

US EPA ARCHIVE DOCUMENT

SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 10/19/84 OUT DEC 24 1984

FILE OR REG. NO. 33753-G

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 9/21/84

DATE RECEIVED BY HED 10/16/84

RD REQUESTED COMPLETION DATE 12/24/84

EEB ESTIMATED COMPLETION DATE 12/17/84

RD ACTION CODE/TYPE OF REVIEW 161/Old Chemical

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

DATA ACCESSION NO(S) 255036

PRODUCT MANAGER NO. J. Lee (31)

PRODUCT NAME(S) Myacide AS

COMPANY NAME The Boots Company PLC

SUBMISSION PURPOSE Submission of data to support registration
of formulating use

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

100.0 Pesticide Name: Bronopol

100.3 Submission Purpose: Submission of subacute avian dietary toxicity study acute fish testing.

101.0 Chemical: 2-Bromo-2-nitropropane-1,3-diol

103.0 Toxicological Properties:

Bobwhite quail LC₅₀ = 4488 (2518-9827) ppm

Rainbow trout LC₅₀ = 41.5 (35.9-45.4) ppm

105.0 Conclusions: The acute rainbow trout study is scientifically sound and does fulfill Registration requirements. The LC₅₀ = 41.5 ppm suggest that Bronopol is slightly toxic to Rainbow trout.

The subacute avian dietary study on Bobwhite quail is scientifically sound and does fulfill Registration requirements. An LC₅₀ = 4488 ppm suggests that Bronopol is slightly toxic to Bobwhite quail.

Michael Rexrode 12/24/84
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Fishery Biologist
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1. Chemical: Bronopol
2. Test Material: 2-Bromo-2-nitropropane-1,3-diol 100% ai
3. Citation: Roberts, N.L. 1984. "The Subacute Dietary Toxicity (LC₅₀) of Bronopol to the Bobwhite Quail," prepared by Huntingdon Research Huntingdon, Cambridgeshire, for the Boots Co., Thurgarton, Nottingham, England.

4. Study Type: Avian Subacute Dietary

Test Species: Bobwhite quail (colinus virginianus)

5. Reviewed by: Miachel Rexrode
Biologist
EEB/HED
6. Reported Results: The LC₅₀ of Bronopol to Bobwhite quail was calculated at 4488 ppm (2518-9827 ppm).
7. Reviewer's Conclusions: This test appears to be scientifically sound and will support Registration. Bronopol is slightly toxic to Bobwhite quail, as confirmed by an LC₅₀ of 4488 ppm.

Methods/Materials

Birds, 1 day old, were obtained from D.R. and R.E. Wise, Monkfield, Bourne, Cambridgeshire. Group mean body weights were in the 11.0-11.4 g range. Test specimens were 11 days old, when placed on treatment (10 per treatment level).

Housing consisted of wooden boxes measuring 83x52x61 cm fitted with wire mesh lids. Additional heat was provided by 300 watt infra-red lamps. Temperature ranged from 26-31°C, while, relative humidity was 48%. Feeding consisted of standard HRC chick diet (Batch 4030) from the Joseph Odam Limited, Eye Mill, Peterborough, Cambridgeshire. Test material was incorporated in the basal diet to form a premix from which the final diets were formulated.

Results: LC_{50} values were calculated using the method of probit line analysis using maximum likelihood program. Mortality is noted in table 1.

Table 1. Subacute Dietary Toxicity Mortality of Bobwhite quail to Bronopol.

Treatment (ppm)	Day of Study									Total
	1	2	3	4	5	6	7	8	9	
100										0
500										0
1000				1	1					2
5000					1	2				3
10,000			3	3	3					9
CONTROL										0

CLINICAL OBSERVATIONS

Birds in Group 8 (bronopol 10,000 ppm) were subdued on Day 5. No other apparent treatment-related abnormalities occurred but, at post-mortem examination, some birds showed signs that they had been bullied (part of beak damaged or missing).

BODYWEIGHTS

Group mean bodyweights are given in Table 2.

Table 2

Group mean bodyweights and bodyweight increases (g/bird) (where fewer than 10 birds were weighed the numbers weighed are given in parentheses)

Group	Treatment (ppm)	Days of study								
		Bodyweight					Bodyweight change			
		-3	0	5	8	9	-3 to 0	0 to 5	5 to 9	
1	Control (0)	11.2	12.8	15.2(9)	17.9(9)	17.8(9)	1.6	2.4	2.6	
2	Control (0)	11.0	13.9	17.6	21.1	22.2	2.9	3.7	4.6	
3	Control (0)	11.3	12.4	16.1	18.2	19.8	1.1	3.7	3.7	
4	Bronopol (100)	11.1	13.1	16.5	19.1	20.1	2.0	3.4	3.6	
5	Bronopol (500)	11.3	13.5	19.0	23.1	22.8	2.2	5.5	3.8	
6	Bronopol (1000)	11.0	12.7	19.0(8)	22.6(8)	23.8(8)	1.7	6.3	4.8	
7	Bronopol (5000)	11.4	12.6	16.4(9)	18.7(7)	20.3(7)	1.2	3.8	3.9	
8	Bronopol (10000)	11.2	11.6	17.0(1)	21.0(1)	21.0(1)	0.4	5.4	4.9	

Group mean bodyweights and bodyweight changes were within normal limits and there were no treatment-related differences.

