249427
RECORD NO.
006315, 006317
028501
SHAUGHNESSEY NO

REVIEW NO.

EEB REVIEW

DATE: IN 08-9-89 OUT 5-21-90

FILE OR REG. NO. 6836-115

PETITION OR EXP. NO.

DATE OF SUBMISSION 1-31-89

DATE RECEIVED BY HED 8-7-89

RD REQUESTED COMPLETION DATE 10-7-89

EEB ESTIMATED COMPLETION DATE 10-7-89

RD ACTION CODE/TYPE OF REVIEW 305

TYPE PRODUCT(S) Microbiocide

DATA ACCESSION NO(S) 409931-01, 02, 03

PRODUCT MANAGER, NO. Walter Francis PM(32)

PRODUCT NAME(S) Dantobrom RW

COMPANY NAME Lonza, Inc.

SUBMISSION PURPOSE Submission of estuarine data to support proposed label amendment for once-through use in industrial cooling water systems

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
006315	1-bromo-3-chloro-5, 5-dimethylhydantoin	60.0
006317	1,3-dichloro-5-ethyl-5-methylhydantion	10.6
028501	1,3-dichloro-5, 5-dimethylhydantoin	27.4

100 Pesticide Name

Dantobrom RW

100.3 Submission Purpose

Submission of estuarine data to support proposed label amendment for once-through industrial cooling water systems

101 Chemical and Physical Properties

101.1 Chemical Name

Active Ingredients
1-bromo-3-chloro-5,5-dimethylhydantoin.....60.0
1,3-dichloro-5,5-dimethylhydantoin.....27.4
1,3-dichloro-5-ethyl-5-methylhydantoin.....10.6
Inert Ingredients.....2.0
Available bromine.....39.2
Available chlorine.....39.9

101.2 Trade Name

Dantobrom RW

103 Toxicological Properties

96-hour LC50 for sheepshead minnow
96-hour LC50 for mysid shrimp
96-hour shell deposition for eastern oysters

105 Conclusions

I. DERS

A. Sheepshead minnow LC50

This study indicates Dantobrom RW is moderately toxic to sheepshead minnow with an LC50 of 1.2 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an estuarine fish study.

B. Mysid shrimp LC50

This study indicates Dontobrom RW is highly toxic to mysid shrimp with an LC50 of 0.9 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an estuarine invertebrate study.

C. Eastern Oyster EC50

This study indicates Dantobrom RW is highly toxic to eastern oyster with an EC50 of 0.86 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an oyster study.

It was stated in the 1985 Registration Standard, if Dantobrom RW was intended for use in the estuarine/marine environment , that three marine/estuarine studies would be required to support the recirculating use pattern (recirculating cooling water and industrial air washer systems). The three required studies were submitted and found acceptable to support registration.

II. Amended Use

The registrant wants to amend the label to include once-through use pattern. Based on available data, the proposed use rates range from 0.1 to 1.0 lb. a.i. per 1000 gallons of water in the system or 12 ppm to 120 ppm of water in the system. These concentrations will exceed the nontarget aquatic organisms LC50's values:

Species	LC50 Value (ppm)	Low Range (ppm)	High Range (ppm)
Rainbow	2.07	5.79 times	57.97 times
Bluegill	1.17	10.25 times	102.56 times
Daphnia m.	0.95	12.63 times	126.31 times
Sheepshead	1.2	10.00 times	100.00 times
Mysid sh.	0.9	13.33 times	133.33 times
Eastern O.	0.86	13.95 times	139.53 times

EEB is unable to complete a risk assessment for the proposed use (once-through) due to lack of pertinent ecological effects data. In order to complete a risk assessment for this use, EEB requires a residue monitoring study to determine the exact concentration of Dantobrom RW entering aquatic environments. EEB realizes that Dantobrom RW will decrease in concentration due to dilution and volatilization. However, the amount of decrease is unknown and needs to be identified prior to registration.

In closing, the registrant has sufficient data to support Dantobrom RW for use in recirculating cooling water and industrial air water systems. However, a residue monitoring study for both freshwater and marine/estuarine environments is required to support the once-through industrial cooling water systems use.

