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Shaughnessy No.: 128821
Date Out of EFGWB: JUL 11 1989

TO: Taylor/J. Miller
Product Manager 25
Registration Division (TS-767)

FROM:

Paul Mastradone, Section Chief
Environmental Chemistry Review Section #1
Environmental Fate and Groundwater Branch

THRU:

Henry Jacoby, Acting Chief
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division (TS-769C)

Attached please find the EFGWB review of:

Reg./File # : 241-286, 241-299

Chemical Name: Imazapyr

Product Type : Herbicide

Product Name : ARSENAL

Company Name : American Cyanamid Company

Purpose : Review studies submitted in support of registration

Date Received: 3-16-89 Action Code: 360

Date Completed: 7-7-89 EFGWB No. 90446, 90910

Total Reviewing Time (decimal days): 3.0

Deferrals to:
_____Ecological Effects Branch, EFED
_____Science Integration & Policy Staff, EFED
_____Non-Dietary Exposure Branch, HED
_____Dietary Exposure Branch
_____Toxicology Branch, HED

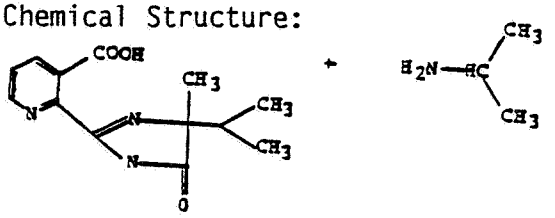
1.0 CHEMICAL: Common name: Imazapyr

Chemical name: 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-nicotinic acid

Trade Name: ARSENAL (as the isopropylamine salt)

Chemical Structure:

(free acid)



2.0 TEST MATERIAL: ^{14}C-Imazapyr (radiolabeled in the pyridine ring)

3.0 STUDY/ACTION TYPE:

Review studies submitted to support registration of ARSENAL.

4.0 STUDY IDENTIFICATION:

Sanders, P. and C. Meyers. 1988. Imazapyr (AC 243,997): Aerobic Aquatic Metabolism. Report No. PD-M Volume 25-51. American Cyanamid Company. MRID No. 41002301.

Tollackson, L. G. 1988. Aerobic Soil Metabolism of ^{13}C- and ^{14}C-AC 243,997 in Sandy Loam Soil at 1.5 ppm Concentration at 25° C. Laboratory Report No. 34927. ABC Laboratories for American Cyanamid Company. MRID No. 41023201

5.0 REVIEWED BY:

Clinton Fletcher
Chemist, Review Section 1
EFGWB/EFED

Signature: Clinton Fletcher
Date: 7-10-89

6.0 APPROVED BY:

Paul Mastradone
Section Chief, Review Section 1
EFGWB/EFED

Signature: Paul J. Mastradone
Date: JUL 11

7.0 CONCLUSIONS:

7.1 EFGWB concludes that the aerobic aquatic study is scientifically sound and satisfies the data requirement for an aerobic aquatic metabolism study. The results of the study indicate that Imazapyr did not degrade when exposed to aquatic conditions maintained in water or sediment. After 4 weeks incubation, 97.6% to 99.9% of the applied radioactivity was recovered from the water and sediment as parent Imazapyr.

stable to degradation or metabolism in water and sediment under aerobic aquatic conditions found in the environment.

7.2 EFGWB concludes that the aerobic soil metabolism study is scientifically sound and (with the previously submitted study) satisfies the data requirement for an aerobic soil metabolism study.

The results of the study indicated that Imazapyr is essentially stable to degradation in soil maintained in the laboratory under aerobic conditions. After 12 months incubation in soil under aerobic conditions, 87.6% of the applied radioactivity was recovered as parent Imazapyr and 7% recovered as $^{14}CO_2$. The half-life was calculated to be 5.9 years.

Based on the results of the study, EFGWB concludes that Imazapyr will be stable to microbial degradation in the soil environment. Rotational crops and non-target organisms will be exposed to parent Imazapyr in the soil environment.

7.3 Data previously reviewed (in review dated March 15, 1984) indicate that Imazapyr is stable to hydrolysis and to degradation in soil maintained under anaerobic conditions, has adsorption coefficients of 1.7 to 4.9 indicating low potential to adsorb to soil (conversely potential to leach in the soil environment) and a field dissipation half-life of approximately 7 months.

In the previously reviewed aerobic soil metabolism study, 82% of the applied radioactivity was extracted (66.2% of which was parent Imazapyr) and 14% of the applied radioactivity was recovered as $^{14}CO_2$. In this study, $^{14}CO_2$ and parent Imazapyr were the only residues identified. No soil degradation products were identified. Based on the results of that study, the calculated half-life for Imazapyr was 17 months.

These results indicate that binding to soil or sediment is not a factor in dissipation of Imazapyr in the soil environment.

Imazapyr does appear to photodegrade in aqueous solution with a half-life of 2.5 to 5.3 days in the laboratory under simulated natural sunlight.

7.4 Based on the above considerations, EFGWB concludes that Imazapyr can remain stable in the soil environment with half-lives sufficiently long enough for Imazapyr to leach and contaminate groundwater.

8.0 <u>RECOMMENDATIONS:</u>

Inform the registrant that the following data requirements have been satisfied with this data submission:

Aerobic aquatic metabolism study

Aerobic soil metabolism study

9.0 BACKGROUND:

The registrant submitted reports on studies conducted to support the registration of ARSENAL (Imazapyr as active ingredient).

In review dated September 15, 1988, an aerobic aquatic metabolism study was requested to support the aquatic (impact) use of ARSENAL on ditchbanks. It was also noted that the registrant agreed to conduct an additional aerobic soil metabolism study as a condition for registration of the ARSENAL forestry use.

In the review dated March 15, 1984, an additional aerobic soil metabolism study (using Imazapyr radiolabeled in another position in the molecule) was requested. This study used carboxyl-^{14}C-Imazapyr (^{14}C-AC 243,997).

10.0 DISCUSSION OF INDIVIDUAL STUDIES:

See individual Data Evaluation Records (DERs).

11.0 COMPLETION OF ONE-LINER:

Data results are included in one-liner.

12.0 CBI APPENDIX: N/A

DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Sanders, P. and C. Meyers. 1988. Imazapyr (AC 243,997): Aerobic Aquatic Metabolism. Report No. PD-M Volume 25-51. American Cyanamid Company. MRID No. 41002301

TYPE OF STUDY: Aerobic Aquatic Metabolism

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED
Signature:
Date: JUL 11 1989

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED
Signature: Paul J Mastradone
Date: JUL 11 1989

CONCLUSIONS:

EFGWB concludes that the aerobic aquatic study is scientifically sound and satisfies the data requirement for an aerobic aquatic metabolism study. The results of the study indicate that Imazapyr did not degrade when exposed to aquatic conditions in water or sediment maintained in the laboratory. After 4 weeks incubation, 97.6% to 99.9% of the applied radioactivity was recovered as parent Imazapyr.

Based on the results of the study, EFGWB concludes that Imazapyr will be stable to degradation under aerobic aquatic conditions in the environment.

MATERIALS AND METHODS:

^{14}C-Imazapyr (radiolabeled in the pyridine ring, specific activity = 44.01 mcCi/mg, 98% radiopure, >95% chemical purity) was added to a series of water and soil sediment samples collected from an irrigation pond. