

7-28-94

DP Barcode : D205637
PC Code No : 081901
EEB Out :

To: Walter Waldrop/Andrew Ertman
Product Manager 71
Special Review and Reregistration Division (7508W)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 081901
Chemical Name : Chlorothalonil
Type Product : Fungicide
Product Name : Bravo 720
Company Name : ISK Biosciences
Purpose : Reregistration data (72-1d)
Action Code : 627 Date Due : 10/18/94
Reviewer : William Erickson Date In : 07/25/94

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

Gdln No.	MRID No.	Cat.	Gdln No.	MRID No.	Cat.	Gdln No.	MRID No.	Cat.
71-1(a)			72-2(a)			72-7(a)		
71-1(b)			72-2(b)			72-7(b)		
71-2(a)			72-3(a)			122-1(a)		
71-2(b)			72-3(b)			122-1(b)		
71-3			72-3(c)			122-2		
71-4(a)			72-3(d)			123-1(a)		
71-4(b)			72-3(e)			123-1(b)		
71-5(a)			72-3(f)			123-2		
71-5(b)			72-4(a)			124-1		
72-1(a)			72-4(b)			124-2		
72-1(b)			72-5			141-1		
72-1(c)			72-6			141-2		
72-1(d)	433021-01	Y				141-5		

Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil: fish acute toxicity test

FROM: *for* Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) *Douglas J. Urban 7/28/94*

TO: Walter Waldrop/Andrew Ertman
Product Manager 71
Special Review and Reregistration Division (7508W)

ISK Biosciences, Mentor, OH, submitted the following study to support reregistration of chlorothalonil:

Shults, S.K., A.W. Brock, and J. Laveglia. 1994. Acute toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through conditions with Bravo 720. Conducted by Springborn Laboratories, Inc., Wareham, MA. MRID No. 433021-01.

The DER is enclosed. The study is sound and fulfills the data requirement for an acute freshwater fish toxicity test with the end-use product. The LC₅₀ value of 61 µg/l classifies Bravo 720 as very highly toxic to rainbow trout.

If you have any questions, please contact Bill Erickson at 305-6212 or Harry Craven at 305-5320.

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DATA EVALUATION RECORD

1. **CHEMICAL:** Chlorothalonil
Shaughnessey No.: 081901
2. **TEST MATERIAL:** Bravo 720; Batch No. 022015; Lot No. 029249;
54.5% ai; a grey viscous liquid.
3. **STUDY TYPE:** 72-1(d). Acute Freshwater Fish Toxicity Test.
Species: Rainbow Trout (*Oncorhynchus mykiss*)
4. **CITATION:**

Author: Shults, S.K., A.W. Brock, J. Laveglia.
Title: Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions with Bravo 720.
Date: July 1, 1994
Lab. Report #: 5727-93-0120-TX-002
Sponsor: ISK Biosciences Corporation
Laboratory: Springborn Laboratories, Inc.
MRID No.: 433021-01

5. **REVIEWED BY:**

William Erickson, Wildlife Biologist
Ecological Effects Branch
Environmental Fate and Effects Division

Signature:

Date:

W. Erickson
7/28/94

6. **APPROVED BY:**

for Harry Craven, Chief, Section 4
Ecological Effects Branch
Environmental Fate and Effects Division

Signature:

Date:

W. Erickson
7/28/94

7. **CONCLUSIONS:** The study is scientifically sound and fulfills the guideline study (71-2d) for an acute toxicity test with the formulated product. The LC_{50} value is 61 $\mu\text{g/l}$, which classifies Bravo 720 as very highly toxic to rainbow trout.
8. **RECOMMENDATIONS**
9. **BACKGROUND**
10. **MATERIALS AND METHODS**

A. Test Organisms:

Guideline Criteria	Reported Information
Species (Scientific Name)	<i>Oncorhynchus mykiss</i>
Mean Weight (0.5-5 grams)	0.56 g (n = 30) range = 0.34-0.84 g
Mean Length (S.L. longest not > 2x shortest)	39 mm (n = 30) range = 33-45 mm
Supplier	Mt. Lassen Trout Farm, Red Bluff, CA
All fish from same source (yes or no)	Yes
All fish from the same year class (yes or no)	Not specified
Other Comments	

B. Source/Acclimation:

Guideline Criteria	Reported Information
Acclimation Period (minimum 14 days)	14 days
Wild caught 7 day quarantine (yes or no)	N/A
Check for signs of disease or injury (yes or no, if yes describe)	No, but checked for mortality
If diseased it can be treated in 48-hr pretest no sign of the disease remains (Report hours prior to test in which no sign of disease or N/A)	N/A
No feeding during the study (When last fed)	48 h prior to testing
<3% mortality 48 hours prior to testing (% mortality, if any)	No mortality

C. Test System:

Guideline Criteria	Reported Information
Describe source of dilution water (prefer soft reconstituted water)	Well water
Does water support test animals without observable signs of stress?	Yes
Was dechlorinated water used (not recommended)	No
Water Temperature (Warm water-17°C or 22°C) (Cold water-12°C)	12°C
pH	7.0-7.2
Dissolved Oxygen (Static 1 st 48 hrs 60%; 2 nd 48 hrs 40%; Flow-through 60%) (% of lowest conc. & hour)	89-94%
Total hardness (40 to 48 mg/L as CaCO ₃ well water)	38-40 mg/l
Total Alkalinity	26-28 mg/l
Specific Conductance	120 µmhos/cm
Total Organic Carbon	0.49
Test Aquaria 1. Material (glass or stainless steel) 2. a. Static volume (18.9 L (5 gal or 19000 cc) with 15 L solution) b. Static or flow-through volume (300x600x300 = 54000 cc.)	Glass (39 x 20 x 25 cm) Flow-through test
Type of Dilution System (Reproducible supply of toxicant)	Intermittent flow proportional diluter with a 60% dilution factor

Flow rate Consistent flow rate-meter systems calibrated before study and checked 2*24 hours - 5 to 10 vol/24 hours	7.2 vol. replacements per aquarium every 24 h
Biomass Loading Rate (Static no > 0.8 g/L ≤ 17°C; >17°C 0.5g/L; Flow-through 1 g/L/24	0.07 g/l/day
Photoperiod (16 L & 8 D)	16 h L
Solvents 1. (Do not exceed 0.5 ml/L for static tests) 2. (Do not exceed 0.1 ml/L for flow-through)	Distilled water
Other Comments	

D. Test Design:

Guideline Criteria	Reported Information
<u>Range Finding Test</u> (LC ₅₀ >100 mg/L with 30 fish, no definitive test required.)	Yes
<u>Definitive Test</u>	
Nominal Concentrations (control+5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be geometric series)	16, 26, 43, 72, 120 µg/l of product and a dilution water control
Controls (Minimum control mortality; static 10%; flow-through 5%)	No mortality
Number of Test Organisms; (Minimum 10/level can be divided among containers)	20 per group (10 per rep)
All organisms must be randomly assigned to test vessels. (yes or no, describe if no)	"impartially selected"

Biological Observations (yes or no)	Yes
Water Parameter Measurements 1. Temperature - record every 6 hrs; >1°C. 2. D.O. beginning, 48 hrs, end for control high, medium, and low dose. 3. pH beginning, 48 hrs, end for control, high, medium, and low dose.	Yes Yes Yes
Chemical Analysis (needed if aeration, volatile, insoluble, precipitate, not steel or glass, known to adsorb, and flow-through) (yes or no)	Yes
Other Comments	

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Mean Measured Concentrations (report conc.)	12, 19, 29, 49, and 89 µg/l of product
Recovery of Chemical (% recovery)	68-77% of nominal
Mortality & Observations (Describe observations & attach mortality tables)	100% mortality at 89 µg/l (see Table 4, attached); at 49 µg/l, several fish with darkened pigmentation, lethargy, partial loss of equilibrium and at water surface; at 29 µg/l, several fish with darkened pigmentation
Author's Comments	

12. STUDY AUTHOR'S CONCLUSIONS / QUALITY ASSURANCE MEASURES: The study is reported to have been conducted in accordance with all pertinent EPA Good Laboratory Practice Regulations (40 CFR, Part 160) except that data for routine water and food contaminant screening analyses for pesticides, PCBs and metals were not collected in accordance with GLP procedures. A Quality Assurance Statement was included in the report.

13. REVIEWER'S DISCUSSION AND INTERPRETATION

A. Test Procedure: The following items did not meet the guideline criteria:

- The report does not specify the condition/health of the fish prior to initiation of the test or if they were treated for disease.
- Fish must be randomly assigned to treatment groups and test vessels; the report states that the fish were "impartially selected".

B. Statistical Analysis:

Guideline Criteria	Reported Information
Binomial (yes, no, or not reported)	96-h LC ₅₀ = 61 µg/l 95% CI = 49-89 µg/l
Moving Average Angle (yes, no, or not reported)	No
Probit (yes, no, or not reported)	No
Other Comments	NOEC = 29 µg/l

C. Discussion/Results: The LC₅₀ value calculated by EEB's TOXANOL program was 60 µg/l, with 95% confidence intervals of 49 and 89 µg/l (see attachment). This LC₅₀ value classifies Bravo 720 as very highly toxic to rainbow trout. The study is scientifically sound and fulfills the guideline (71-2d) for an acute toxicity test with the formulated product.

D. Adequacy of the Study:

1. Classification: Core, for the formulated product.
2. Rational: N/A.
3. Repairability: N/A.

14. COMPLETION DATE OF ONE-LINER FOR STUDY: 7/26/94.

CHLOROTHALONIL

Page 9 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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.

LC50 FISH

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
89	20	20	100	9.536742E-05
49	20	3	15	.1288414
29	20	0	0	9.536742E-05
19	20	0	0	9.536742E-05
12	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 49 AND 89 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 60.43026

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.
