DATA EVALUATION RECORD

I. Study Type: Batch Equilibrium

II. Citation:


III. Reviewer:

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Title: Soil Chemist
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IV. Approved by:

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V. Conclusions:

The study provides acceptable data on methyl(E)-2-[2-{6-(6-2-cyanophenoxy)pyrimidin-4-yl oxy]phenyl}-3-methoxyacrylate (ICIA5504) partitioning in mineral soils. These data in conjunction with batch equilibrium data (MRID 43678181) fulfill the unaged portion of the 163-1 data requirement. No additional data are needed at this time.

Radiolabeled ICIA5504 had Freundlich adsorption coefficients 6.2 ml/g (Koc=210; 1/n=0.85) in the Kenny Hill sandy loam soil, 4.0 ml/g (Koc=240; 1/n=0.82) in the East Anglia loamy sand soil, 1.5 ml/g (Koc=540; 1/n=0.90) in the Lilly Field sand soil, 9.5 ml/g (Koc=580; 1/n=0.90) in the Nebo silty clay loam soil, and 15 ml/g (Koc=540; 1/n=0.90) in the Pickett Piece clay loam soil.

The reported data indicate ICIA5504 should be relatively immobile to mobile in terrestrial and aquatic environments.

VI. Materials and Methods:

United Kingdom test soils were classified as the Hyde Farm sandy loam, East Anglia loamy sand, Kenny Hill loamy sand, Lilly Field sand, Nebs silty clay loam, and Pickett Place clay loam. Physicochemical properties of the test soils are shown in Table 2. The test soils were air-dried, passed through a 2mm sieve, irradiated with gamma rays (25 Kgy for 250 g), and then stored at 5°C.
Preliminary Study

Subsamples (4g) of Hyde Farm were placed into each of 12 Teflon centrifuge tubes, suspended in 19 ml of sterile, pesticide-free 0.1M CaCl$_2$, and then mechanically shaken for 16 hours. After pre-equilibration, ten samples of each soil type were amended with radiolabeled ICIA5504 (cyanophenyl labeled; SA=2.307 Gbq mmol$^{-1}$; radiopurity= 99%) to yield a nominal concentration of 0.2 µg/ml. Two samples of each soil type were not amended with ICIA5504 to serve as treatment controls. In addition, two soilless samples of 0.01M CaCl$_2$ containing radiolabeled ICIA5504 at a nominal concentration of 0.2 µg/ml were used to estimate adsorption onto the Teflon centrifuge tube. Samples were mechanically shaken for 2, 4, 6, 16, 24, and 48 hours.

Definitive Study

Subsamples (3g) of each soil type were placed into each of 22 Teflon centrifuge tubes, suspended in 19 ml of sterile, 0.01 CaCl$_2$, and then mechanically shaken for 16 hours. After pre-equilibration, four samples of each soil type were amended with radiolabeled ICIA5504 (cyanophenyl; SA=2.307 Gbq mmol$^{-1}$; radiopurity = 99%) to yield nominal concentrations of 0.05, 0.1, 0.2, 0.4, and 0.8 µg/ml. The water solubility of ICIA5504 is 6 µg/ml. The remaining sample of each soil type was not amended with ICIA5504 to serve as a treatment control. The samples were mechanically shaken for 24 hours at 20°C. After equilibration, the samples were centrifuged to separate soil and water phases. Duplicate samples of each soil type were retained for chemical analysis. The remaining samples were used in the desorption study. These samples were treated exactly as described in the adsorption study except the soil pellet of each sample was retained for the desorption study. The soil pellet was suspended in pesticide-free 0.01M CaCl$_2$ and then mechanically shaken for 16 hours at 20°C. Supernatant and soil were taken for chemical analysis.

Analytical

All treatments for the Hyde Farm, Kenny Hill, and Lilly Field soils and 0.2 and 0.8 µg/ml treatments for the Nebo, East Anglia, and Fickett Piece soils were analyzed for radiolabeled ICIA5504. Radiolabeled residues in supernatant were extracted using a solid phase C18 column, eluted with acetone, and then concentrated under a stream of air. Soil samples were extracted with acetone.

Soluble radiolabeled residues in supernatant and soil extracts were separated using 1-D TLC with a n-hexane:ethyl acetate:glacial acetic acid solvent system. Separated residues were identified by co-chromatography with known standards. The $^{14}$C content in soil extracts and supernatant was determined by LSC. The $^{14}$C content in extracted soil was determined by combustion-LSC.
VII. Study Author’s Conclusions

A. Preliminary studies indicate radiolabeled ICIA5504 reached a pseudo-equilibrium or steady-state after 16 hours of mechanical shaking (Table 9 and Figure 4). The registrant stated ICIA5504 was stable in 0.01M CaCl₂ solution.

B. The material balance of radioactivity ranged from 63% to 103% of applied ICIA5504 in all treatments for the Hyde Farm, Kenny Hill, and Lilly Field soils and the 0.2 and 0.8 µg/ml treatments for the Nebo, East Anglia, Pickett Piece soils (Tables 10, 11, 12, and 13).

C. Radiolabeled ICIA5504 was stable during the 48 hour batch equilibrium study (Tables 16, 17, and 18).

D. Radiolabeled ICIA5504 had Freundlich adsorption coefficients 6.2 ml/g (Kₒc=210; 1/n=0.85) in the Kenny Hill sandy loam soil, 4.0 ml/g (Kₒc=240; 1/n=0.82) in the East Anglia loamy sand soil, 1.5 ml/g (Kₒc=540; 1/n=0.90) in the Lilly Field sand soil, 9.5 ml/g (Kₒc=580; 1/n=0.90) in the Nebo silty clay loam soil, and 15 ml/g (Kₒc= 540; 1/n=0.90) in the Pickett Piece clay loam soil (Table 6).

E. Radiolabelled ICIA5504 had Freundlich desorption coefficients of 8.0 ml/g in the Kenny sandy loam soil, 11 ml/g in the Hyde Farm sandy clay loam, 4.6 ml/g in the East Anglia loamy sand soil, 2.3 ml/g in the Lilly Field sand soil, 10 ml/g in the Nebo silty clay loam soil, and 15 ml/g in the Pickett Piece clay loam soil (Table 8).

F. The registrant classified the mobility of ICIA5504 as low to medium mobility according to McCall’s Mobility Classification Scale. The Freundlich adsorption coefficients, expressed as Kₒc, ICIA5504 were inversely related to soil pH (Figure 3). The registrant attributed this relationship to the protonation of soil surface acidic groups which encouraged adsorption of neutral ICIA5504.

VIII. Reviewer’s Comments

A. The USDA soil taxonomy classification of test soils was taken from MRID 4378182. EFGWE appreciates the registrant’s effort to cross-reference the United Kingdom soils into USDA soil taxonomy.

B. The registrant provided chromatograms with a single peak as evidence of stability of ICIA5504 during equilibration. EFGWE notes the registrant did not provide a reference chromatogram for ICIA5504. In future studies, the registrant should provide a standard chromatogram as a reference for retention time.
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.
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