DATA EVALUATION RECORD

STUDY 4

CHEM 129016 XRD-498 §162-1

STUDY ID 41931731

Lehmann, R.G.; Holbrook, D.L.; Altscheffel, S.A.; Batzer, F.R.; Brown, S.M.; White, F.H. AEROBIC SOIL METABOLISM OF ANILINE-LABELED DE-498 IN HOYTVILLE SOIL. Preformed and Submitted by DowElanco; Midland, MI under Dow Protocol No. 89002; Study completed on 31 May 1991; Received by EPA 19 June 1991.

DIRECT REVIEW TIME = 1.4 day

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CONCLUSIONS:

The aerobic soil metabolism study is marginally acceptable to fulfill the data requirement for EUP only. However, the study is not acceptable to meet Subdivision N Data Requirement for the following reason:

In order to fully understand the soil metabolic fate, EFGWB requires that the pattern of formation and decline of degradates and XRD-498 be explained.

A new aerobic soil metabolism study is required which fully addresses the pattern of formation and decline of degradates and XRD-498. A higher application rate or lower detection limit will probably be needed in order to determine the degradation process in the new studies.

This study is of the [^{14}C-aniline]XRD-498 material which had a half-live of two months when applied to clay soil at 26°C and 75% of 1/3 bar moisture. Four degradates were noted to be present in small quantities (not >2.2% of applied, 0.005 ppm)(See Table III). The average material balance was 99% of applied. The [^{14}C-pyrimidine]XRD-498 material was discussed in a previous review (WGM;06/22/90) which had very similar reported results.

MATERIALS AND METHODS:

Test Material: [^{14}C-aniline]XRD-498 was used which was reported to have a specific activity of 28.0 mCi/mmol

An unlabeled standard was obtained from DowElanco for analytical purposes. The purity of this standard was reported to be >99%.

Stock Solution: Stock solution was prepared by adding 5.7×10^5 dpm/mL = 3.0 µg/mL. This stock solution was reported to be >99% radiochemically pure by HPLC analysis.

Soil: See Table 1 for soil characterization.

Sampling: 0, day 7, day 14, day 28, day 56, day 84, day 140, day 203, day 273, and day 365.

Test System: See Figure 4.

METHODOLOGY:

Clay soil was sieved through a 2 mm sieve and brought to 75% of 1/3 bar moisture capacity. Fifty grams of moist soil were added to the incubation flasks, and test material was applied in 3.35 mL quantities of stock solution containing 1.9×10^6 dpm to yield soil concentration of ≈0.23 ppm. This concentration is roughly equivalent to six times the field concentration (0.04 ppm) - in a 6 inch deep core of soil- that would be present after applying XRD-498 at the maximum label rate of 79 gm/hectare.

One hundred mL of 0.2 N NaOH were added to the sidearm of each incubation flask. The flasks were closed with ground glass stoppers amended with stop-cock sealer, and placed in the dark at 26 ± 1°C. The flask were attached to an oxygen manifold to allow continual aeration during the incubation period. Zero time samples were prepared as described above and immediately frozen.

The amount of CO_2 formed was checked by counting triplicate aliquots of the 0.2 N NaOH trap after sacrificing of each sample.

For extraction of soil, 5 to 10 gram portions of moist soil was shaken for one hour with extracting solution (90% acetone, 10% water), centrifuged, and the extract was removed. Two additional extractions were performed, and the three extracts were combined into a flask (25 to 50 mL) and made to volume. Triplicate aliquots of extract were counted to determine total extracted ^{14}C.

Extracts were then assayed by HPLC. Ten mL of extract were first evaporated to near dryness, then brought up with 1 mL of 20% acetonitrile, 80% water (containing 1% acetic acid). Aliquots were counted for radioactivity, and a similar aliquot was injected into a HPLC system.

The extracted soils were air-dried and assayed to determine soil residue ^{14}C.

Storage stability tests were performed, as well.

DATA SUMMARY:

The half-life for [^{14}C-aniline]XRD-498 when applied to clay soil and aerated in the dark was calculated by registrant to be 54 days. This is consistent with the 60 day half-life and the 59 half-life reported form two previous studies using clay soil. Numerous small peaks were partitioned by HPLC. The authors only addressed the four major metabolites. All of the metabolites were <10% and <0.01 ppm. One metabolite (Peak 1) was present at maximum concentration between 4 to 5% of applied. However, the peak (Peak 1) for the metabolite was unusually rounded or mesa-like. Further analysis indicated that Peak 1 consisted of at least 2 compounds and possibly more than two compounds which means that the maximum concentration of

any metabolite is 2.2% of applied (or 0.0051 ppm) with an application rate of 0.23 ppm. Under normal application rate the maximum concentration of any metabolite would not be expected to be >0.0017 ppm.

Material balances ranged from 88.9 to 105.9 for the testing period. The average material balance being 99% of applied.

COMMENTS:

1. Frozen storage of XRD-498 has been reported in several previous studies. In this study, repeated analysis of several samples, which were separated by 2½ months of frozen storage, showed little change in results (See Appendix D) and varied from 90.9 to 105.2% total recovery.

2. Soil moisture content was monitored for the testing period (See Appendix B) and varied from 71.2 to 91.3% of ⅓bar.

3. Assuming first order degradation kinetics, the registrant calculated the half-life. Data for all the sampling intervals did not readily conform to first order kinetics. Since data used to calculate the first order kinetics conformed more closely to first order kinetics, this degradation half-life was presented in the study.

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