Curtis E. Laird 4-26-90
Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Norman J. Cook 5.17-90
Norman J. Cook, Head-Section 2
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

James W. Akerman, Chief 5/16/90
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

DATA EVALUATION RECORD

1. CHEMICAL: Dantobrom RW

2. TEST MATERIAL: 98.0% (Technical a.i.)

a. 006315 1-bromo-3-chloro-5,5-dimethyhydantoin ------ 60.0%
b. 006317 1,3-dichloro-5-ethyl-5-methylhydantoin ----- 10.6%
c. 028501 1,3-dichloro-5,5-dimethylhydantoin --------- 27.4%

3. TEST TYPE: 96-HOUR Shell Deposition

Test Species: Eastern Oyster (Crassastrea virginia)

4. STUDY INDENTIFICATION: Surprenant, D.C. (1988) Acute Toxicity of Dantobrom RW To Eastern Oysters (Crassostra virginica) under Flow-through conditions; prepared by Springborn Life Science, Inc. for Lonza, Inc. Fair Lawn, New Jersey 07410; Report No. 88-8-2794; Acc. No. 409931-01.

5. REVIEWED BY:

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-26-90

6. APPROVED BY:

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J Cook
Date: 5.17.90

7. CONCLUSIONS: This study indicate Dantobrom RW is highly toxic to eastern oysters with an EC50 of 0.86 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an oyster study. The NOEL was 0.37 ppm (as $mgBr_2/L$).

8. RECOMMENDATIONS: N/A

9. BACKGROUND:

This study was submitted in support of Dantobrom RW registration for once-through industrial cooling water systems.

10. DISCUSSION OF INDIVIDUAL TEST: N/A

11. MATERIAL TESTED:

A. Tested Animals: Test animals were eastern oysters (Crassostrea virginica from Agricultural Research Corporation; size = 40 ± 5 mm.

B. Test Design: Oysters were tested in 11.0 liter glass aquarium: temperature was 11oC; turnovers = 6.5/24 hours; salinity was 32 o/oo; Photoperiod 16 L/8D.

C. Dose: Bioassay using a flow-through method; 30 oysters per dose level; five dose levels plus control (0, 0.17, 0.37, 0.60, 1.0, and 2.0 ppm mean measured concentrations corresponding to 0, 0.58, 0.97, 1.6, 2.7, and 4.5 ppm nominal). The authors measured concentrations as total oxidant, but reported them as mgs total bromine per liter solution ($mgBr_2/L$).

D. STATISTICAL ANALYSIS: Probit Analysis

12. Reported Results: The study author found the 96-hour EC50 to be 0.84 ppm (as $mgBr_2/L$).

13. STUDY AUTHOR'S CONCLUSION/QA MEASURES: The 96-hour EC50 was 0.84 ppm (as $mgBr_2/L$). The raw data and final report for this study were inspected by the Springborn Life Science, Inc., Quality Assurance Unit (QAU) to Assure Compliance with the study protocol, laboratory standard operating precedures and the pertinent EPA Good Laboratory Practice Regulations. It was the opinion of the QAU that this report accurately reflects the raw data collected 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

B. STATISTICAL ANALYSIS:

Probit metod showed the 96-hour EC50 to be 0.86 ppm (as $mgBr_2/L$).

C. DISCUSSION/RESULTS: Dantobrom RW is highly toxic to eastern oyster with an EC50 of 0.86 ppm (as $mgBr_2/L$) .

D. ADEQUACY OF STUDY:

1. Category: Core

2. Rationale: N/A

3. Reparability: N/A

15. Completion of one-liner for study Yes

16. CBI Appendix N/A

RIN # 3113-00

EPA Data Evaluation Records

(DERS)

Page_____ is not included in this copy.

