

US EPA ARCHIVE DOCUMENT

EEB BRANCH REVIEW

DATE: IN 5-1-84 OUT 7-26-84

FILE OR REG. NO. 38906-RE, 38906-RG, 38906-RU

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 2-23-84

DATE RECEIVED BY HED 4-30-84

RD REQUESTED COMPLETION DATE 8-20-84

EEB ESTIMATED COMPLETION DATE 8-13-84

RD ACTION CODE/TYPE OF REVIEW 116/New Chemical

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. A.E. Castillo (32)

PRODUCT NAME(S) DantoBrom Products

COMPANY NAME GLYCO Inc.

SUBMISSION PURPOSE Submission of Data to Support Proposed

Registrations of Microbiocide Uses

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

ACTIVE INGREDIENTS: Weight Percent

006315	1-bromo-3-chloro-5,5-dimethylhydantoin,	60.0
028501	1,3-dichloro-5,5-dimethylhydantoin,	27.4
006317	1,3-dichloro-5-ethyl-5-methylhydantoin,	10.6
	Inert Ingredients	2.0
	Available bromine,	39.2
	Available chlorine,	44.4

100 Pesticide Name

DantoBrom

100.3 Submission Purpose

Submission of data to support proposed registration of microbiocide uses.

101 Chemical and Physical Properties

101.1 Chemical

Active Ingredients:

	<u>Weight percent</u>
1-bromo-3-chloro-5,5-dimethylhydantion	60.0
1,3-dichloro-5,5-dimethylhydantsin	27.4
1,3-dichloro-5-ethyl-5-methylhydantsin	10.6
Inert Ingredients	2.0
Available Bromine	39.2
Available Chlorine	44.4

101.2 Common Name

DantoBrom

103 Toxicological Properties

96-hour LC₅₀ for Rainbow trout;
96-hour LC₅₀ for Bluegill Sunfish and
48-hour LC₅₀ for Daphnia magna

105 Conclusions

The 96-hour fish study indicates DantoBrom is highly toxic to rainbow trout and moderately toxic to bluegill sunfish with an LC₅₀ of 0.5 and 1.15 ppm.

The 48-hour aquatic invertebrate study indicates DantoBrom is highly toxic to daphnia magna with an LC₅₀ of 0.34 ppm.

The above fish and aquatic invertebrate studies do not meet the requirement in support of registration because a formulated product was used instead of technical grade material.

105.1

Adequacy of Toxicity Data

105.1.1 Bromochlorodimethylhydantoin (1-bromo-3-chloro-5,5-dimethylhydantoin 90%).

<u>Species</u>	<u>Review Date</u>	<u>Results</u>	<u>Category</u>
Bobwhite Quail	6-11-84	>2510 mg/kg	Core
Bobwhite Quail	6-12-84	>5620 ppm	Core
Mallard Duck	6-12-84	>5620 ppm	Core
Rainbow Trout	6-14-84	0.66 ppm	Core
Bluegill Sunfish	6-14-84	1.13 ppm	Core
Daphnia Magna	6-15-84	0.87 ppm	Core

105.1.2 Dichlorodimethylhydantoin (1,3-dichloro-5,5-dimethylhydantoin 97%)

<u>Species</u>	<u>Review Date</u>	<u>Results</u>	<u>Category</u>
Bobwhite Quail	6-18-84	1715 mg/kg	Core
Bobwhite Quail	6-19-84	>5620 ppm	Core
Mallard Duck	6-18-84	>5620 ppm	Core
Rainbow Trout	6-19-84	0.83 ppm	Core
Bluegill Sunfish	6-19-84	2.3 ppm	Core
Daphnia Magna	6-19-84	0.47 ppm	Core

For more detail see review (38906-RU) by C. Laird on 7-18-84.

105.2 Inadequacy of Toxicity Data

<u>Species</u>	<u>Review Date</u>	<u>Results</u>	<u>Category</u>
Bluegill Sunfish	7-5-84	1.15 ppm	Supplementa
Rainbow Trout	7-5-84	0.5 ppm	Supplementa
Daphnia magna	7-6-84	0.3 ppm	Supplementa

The above fish and aquatic invertebrate studies conducted with the following active ingredients (% by weight) are considered to be supplement and do not meet the requirement in support of registration because a formulated product was used instead of technical grade material:

<u>ACTIVE INGREDIENTS:</u>	<u>Weight Percent</u>
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,	44.4

105.3 Data Required

Prior to consideration of DantoBrom for the proposed uses, the following minimal studies are required:

- (a) the avian acute oral LD₅₀ for one species of waterfowl (mallard duck, preferably) or one species of upland game bird (bobwhite quail or ring-necked pheasant);
- (b) the dietary LC₅₀ for one species of waterfowl (mallard duck) and one species of upland game bird (bobwhite quail, or ring-necked pheasant);
- (c) the 96-hour LC₅₀'s for a coldwater species (rainbow trout) and a warmwater species (bluegill sunfish) of fish;
- (d) the acute 48-hour LC₅₀ for an aquatic invertebrate (Daphnia sp., preferably).

