DATA EVALUATION RECORD

STUDY 1

CHEM 417300 Glyphosate acid §161-1
CAS No. 1071-83-6
FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 44320642
Bowler, D. 1996. Glyphosate acid: [P-methylene-^{14}C]glyphosate acid: aqueous hydrolysis at pH 5, 7, and 9 and 25 °C. Laboratory Project ID: PMS 406. Unpublished study performed by ZENECA Inc., Richmond, CA and submitted by ZENECA Ag Products, Wilmington, DE.

DIRECT REVIEW TIME = 37 Hours

REVIEWED BY:	J. M. Franti, B.S.	Signature:
TITLE:	Scientist	Date:
EDITED BY:	B. S. Perkovich, M.E.M.	Signature:
TITLE:	Scientist	Date:
APPROVED BY:	P. H. Howard, Ph.D.	Signature:
TITLE:	Project Manager	Date:
ORG:	Syracuse Research Corp. Arlington, VA 22202	
TEL:	703/413-9369	

APPROVED BY:	Kevin Poff
TITLE:	Chemist
ORG:	FMB/EFED/OPP
TEL:	703/305-5028

SIGNATURE:

CONCLUSIONS

Degradation - Hydrolysis

1. This study is scientifically valid and provides useful information on the hydrolysis of glyphosate acid.

2. This study meets Subdivision N Guidelines for the fulfillment of EPA data requirements on hydrolysis.

3. Radiolabeled [phosphonomethylene-^{14}C]glyphosate acid, at a nominal concentration of 10 ppm, was hydrolytically stable in pH 5, pH 7 and pH 9 sterile aqueous buffer solutions incubated in darkness at 25 ± 1 °C for up to 30 days. Following the incubation period, 99.1%, 96.7%, and 97.9% of the applied radioactivity remained as parent compound in the pH 5, 7 and 9 buffer systems, respectively.

METHODOLOGY

Radiolabeled [phosphonomethylene-^{14}C]glyphosate acid {carboxymethylaminomethylphosphonic acid; radiochemical purity 97.9%, specific activity 45.2 ± 0.48 mCi/mmol; pp. 15, 22; Appendix B, p. 51}, was filter-sterilized (0.2 μm) and added by pipette to sterile 0.1 M pH 5 (biphthalate), pH 7 (phosphate), and pH 9 (borate) buffer solutions at a nominal concentration of 10 ppm (pp. 16-17, 22). The treated solutions were stirred for 5 minutes on a magnetic stirrer, and aliquots (10 mL) were placed into autoclaved Teflon® tubes (p. 18). The treated solutions were placed in a water bath maintained at 25 ± 1 °C, and the bath was covered with aluminum foil to ensure darkness (p. 19); a figure was not provided. Duplicate samples were collected for analysis at 0, 2, 5, 9, 14, 21, and 30 days posttreatment. The pH and temperature of the test systems were measured daily; data were provided in Tables I and II, respectively (pp. 29, 30).

At each sampling interval, duplicate aliquots of each sample were analyzed for total radioactivity by LSC; the limit of detection was twice the background level (p. 20; Appendix D, p. 55). Samples were analyzed using HPLC (Bio-Rad HRLC Glyphosate Analysis Column) with an isocratic mobile phase of methanol:0.005 M phosphate buffer (pH 2.1; 4:96, v:v) with radioactive flow detection (p. 21). To confirm compound identities, selected samples were analyzed by TLC on silica gel plates developed in methanol:water:ammonium hydroxide:10% trichloroacetic acid (12:6:3:1, v:v:v:v; p. 20). Areas of radioactivity were quantified by radioimaging scanning.

DATA SUMMARY

Radiolabeled [phosphonomethylene-^{14}C]glyphosate acid (radiochemical purity 97.9%), at a nominal concentration of 10 ppm, was hydrolytically stable in pH 5, pH 7, and pH 9 sterile aqueous buffer solutions incubated in darkness at 25 ± 1 °C for up to 30 days. Following the incubation period, 99.1%, 96.7%, and 97.9% of the applied radioactivity remained as parent compound in the pH 5, 7 and 9 buffer systems, respectively (Appendix E, pp. 56-58).

The material balances (based on LSC analysis of individual replicates) were 98.7-104.0% of the applied radioactivity for the pH 5 test system (Table III, p. 31). Material balances were 98.5-110.2% of the applied radioactivity for the pH 7 test system, with the exception of 117.9% of the applied in two replicates, at 0 and 2 days posttreatment. Material balances were 99.4-106.6% of the applied radioactivity for the pH 9 test system.

COMMENTS

1. The solubility of the test substance in the three buffer systems was not reported. The study author stated that the water solubility was 0.91g/100 mL at 25 °C (unspecified pH; p. 15). The solubility of the test compound in the three buffer systems should be reported to allow the reviewer to adequately assess whether the compound was available in solution for hydrolytic degradation.

2. Microbial analysis of the test systems to confirm their sterility throughout the incubation period were not performed, but may not have been necessary since degradation not was observed.

3. Method detection limits were not reported for HPLC analysis. Method detection limits and limits of quantitation should be reported to allow the reviewer to evaluate the adequacy of the methods for determination of parent and degradates in the test system.

4. A phosphate buffer system was utilized to study the hydrolysis of the parent at pH 7 (p. 16); it is recommended that borate or acetate buffers be utilized. In addition, the concentration of the buffer solutions was 0.1 M (p. 16). Subdivision N Guidelines recommend buffer concentrations of 0.01 M in order to minimize buffer effects.

5. The reviewer noted that the registrant-calculated half-lives of the parent compound were 2710 days ($r^2 = 0.39$), 1627 days ($r^2 = 0.61$), and 3476 days ($r^2 = 0.52$), respectively, in the pH 5, 7, and 9 buffer solutions (Appendix E, pp. 56-58). The registrant-calculated half-lives were not reported in the data summary because they are extrapolated beyond the scope of the observed data.

Page _____ is not included in this copy.

Pages 4 through 15 are not included in this copy.

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