Pages 7 through 8 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

1. CHEMICAL: Dantobrom RW

2. TEST MATERIAL: 98.0% (Technical a.i.)

a. 006315 1-bromo-3-chloro-5,5-dimethylhydantoin----- 60.0%
b. 006317 1,3-dichloro-5-ethyl-5-methylhydantoin----- 10.6%
c. 028501 1,3-dichloro-5,5-dimethylhydantoin--------- 27.4%

3. TEST TYPE: 96-hour LC50

Test Species: Mysid shrimp (Mysidopis bahia)

4. STUDY IDENTIFICATION: Surprenant, D.C. (1988) Acute Toxicity of Dantobrom RW to Mysid Shrimp (Mysidopis bahis) under flow-through conditions; Report #88-8-2797; Prepared by Springborn Life Sciences, Inc. for Lonza, Inc., Fair Lawn, NJ. 07410; Acc. #409931-02

5. REVIEWED BY:

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-26-90

6. APPROVED BY:

Norman J. Cook
Surpervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 5.17.90

7. CONCLUSIONS: This study indicates Dantobrom is highly toxic to mysid shrimp with an LC50 of 0.9 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an estuarine/marine invertebrate LC50 study. The NOEL was 0.10 ppm (as $mgBr_2/L$).

8. RECOMMENDATIONS: N/A

9. BACKGROUND:

This study was submitted in support of Dantobrom RW registration for once-through use.

10. DISCUSSION OF INDIVIDUAL TEST: N/A

11. MATERIAL TESTED:

A. Test Animals: Test animals were mysid shrimp from laboratory shock; age = < 24 hours old.

B. Test Design: Shrimp were tested in 11.0 L glass aquarium: temperature was 25 ± 1oC; photoperiod was 16L/8Dk; turnovers = 7/day; salinity was 31 o/oo.

C. Dose: Flow-through bioassay using measured concentrations, twenty shrimp per dose level; six dose levels plus negative control (0, 0.09, 0.1, 0.22, 0.6, 0.74, 1.4 ppm measured concentrations corresponding to 0.35, 0.53, 0.82, 1.3, 2.0, and 3.0 ppm nominal. The authors measured concentrations as total oxidant but reported them as $mgBr_2/L$).

D. Statistical Analysis: Probit Analysis

12. Reported Results: The study author found the 96-hour LC50 to be 0.9 ppm (as $mgBr_2/L$).

13. STUDY AUTHOR'S CONCLUSION/QA MEASURES: The 96-hour LC50 was 0.93 ppm (as $mgBr_2/L$). The raw data and final report for this study were inspected by Springhorn Life Sciences, Inc., Quality Assurance Unit (QAU) to assure compliance with the study Protocol, laboratory standard operation procedures and the pertinent EPA Good Laboratory Practice Regulation. It was the opinion of the QAU that this report accurately reflects the raw data collected during this study.

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

A. TEST PROCEDURE: The test procedures complied with the recommended EPA Protocol of Oct. 1982

B. STATISTICAL ANALYSIS: The statistics were verified with Stephan's computer program.

C. DISCUSSION/RESULT: Dantobrom RW is highly toxic to mysid shrimp with an LC50 of 0.9 ppm (as $mgBr_2/L$).

D. ADEQUACY OF STUDY:

1. Category: Core

2. Rationale: N/A

3. Reparability: N/A

15. Completion of one-liner for study: Yes

16. CBI Appendix N/A

Laird Dantobrom Mysid shrimp 08-15-89

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.4	20	20	100	9.536742E-05
.74	20	3	15	.1288414
.6	20	3	15	.1288414
.22	20	1	5	2.002716E-03
.1	20	0	0	9.536742E-05
9.536742E-02		20	0	0
9.536742E-05				

THE BINOMIAL TEST SHOWS THAT .74 AND 1.4 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 .9257828

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	8.643128E-02	.8973599	.8054463	1.016134

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 5.046714

95 PERCENT CONFIDENCE LIMITS =-5.691759 AND 15.78519

LC50 = .8729203

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = .489019

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

DATA EVALUATION RECORD

1. CHEMICAL: Dantsbrom RW

2. TEST MATERIAL: 98.0% (technical a.i.), a white powder

a. 1-bromo-3-chloro-5,5-dimethylhydantoin ------- 60.0%
b. 1,3-dichloro-5-ethyl-5-methylhydantoin ------- 10.6%
c. 1,3-dichloro-5,5-dimethyhydantoin ---------- 27.4%

3. TEST TYPE: 96-hour LC_{50}

Test Species: Sheepshead Minnow (Cypinodon variegatus)

4. STUDY IDENTIFICATION: Surprenant, Donald C. (1988) Acute Toxicity of Dantobrom RW to Sheepshead Minnow (Cypinodon variegatus) under flow-through conditions; Report No. 88-8-2795; Prepared by Springborn Life Sciences, Inc., for Lonza, Inc., Fair Lawn, N.J. 07410; Acc. No. 409931-03.