The above studies are required on the technical grade material for: 1,3-dichloro-5-ethyl-5-methylhydantoin.

If this product is intended for use in offshore oil recovery systems then the following data are required on the technical grade material of each active ingredient in the product.

1. The 96-hour LC₅₀ for a marine or estuarine fish;
2. The 96-hour LC₅₀ for shrimp; and
3. The 48-hour EC₅₀ for oyster embryolarvae or 96-hour EC₅₀ shell deposition study with oyster.

105.4 Use Patterns

105.4.1 38906-RE (Formulated Product) DantoBrom Aid in the control of bacterial, fungal and algae slimes in recirculating cooling water systems and airwashers.

105.4.2 38906-RU (Manufacturing Product) DantoBrom
For Reformulating and/or Repacking Use

105.4.3 38906-RG (Formulated Product) DantoBrom

For use in spas and hot tubs. DantoBrom S will disinfect spas and hot tubs and keep the water clean, and free of odor.

Curtis E. Laird 7-25-84
Curtis E. Laird
Fishery Biologist
Ecological Effects Branch/HED

Norman Cook 7-26-84
Norman Cook
Head, Section #2
Ecological Effects Branch/HED

Clayton Bushong
Chief
Ecological Effects Branch/HED

Clayton Bushong
7/26/84

1. Chemical: DantoBrom

<u>2. Formulation:</u> ACTIVE INGREDIENTS:	<u>Weight Percent</u>
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,	44.4

3. Citation: Spare, W.C. (1982) The Acute Toxicity of GSD-560 to the Bluegill Sunfish (*Lepomis macrochirus*); Project #82-E-1812B; Prepared by Biospherics Incorporation for Glyco Incorporation, Head of Trenton Avenue, P.O. Box 3187, Williamsport, Pennsylvania 17707; Acc. #253074 & 72.

4. Reviewed By: Curtis E. Laird
Fishery Biologist
EEB/HED

5. Date Reviewed: 7-5-84

6. Study Type: 96-hour LC₅₀

A. Test Species: Bluegill Sunfish

7. Reported Results: The 96-hour LC₅₀ to Bluegill Sunfish was 1.2 ppm. This value was based on normal concentration of the test material.

8. Reviewer's Conclusions: This study indicates DantoBrom is moderately toxic to bluegill sunfish with an LC₅₀ of 1.2 ppm. This study does fulfill the requirement in support of registration for a formulated product only.

Material/Methods

Test Procedure

The test procedure complied with the recommended EPA protocol of Oct. 1982 (part 158), except a formulated product was used instead of technical grade material.

Statistical Analysis

Binomial probability

Discussion/Results

The 96-hour LC₅₀ of ppm was calculated by the binomial probability method. Behavioral observations showed sign of hyperercitable. The no effect level was 0.9 ppm.

Reviewer's Evaluation

A. Test Procedure

The test procedure complied with the recommended EPA protocol of oct. 1982 (part 158), except a formulated product was used instead of technical grade material.

B. Statistical Analysis

The binomial test shows the 96-hour LC₅₀ value to be 1.6 ppm.

C. Conclusions

1. Category: Supplemental
2. Rationale: See test procedure above.
3. Repairability: Not repairable to core.
However, this study is core for a formulated product.

LAIRD DANTOBROM 96-HOUR LC50 FOR BLUEGILL SUNFISH

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
9	10	10	100	.0976563
5	10	10	100	.0976563
3	10	10	100	.0976563
1.7	10	10	100	.0976563
.9	10	1	10	1.07422

THE BINOMIAL TEST SHOWS THAT .9 AND 1.7 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 1.15669

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.

