DATA EVALUATION RECORD

STUDY 3

CHEM 129116 **Cloransulam-Methyl** §162-3
(XDE-565)
FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 437154-03
Erhardt-Zabik, S., P.L. Havens, and K.F. Hawes. 1995. The anaerobic aqueous metabolism of XDE-565. Laboratory Study ID ENV91110. Unpublished study performed and submitted by DowElanco, Indianapolis, IN.

REVIEWED BY: Nelson Thurman Nelson Thurman DATE: 7/11/96
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CONCLUSIONS:

1. This study is marginally acceptable, fulfilling the minimum EPA data requirements for registering pesticides by providing information on the metabolism of cloransulam-methyl under anaerobic aquatic conditions.

2. Cloransulam-methyl (XDE 565) degraded under anaerobic aquatic conditions with a half-life of approximately 16 days at 25°C. The parent declined below detection limits by 120 days. The XDE-565 acid metabolite increased to a peak of 29-36% at 65 days before declining with a half-life of 45 days. The 5-hydroxy acid metabolite plateaued at 14-22% of the applied from 65 to 273 days and declined with an estimated half-life of 60 days. Another metabolite, N-(2-carboxyphenyl-6-chloro)-[1-methyl-5-(2-fluoroethenyl)-1,2,4-triazolo-3-sulfonamide], comprised <5% of the applied radioactivity through 28 days before increasing steadily to 52-66% after 365 days.

3. The study is deemed marginal because the sediments were not completely characterized (pH and CEC were omitted). While the pH was measured at the sampling times, it is unclear whether the measurements were made for the water, sediments or the mix (all of which are likely to differ). Because of these gaps in data, relationships with sediment properties cannot be determined and applicability of the results of this study to broader conditions is limited.

METHODS:

Test Substance and Medium: Experiments were conducted using both phenyl (aniline) ring labeled (AN) XDE-565 (29.9 mCi/mMole; ≥96% pure) and triazolopyrimidine ring labeled (TP) XDE-565 (27.8 mCi/mMole; ≥96% pure). The sediment (8.2% organic matter; 23% clay, 22% sand; silt loam; see Comment 1) and water (pH 7.3; total suspended solids 1010 mg/L) were collected from a lake in an agricultural watershed in Washington Co, MS.

Experimental Design: Biometer flasks containing 2:1 water: sediment, spiked with finely-ground alfalfa (Comment 2), were connected to 0.2N NaOH trapping solution, flushed with O_2-free nitrogen,

and incubated in dark at 25°C or 5°C for 40 days. XDE-565 applied at 0.055 ppm (AN label, 25°C), 0.059 ppm (TP label, 25°C), or 0.063 ppm (TP, 5°C). 10X samples were prepared for product isolation. Samples were taken at 0, 3, 7, 15, 28, 65, 120, 273, and 365 days for the 25°C samples and at 0, 20, 35, 70, and 140 days for the 5°C samples. Eh and pH were measured at several sample intervals.

Extraction and Analysis: Water and sediment were separated by centrifugation. Sediment samples were extracted with acetone/ethyl acetate/1N HCl (85:10:5). Non-extractable residues determined by combustion and trapping of $^{14}CO_2$. Bound residues for 273 and 365 da TP-label samples and the 377 da exaggerated rate samples were extracted by citrate buffer digestion and NaOH for characterization. The NaOH trapping solutions were removed and assayed for dissolved $^{14}CO_2$. Radioactivity was determined using LSC. Sample extracts were analyzed by reverse phase HPLC with an acidified (1% acetic acid) acetonitrile:water mobile phase. Minimum detectable level for both labels was 0.3% (59 ppb) of the applied radioactivity. Confirmation of chemical identity was made by either reverse or normal phase TLC. Unknown degradates were analyzed by LC/MS.

DATA SUMMARY:

25°C Anaerobic Aquatic System: The test system appeared to remain anaerobic throughout the study (Comment 3). The material balance ranged from 91 to 112%. The results of the AN-label and TP-label studies were similar, indicating that the two ring structures were not separated during the study. The majority of the radioactivity was associated with the water fraction throughout the first 28 days (Table V). From 65 to 120 days, the water fraction contained approximately half of the applied radioactivity; from 273 to 365 days, the majority of the radioactivity was found in the sediment fraction (combined total of extracted and nonextracted fractions). The decline in radioactivity in the water fraction coincided with the decline and disappearance of the parent cloransulam methyl (XDE 565) (Tables VI and VII). The amount of unextracted residues (labeled "Combustion" in Table V) increased throughout the study to a maximum of 20-32% after 365 days.

Cloransulam methyl declined in concentration from an initial 87-94% of the applied to 54-65% after 28 days (combined water and sediment fractions) and below limits of detection at 120 days. The rate of metabolism followed apparent first-order kinetics, with a calculated half-life of 15.8 days. The parent remained predominantly within the water fraction. The acid metabolite increased to a peak of 29-36% at 65 days before declining to <2% after 365 days. The 5-hydroxy acid metabolite plateaued at 14-22% of the applied from 65 to 273 days, declining to 2-6% at 365 days. The estimated half-lives, assuming first-order rates for both the parent and degradates, were 45 days for the acid and 60 days for the 5-hydroxy acid metabolites. "Unknown 1," identified as N-(2-carboxyphenyl-6-chloro)-[1-methyl-5-(2-fluoroethenyl)-1,2,4-triazolo-3-sulfonamide], comprised <5% of the applied radioactivity through 28 days before increasing steadily to 52-66% after 365 days. Substantial portions of the metabolite residues remained in the water fraction, although the metabolites demonstrated a higher affinity for the sediments than did the parent (Table VIII). A proposed metabolic pathway is illustrated in Figure 15.

5°C Anaerobic Aquatic System: As would be expected, metabolism proceeded at a slower rate in the 5°C samples. The calculated half-life for cloransulam methyl was 237 days. The XDE-565 acid was the major metabolite, increasing to approximately 10% of the applied after 140 days. The 5-hydroxy acid and "Unknown 1" were detected at ≤1% at 140 days.

REVIEWER'S COMMENTS:

1. The sediment used in the experiment was not completely characterized because of limited sample size. The reviewer believes that better prioritization of data needs could have been employed. While pH and CEC, two important properties useful in understanding adsorption and metabolism dynamics, were not determined, bulk density, a meaningless parameter in a lab bench study on metabolism, was analyzed. The study authors state that pH was measured at the sampling times, but are unclear as to whether the measurements were made for the water or sediments or the mix (all of which are likely to differ). Because of these gaps in data, relationships with sediment properties cannot be determined and applicability of the results of this study to broader conditions is limited.

2. The finely-ground alfalfa was added as an organic matter source. While the amount added (equivalent to 1% by weight) was low, the organic matter content of the sediment (8.2%) was adequate for the microbial activity in the study.

3. The pH and redox potential were not measured every time (Table IVa,b). Where both measurements are made (28, 65, 273 da), the Eh-pH is within the anaerobic range. For the 0 and 3 day samples, no measurements were taken to confirm anaerobicity. For the remaining samples, anaerobic conditions can be inferred assuming that the pH did not vary. In all likelihood, anaerobic conditions existed during the study as long as no leaks occurred in the system.

STUDY AUTHORS' RESULTS AND CONCLUSIONS

INCLUDING PERTINENT TABLES AND FIGURES

Chlorantraniliprole Methyl Review

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