FOOD CONSUMPTION

Food consumption results are shown in Table 3.

Table 3

Group mean food consumption (g/bird/day)

Group	Treatment (ppm)	Days of study								
		-3 to -1	1	2	3	4	5	1 to 5	6 to 9	
1	Control (0)	4.5	4.2	1.6	1.1	0.5	2.1	1.9	4.0	
2	Control (0)	5.5	3.6	1.4	2.0	1.3	3.1	2.3	4.3	
3	Control (0)	4.2	3.0	2.0	1.9	0.9	2.5	2.1	5.3	
4	Bronopol (100)	4.5	4.8	1.0	1.1	0.8	2.8	2.1	4.3	
5	Bronopol (500)	4.4	3.7	1.2	2.2	1.9	2.8	2.4	5.2	
6	Bronopol (1000)	4.1	3.7	2.5	2.4	1.3	2.6	2.5	4.3	
7	Bronopol (5000)	6.0	3.0	2.7	2.0	0.6	2.9	2.2	5.6	
8	Bronopol (10000)	3.8	3.0	0.7	1.1	0.3	12.0†	1.5*	14.0†	

† Food spillage, only one bird in the pen

* Excluding Day 5 food consumption

Reviewer's Evaluation:

This test appears to be scientifically sound and will support Registration. The subacute dietary LC₅₀ was confirmed at 4488 ppm using the Probit method. This level suggests that Bronopol is slightly toxic to Bobwhite quail.

Category: Core

1. Chemical: Bronopol
2. Test Material: 2-Bromo-2-nitropropane-1,3-diol 100% ai
3. Citation: Watson, J.E. 1984. "Bronopol: Acute LC₅₀ to Rainbow Trout (Salmo gairdneri). Prepared by Imperial Chemical Industries Brixham Laboratory, Brixham, Devon England, for the Boots Co. PIC, Nottingham.
4. Study Type: Acute Fish LC₅₀
Test Species: Rainbow trout (Salmo gairdneri)
5. Reviewed by: Miachel Rexrode
Fishery Biologist
EEB/HED
6. Reported Conclusions: The 96 hour LC₅₀ of Bronopol to rainbow trout was 41.2 mg/l.
7. Reviewer's Conclusions: This study appears to be scientifically sound and will support Registration. Bronopol is slightly toxic to rainbow trout with an LC₅₀ = 41 ppm.

Methods/Materials

Test fish were selected from brood stock and raised at the laboratory. These specimens were about 1.07 (0.42-1.58 g) in weight and 42.4 mm (35-48 mm) in length. Twenty trout were used in each test concentration and in controls. A continuous flow test system was used (test volume 20 liters) to determine the 24, 48, 72 and 96 hour LC₅₀ values.

Twenty-liter glass vessels were used to hold test fish with test solution renewal at a rate of 200 ml/min. A 95% exchange of the test solutions was calculated to occur within 4.5 hours. The concentrated stock solutions, which were prepared with deionized water, were fed to the system by a series of peristaltic pumps and a further supply of these pumps was used to supply freshwater. Physical water parameters were monitored as follows: Dissolved O₂: 9.8-10.8 mg/l; pH: 7.6-7.9; Temperature: 12.6°C; Hardness: 67.6-76.3 ppm CaCO₃; Alkalinity 28.8 ppm CaCO₃; conductivity: 140-150 micro-siemens/cm.

Results:

Concentration levels and percentage mortalities are listed in table 1. Twenty fish were tested per concentration.

Table 1. Percentage Mortalities of Rainbow trout

Concentration (mg/kg)	Measured conc. (mg/l)	Percentage mortality			
		24 hr	48 hr	72 hr	96 hr
180	143.6	100	100	100	100
100	73.2	15	90	100	100
75	55.1	0	45	85	90
56	41.2	0	5	30	50
32	23.0	0	0	0	0
18	13.8	0	0	0	0
10	7.4	0	0	0	0
Control		0	0	0	0

Reviewer's Evaluation:

This study appears to be scientifically sound and will support Registration. Data (measured concentrations) was analyzed with the binomial test and confirmed the value presented in this report. Bronopol appears to be slightly toxic to rainbow trout with an LC₅₀ = 41 ppm.

Category: Core

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