

7-6-88

DATA EVALUATION RECORD

PAGE 1 OF

CASE: GS0058

BENEFIN

CONT-CAT: 02 GUIDELINES: 121-1 71-1 72-4
 81-3 81-4 81-5
 82-1

Accession No. 234214; Prepared by H. C. West,
J. L. Hamelink, W. D. Braddie, D. R. Brannon and
D. M. Morton, Toxicology Division, Lilly Research
Laboratories, Study No. 7008-77; Dated: May 18-26,
77; Title: The Toxicity of Compound 54521
(Benefin) in Bobwhite (Colinus virginianus) Eight
Day Dietary Study: Submitted by Elanco Products
Co., A Division of Eli Lilly and Co., Indianapolis,
Indiana 46206.

REVIEW RESULTS:

VALID ☒INVALID ☐INCOMPLETE ☐

GUIDELINE:

SATISFIED ☒PARTIALLY SATISFIED ☐ NOT SATISFIED ☐

DIRECT RVW TIME = 1 Hour

START DATE: 7-6-88

END DATE: 7-6-88

REVIEWED BY: Charles Lewis

TITLE: Agronomist

ORG: EEIS/HED

LOC/TEL: C m II 552-7467

SIGNATURE: Charles Lewis

DATE: 7-6-88

APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE:

DATE:

VALIDATION SHEET

Page 1 of 3

FORMULATION:	CHEMICAL NAME:	VALIDATOR:	DATE:
% a.i.	N-butyl-N-ethyl-	D. J. Urban	7/25/78
96.4%	a,a,a,-trifluoro-2,	TEST TYPE:	
	6-dinitro-p-		
	toluidine.		
Compound 54521		Avian Subacute Dietary	
		LC ₅₀ - Bobwhite quail,	
		(<u>Colinus virginianus</u>)	
		TEST ID #:	ES-D1

CITATION: Accession No. 234214; Prepared by H. C. West, J. L. Hamelink, W. D. Braddie, D. R. Brannon and D. M. Morton, Toxicology Division, Lilly Research Laboratories, Study No. 7008-77; Dated: May 18-26, 77; Title: The Toxicity of Compound 54521 (Benefin) in Bobwhite (Colinus virginianus) Eight Day Dietary Study: Submitted by Elanco Products Co., A Division of Eli Lilly and Co., Indianapolis, Indiana 46206.

VALIDATION CATEGORY: Core

- RESULTS:
1. There were no mortalities at 1000 ppm 2500 ppm and 5000 ppm nominal dietary concentrations of Benefin. The measured concentrations, by assay, were 851 ppm, 2160 ppm and 4360 ppm, respectively.
 2. Food consumption and body weight gain were depressed at the 5000 ppm dietary concentrations.
 3. There was no difference in behavior, appearance and posture between treated and untreated birds.
 4. The no-effect level was 2500 ppm (0.25 w/w) Benefin in the diet.

VALIDATION CATEGORY RATIONALE: All requirements (standards and protocols) were met for this test to be classified "core".

CATEGORY REPAIRABILITY/RATIONALE: N.A.

ADDITIONAL INFORMATION:

TEST: 8-Day Acute Dietary LC₅₀

PROTOCOL: Similar to EPA Proposed Guidelines in Fed.
Reg. July, 10, 1978, Part II.

SPECIES: Bobwhite quail (Colinus virginianus)

AGE & SEX: 12 days old at the start of the test. No
attempt was made to separate the birds by
sex.

INITIAL WEIGHT: 16.5 ± 0.3 g (Mean ± S.E.)

PEN FACILITIES: The eight cages of birds were randomly
assigned positions on two cage racks.

TEST DIETS: Prepared in 1.5 kg lots with a Hobart paddle
mixer by placing the appropriate amount of
compound 54521 in a basic mash diet-AN12CK412T25.
Water was available to all groups ad libitum.

CONCENTRATIONS & DOSAGE MORTALITY: Replicate groups of
birds were given diets containing 0.0%, 0.1%,
0.25%, or 0.5% w/w of the compound. There were
no mortalities at any test level.

OBSERVATIONS ON SIGNS OF INTOXICATION: No differences
in behavior, appearance and posture were noticed
in the groups of treated birds relative to the
untreated control birds.

FOOD CONSUMPTION:

<u>Diet Conc. %</u>	<u>Number of Birds</u>	<u>Total Food Consumption, g</u>	
		<u>Days 1-5</u>	<u>Days 6-8</u>
0.00	10	226	97
0.10	10	223	90
0.25	10	208	88
0.50	10	172	95

WEIGHT GAIN:

<u>Total Body Weight, g</u>			<u>Individual Weight Gain, g (Mean \pm S.D.)</u>	<u>Dunnett's t-Value For Weight Gain</u>
<u>Day 0</u>	<u>Day 5</u>	<u>Day 8</u>		
162	267	346	20.5 \pm 5.1	--
171	264	340	16.5 \pm 4.8	-1.93
168	253	333	16.5 \pm 5.0	-2.13
159	214	294	13.5 \pm 1.8	-3.72 ^b

STATISTICAL DESIGN: Random placement of birds into 8 groups of 5 birds each.

STATISTICAL PROCEDURE FOR HANDLING DATA: Dunnett, C. W., 1964. New tables for multiple & comparisons with a control. Biometrics 20: 482-491.