1. Chemical: DantoBrom

2. Formulation: ACTIVE INGREDIENTS:

Weight
Percent

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,	44.4

3. Citation: Spare, W.C. (1982) The Acute Toxicity of GSD-560 to Rainbow Trout (Salmo gairdner); Project #82-E-1812R; Prepared by Biospherics Incorporation for Glyco Incorporation, Head of Trenton Avenue, P.O. Box 3187, Williamsport, Pennsylvania 17701; Acc #253074 & 72.

4. Reviewed By: Curtis E. Laird
Fishery Biologist
EEB/HED

5. Study Type: 96-hour LC₅₀

A. Test Species: Rainbow Trout

6. Date Reviewed: 7-5-84

7. Reported Results: The 96-hour LC₅₀ to rainbow trout was 0.5 mg/l and the no effect level was 0.3 mg/l.

8. Reviewer's Conclusions: This study indicates DantoBrom is highly toxic to rainbow trout with an LC₅₀ of 0.5 ppm. However, This study does fulfill the requirement in support of registration for a formulated product only.

Material/Methods

Test Procedure

The test procedure complied with the recommended EPA of Oct. 1982 (part 158), except a formulated product was used instead of technical grade material.

Statistical Analysis

Binomial Probability

Discussion/Results

The reported 96-hour LC_{50} was 0.5 ppm and the no effect level was 0.3 ppm. The toxic symptoms were quiescent, gyrating, irritated and light discolored. Ten animals per dosage level was used.

Reviewer's Evaluation

A. Test Procedure

The test procedure complied with the recommended EPA protocol of Oct. 1982 (part 158), except a formulated product was used instead of technical grade material.

B. Statistical Analysis

The binomial test shows that the 96-hour LC_{50} to be approximately 0.5 ppm.

C. Conclusions

1. Category: Supplemental
2. Rationale: See test procedure above
3. Repairability: Not repairable to core.

LAIRD DANTOBROM 96-HOUR LC50 FOR RAINBOW TROUT

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
3	10	10	100	.0976563
1.7	10	10	100	.0976563
.9	10	10	100	.0976563
.5	10	5	50	62.3047
.3	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT .3 AND .9 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 .5

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.

1. Chemical: DantoBrom

2. Formulation:

ACTIVE INGREDIENTS:	<u>Weight Percent</u>
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,	44.4

3. Citation: Spare, W.C. (1982) The Acute Toxicity of GSD-560 to Daphnia magna Straus; Project No. 82-E-1812D; Prepared by Biospherics Incorporation for Glyco Incorporation, P.O. Box 3187, Williamsport, Penn. 17701; Acc. #253074 & 72.

4. Reviewed by: Curtis E. Laird
Fishery Biologist
EEB/HED

5. Review Date: 7-6-84

6. Study Type: 48-hour LC₅₀

A. Test Species: Daphnia magna Straus

7. Reported Results: The 48-hour LC₅₀ of 0.4 mg/l (0.3 - 0.5 mg/l confidence interval) was calculated by the binomial probability method. The 48-hour no observed effect concentration was less than 0.3 mg/l.

8. Reviewer's Conclusions: This study indicates DantoBrom is highly toxic to daphnia magna with an LC₅₀ of 0.3 ppm. However, this study does not fulfill the requirement in support of registration because a formulated product was used instead of technical material.

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Material/Methods

Test Procedure

The test procedure complied with the recommended EPA protocol of Oct. 1982 (part 158), except a formulated product was used instead of technical grade material.

Statistical Analysis

Probit Analysis

Discussion/Results

The 48-hour LC₅₀ value is 0.34 ppm. The no effect level is less than 0.3 ppm. The toxic symptoms were not mentioned. 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 scientifically sound results.

Reviewer's Evaluation

A. Test Procedure

The test procedure complied with the recommended EPA protocol of Oct. 1982 (part 158), except the a formulated product was used instead of technical grade material.

B. Statistical Analysis

The binomial test shows the 48-hour LC₅₀ to be 0.34 ppm.

C. Conclusions

1. Category: Supplemental
2. Rationale: See test procedure above.
3. Repairability: Not repairable to core. However, this study is core for a formulated product.

LAIRD DANTOBROM 48-HOUR LC50 FOR DAPHNIA MAGNA

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
3	20	20	100	9.53674E-05
1.7	20	20	100	9.53674E-05
.9	20	20	100	9.53674E-05
.5	20	20	100	9.53674E-05
.3	20	5	25	2.06947

THE BINOMIAL TEST SHOWS THAT .3 AND .5 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 .344193

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.

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