7-30-96

DATA EVALUATION RECORD

I. Study Type: Hydrolysis

II. Citation:

Steel, T.K. and R.S. Joseph. 1994. ICIA5504: Aqueous Hydrolysis at pH 5, 7, and 9 at 25 and 50°C. Performed by Zeneca Agrochemicals (Zeneca Limited), Berkshire, U.K. Submitted by Zeneca Agricultural Products (Zeneca Inc.), Wilmington, Delaware. MRID 43678172.

III. Reviewer:

Name: James A. Hetrick, Ph.D. James A. Hetrick
Title: Soil Chemist
Organization: EFGWB/EFED/OPP 30 JUL 1996

IV. Approved by:

Name: Paul J. Mastradone, Ph.D. Paul J. Mastradone
Title: Section Chief
Organization: EFGWB/EFED/OPP 30 JUL 1996

V. Conclusions:

The study provides acceptable data on the hydrolysis of methyl (E)-2-{2-[6-(6-2-cyanophenoxy)pyrimidin-4-yloxy]pheny}-3-methoxy-acrylate (ICIA5504) in pH 5, 7, and 9 buffer solutions. No additional data are needed this time.

Radiolabeled ICIA5504, at a nominal concentration of 2.8 µg/ml, was stable in pH 5, 7, and 9 buffer solutions at 25°C and pH 5 and 7 buffer solutions at 50°C. Radiolabeled ICIA5504 degraded slowly ($t_{1/2}$=209 hours; 8.7 days) in pH 9 buffer solution at 50°C. Transformation products of ICIA5504 were identified as (E0-2-(2-[6-(2-cyanophenyoxy)pyrimidin-4-yloxy]pheny}-3-methoxyacrylic acid (5504/02) and 5504/20.

The reported data indicate ICIA5504 will be stable in aquatic environments.

VI. Materials and Methods:

Aliquots (25ml) of sterile, buffer solutions (acetic acid, pH=5; acetate, pH=7; boric acid, pH 9) were dispensed into separate 30 ml Hypovials. For the 25°C incubation treatment, eighteen vials were prepared for each buffer solution. For the 50°C incubation treatment, ten vials were prepared for pH 5 and 7 buffer solutions. Twenty-four vials were prepared for the pH 9 buffer solution. Each aliquot of buffer solution was amended with radiolabeled ICIA5504 (cyanophenyl labeled; SA=2.307 Gbq $mmol^{-1}$; radiopurity >98.7%) to yield a nominal concentration of 2.8 µg/ml.

(1)

The buffer solutions were maintained at temperature of 25°C or 50°C in the dark. Triplicate samples were taken immediately posttreatment for the 25°C treatments. Duplicate samples of each buffer solution were taken at 11, 20, and 31 days posttreatment for the 25°C treatment. Duplicate samples of buffer solution were taken at immediately posttreatment and then 6 days posttreatment for the 50°C treatment in pH 5 and 7 buffer solutions; and immediately posttreatment, 3, 6, 8, 10, 12 days posttreatment for 50°C in pH 9 buffer solution.

Storage Conditions

Samples for the 25°C and the pH 9, 50°C treatments were stored frozen (-14 to -20°C) for 18 and 34 days, respectively. All other samples were analyzed immediately on the day of sampling.

Analytical

The pH of buffer solution at each sampling time was monitored using a pH meter. The sterility of the buffer solutions at the initiation and termination of the experiment was determined using microbial plate counts on nutrient agar.

Radiolabeled residues in buffer solution were separated using reverse and normal phase 1-D TLC. Normal phase eluents were diethyl ether:N-Hexane (No. 1), dichloromethane:diethyl ether (No. 3), chloroform:methanol:water:formic acid (No. 9), and diethyl ether:hexane:methanol:acetic acid (No. 11). Reverse phase eluents were acetonitrile:water (No. 4) and methanol:ammonium acetate (No. 16). Separated residues were identified using co-chromatography with known standards. Transformation products from the pH 9, 50°C treatments were also identified using HPLC-MS and HPLC-MS-MS. The ^{14}C content was determined by LSC.

VII. Study Author's Conclusions

A. The material balance of radioactivity ranged from 78.3 to 100.3% of applied in the 25°C treatment and 93.6 to 100.5% of applied in the 50°C (Tables 3 and 4). (Reviewer Note: The registrant did not address the low material balance observed in pH 5 and 7 buffer solution at 11 days posttreatment. However, the registrant indicated that ICIA5504 crystallized out of aqueous solution during freezer storage. The reviewer notes that samples for the 25°C treatment were stored frozen for 18 days.)

B. Radiolabeled ICIA5504, at a nominal concentration of 2.8 µg/ml, was stable ($t_{1/2}$ > 30 days) in pH 5, 7, and 9 buffer solutions at 25°C (Table 3). Radiolabeled ICIA5504 was stable in pH 5 and 7 buffer solutions at 50°C (Table 4). Azoxystrobin degraded slowly ($t_{1/2}$= 209 hours) in pH 9 buffer solution at 50°C. (Table 4; Figures 1 and 2).

C. Transformation products of ICIA5504 were identified as 5504/02 and 5504/20 (Appendices 7b and 7c).

C

VIII. Reviewer's Comments

A. The registrant did not specifically address the low material balance (78% of applied) of ICIA5504 in pH 5 and 7 buffer solution at 11 days posttreatment. The registrant indicated that ICIA5504 crystallized out of aqueous solution during freezer storage. The reviewer notes that samples for the 25°C treatment were stored frozen for 18 days. EFGWB believes that repeating the hydrolysis study would not yield additional information because ICIA5504 is stable to hydrolysis. No additional hydrolysis data are needed this time.

B. The reviewer notes unidentified transformation products were detected in the pH 9, 50°C treatments. Identification of the unidentified transformation products is not required because ICIA5504 should be stable to abiotic hydrolysis under normal environmental conditions.

AZOXYSTROBIN

Page _____ is not included in this copy.

Pages 4 through 8 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.