from 71 to 78 percent of nominal concentration.
- d. Design - Twenty daphnids per dose level; 5 dose levels plus control (0, 0.03, 0.062, 0.12, 0.25, and 0.50 ppm).
- e. Statistics - Probit analysis shows BCDMH to be highly toxic to Daphnia magna with an LC₅₀ of 0.10 ppm.

12. Reported Results:

The study author found the 48-hour LC₅₀ to be 0.097 ppm. The no-observed-effect level was 0.022 ppm.

13. Study Author's Conclusions:

The 48-hour LC₅₀ was 0.10 ppm.

The data contained in this report were audited by the Quality Assurance Unit to assurance compliance with the Protocols, Standard Operating Procedures and the pertinent EPA Good Laboratory Practice Regulations on the following dates: 3 and 5 September 1986. All discrepancies were reported immediately to the study director and management.

14. Reviewer's Discussion and Interpretation of the Study

- a. Test Procedures - Test procedure complied with the recommended EPA Protocol of October 1982 (Part 158).
- b. Statistical Analysis - Probit analysis showed the 48-hour LC₅₀ to be 0.10 ppm.
- c. Discussion/Results - BCDMH is highly toxic to Daphnia magna with an LC₅₀ of 0.10 ppm.
- d. Adequacy of Study
 - 1) Category - Core.
 - 2) Rationale - N/A.
 - 3) Reparability - N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.