

10-8-91

Data Evaluation Record

1. Chemical: F6285 (2-(2,4-dichloro-5-methylsulfonylamidophenyl)-4-difluoromethyl-2,4-dihydro-5-methyl-3H-1,2,4-triazol-3-one)
Shaughnessy No.: 129081
2. Test Material: F6285, 94.3% a.i., lot #21-89-1403, EF301-72,
CAS#122836-35-5, a cream-colored powder.
3. Study type: Avian Dietary LC₅₀
Test Species: Mallard duck (Anas platyrhynchos)
4. Study ID: Beavers, Joann B., Grimes, Jennie, Smith, Gregory J.,
and Lynn, Steven P. F6285: A dietary LC₅₀ study with the
mallard. Performed by Wildlife International, 305 Commerce
Drive, Easton, MD for the FMC Corporation. WI study ID #104-
163. FMC study #A89-3091. MRID 419116-19.
5. Reviewed by: Kathryn Valente
Biologist
EEB/EFED
Signature: *Kathryn F. Valente*
Date: 10/7/91
6. Approved by: Allen Vaughan
Acting Head, Section II
EEB/EFED
Signature: *Allen W. Vaughan*
Date: 10.8.91
7. Conclusions: The study is scientifically sound and is
classified as core. With an LC₅₀ of >5620 ppm, the test
material is considered to be practically non-toxic to the
mallard. The NOEL was 3160 ppm.
8. Recommendations: N/A
9. Background information: This study was submitted in support of
an Experimental Use Permit.
10. Discussion of Individual Tests: N/A
11. Materials and Methods:
 - a. Test animals: Mallards were obtained from Whistling
Wings, Box 1, 113 Washington Street, Hanover, Illinois
61041. The birds were 10 days old at test initiation.
All test birds were acclimated to the caging and
facilities from the time they were received until
testing. The birds were maintained on a 16 hour light/8
hour dark photoperiod at 33° C +/- 2° C in the brooder
compartment (22.6° C +/- 0.5° C average ambient
temperature) and average relative humidity of 50% +/- 6%.

b. Dosing regime: The test substance was dissolved in acetone and mixed with corn oil into the basal diet (Wildlife International's Game Bird Ration) with a Hobart mixer. The concentration of corn oil in the test and control diets was 2%. One hundred mL of acetone was used in the preparation of each of the test diets. There was no acetone added to the control diet. Nominal dietary test concentrations of F6285 used were 562, 1000, 1780, 3160 and 5620 ppm. Birds were maintained on the test diets for 5 days, followed by a 3 day post-exposure observation period during which the birds were maintained on the untreated basal diet.

c. Study design: Ten birds were assigned to each treatment level, including three control groups. The birds could not be differentiated by sex due to age. Observations for mortality and sublethal effects were made two times daily throughout the exposure and post-exposure periods. Individual body weights were measured at test initiation, on day 5 and at the end of the test, day 8. Average estimated feed consumption was determined for each group for days 0-5, and 6-8.

d. Statistics: The lack of mortality in this study prevented the calculation of an LC_{50} value using the computer program of Stephan et al, which normally calculates LC_{50} values using probit analysis, moving average method or the binomial probability method. An estimation of the LC_{50} was therefore made by visual inspection of the mortality data.

12. Reported Results: Mallards were exposed to five nominal concentrations of F6285: 562, 1000, 1780, 3160 and 5620 ppm. There were no mortalities in the control, 562, 1000 or 1780 ppm treatment groups. There was one mortality due to a head injury at 3160 ppm, and one treatment-related mortality at 5620 ppm. The birds in the 5620 ppm group showed signs of toxicity beginning the morning of day 3 and lasting until the morning of day 7, except for the one bird which was found dead on day 8. The signs of toxicity observed were: reduced reaction to external stimuli, lower limb weakness, depression, lethargy, wing droop, loss of coordination and shallow, rapid respiration. Necropsies were performed on all mortalities, the control birds and one-half of the birds from each treatment. Two of the control birds had retained yolk sacs, and the one mortality from the 5620 ppm group had an enlarged left adrenal gland, a small, autolyzed pancreas and black gritty material in the stomach. A reduction in body weight gain was noted in the 5620 ppm group during the period of time from day 0-5. Based on these results, the LC_{50} was determined to be >5620 ppm, and the NOEL was determined to be 3160 ppm.
13. Study Author's Conclusions/Quality Assurance Report: The LC_{50} value was >5620 ppm. The NOEL was 3160 ppm.

Quality Assurance and Good Laboratory Practice statements were

included in the report. There was one exception to the GLP noted: Analyses to determine the purity and stability of the test material, as well as to determine the composition of the test material, have been performed, but the results have not yet been reported.

14. Reviewer's Discussion and Interpretation of the Results:

a. Test Procedure: The test design and procedure were generally in accordance with protocols recommended by the Guidelines. There was no acetone added to the control diet, whereas 100 mL of acetone was added to each test diet; however, this is not expected to affect the results. Also, the control diets were made daily and presented to the birds fresh, while the treated diets were only made once and left in front of the birds throughout the entire exposure period; however, this is not expected to affect the results because the feed analysis shows that the chemical is stable in the feed for the duration of the test.

b. Statistical Analysis: The LC_{50} could not be directly calculated due to the lack of mortality. However, the study shows that the LC_{50} is greater than 5000 ppm, which is in accordance with the Guidelines.

c. Discussion/Results: The study is scientifically sound and generally in accordance with the Guidelines. The study is classified as core.

d. Adequacy of the study:

- (1) Classification: Core
- (2) Rationale: N/A
- (3) Repairability: N/A