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. Braddle, D. R. Brannon and D. M. Morton, Toxicology Division, Lilly Research Laboratories, Study No. 7011-77; Dated: June 8-16, 77; Title: The Toxicity of Compound 54521 (Benefin) in Mallards (Anas platyrhynchos) Eight Day Dietary Study; Submitted by Elanco Products Co., A Division of Eli Lilly & Company, 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: EEB/HED

LOC/TEL: CM II, 557-7463

SIGNATURE: Charles Lewis DATE: 7-6-88

APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE: DATE:

08435

VALIDATION SHEET

FORMULATION:	CHEMICAL NAME:	VALIDATOR:	DATE:
% a.i.	N-butyl-N-ethyl-a, a,a trifluoro-2,6	D. J. Urban	7/29/78
96.4%	dinitro-p-toluidine	TEST TYPE:	
Compound 54521		Avian Subacute Dietary LC_{50} Mallard Duck (Anas platyrhynchos).	
		TEST ID #: ES-E1	

CITATION: Accession No. 234214; Prepared by H. C. West, J. L. Hamelink, W. D. Braddle, D. R. Brannon and D. M. Morton, Toxicology Division, Lilly Research Laboratories, Study No. 7011-77; Dated: June 8-16, 77; Title: The Toxicity of Compound 54521 (Benefin) in Mallards (Anas platyrhynchos) Eight Day Dietary Study; Submitted by Elanco Products Co., A Division of Eli Lilly & Company, 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 770 ppm, 2100 ppm, and 4550 ppm, respectively.

2. Body weight gain was slightly depressed at the 5000 ppm dietary concentration, but compared to the controls, this depression was not significant at the 0.05 level.

3. There was no difference in behavior, appearance and posture between treated and untreated birds.

4. The reported no-effect level was 2500 ppm Benefin in the diet; however, this reviewer suggests 2500 ppm as the more appropriate no-effect level.

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 LC_{50}

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

SPECIES: Mallard Duck (Anas platyrhynchos)

AGE & SEX: 13 days old at the start of the test. No attempt was made to separate the birds by sex.

INITIAL WEIGHT: 203.2 ± 6.7 g (mean ± S.E.)

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

TEST DIETS: Prepared in 2.5 kg lots by placing the appropriate amount of compound 34521 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: Behavior, appearance, food consumption and weight gain were not affected by treatment.

FOOD CONSUMPTION:

Diet Conc. %	Number of Birds	Total Food Consumption, g	
		Days 1-5	Days 6-8
0.00	10	2214	2368
0.10	10	1773	2409
0.25	10	1812	2427
0.50	10	1973	2427

WEIGHT GAIN:

Total Body Weight, g			Individual Weight Gain, g (Mean + S.D.)	Dunnett's t-Value For Weight Gain
Day 0	Day 5	Day 8		
1990	2728	3767	177.70 ± 44.23	---
1978	2463	3565	158.70 ± 27.71	-1.22
1893	2451	3420	152.70 ± 21.26	-1.61
2268	2706	3671	140.30 ± 45.77	-2.41

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.