5. REVIEWED BY:

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 4-26-90

6. APPROVED BY:

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 5.17.90

7. CONCLUSIONS: This study indicates Dantobrom RW is moderately toxic to sheepshead minnow with an LC_{50} of 1.2 ppm (as $mgBr_2/L$). This study does fulfill the requirement in support of registration for an estuarine/marine fish study. The NOEL was less than 0.19 ppm (as $mgBr_2/L$), the lowest measured concentration.

8. RECOMMENDATIONS: N/A

9. BACKGROUND: This study was submitted in support of Dantobrom RW registration including once-through use.

10. DISCUSSION OF INDIVIDUAL TEST: N/A

11. MATERIAL TESTED:

A. Test Animals: Test animals were sheepshead minnow from a commercial supplier in New York; Weight = 0.27g; length = 25 mm.

B. Test Design: Fish were tested in 11.0 L glass aquaria; temperature ranged from 22-25 C; photoperiod was 16L/8D; turnover = 6.5/24 hours; Salinity ranged from 32-34 0/00.

C. Dose: Flow-through bioassay using measured concentration; ten fish per dose level; 6 dose levels plus negative control (0, 0.19, 0.20, 0.46, 0.88, 1.2 and 2.1 ppm mean measured concentrations ~~to~~ correspondingly 0, 0.46, 0.70, 1.1, 1.7, 2.6, and 3.9 ppm nominal. The authors measured concentrations as total oxident but reported them as $mgBr_2/L$.

D. Statistical Analysis: The moving average method

12. REPORTED RESULTS: The study author found the 96-hour LC_{50} to be 1.4 (0.88 - 2.1) ppm (as $mgBr_2/$).

13. STUDY AUTHOR'S CONCLUSION/QA MEASURES: The 96-hour LC_{50} was 1.4 ppm (as $mgBr_2/L$). The raw data and final report for this study were inspected by Springborn Life Science, Inc., Quality Assurance Unit (QAU) to assure compliance with the study protocol, laboratory standard operating procedures and the pertinent EPA Good Laboratory Practice Regulation. It was the opinion of the QAU that this report accurately reflects 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 Oct. 1982.

B. Statistical Analysis: The moving average method showed the 96-hour LC_{50} to be 1.2 (0.99 - 1.6) ppm (as $mgBr_2/L$).

C. Discussion/Result: Dantabrom RW is considered to be moderately toxic to sheepshead minnow with an LC_{50} of 1.2 ppm (as $mgBr_2/$).

D. Adequacy of Study:

1. Category: Core
2. Rationale: N/A
3. Reparability: N/A

15. Completion of one-liner for study: Yes

16. CBI Appendix: N/

Laird Dantobrom Sheepshead minnow 8-14-89

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PER CENT)
2.1	10	10	100	9.765625E-02
1.2	10	3	30	17.1875
.88	10	2	20	5.46875
.46	10	1	10	1.074219
.2	10	2	20	5.46875
.19	10	3	30	17.1875

The binomial test shows that 0 and 2.1 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 LC_{50} for this set of data is 1.363518

Results calculated using the moving average method :

Span	G	LC_{50}	95 percent	confidence level
3	.1454285	1.223616	.9929595	1.564046

Results calculated using the probit method

Iterations	G	H	Goodness of fit probability
4	3.098189	3.442419	8.068025E-03

Since the probability is less than 0.05, results calculated using this probit method probably should not be used.

SLOPE = 1.375545

95 percent confidence limits = -1.045645 and 3.796735

LC_{50} = 1.186325

95 percent confidence limits = 0 and + infinity

LC10 = 1.1415577

95 percent confidence limits = 0 and .6405812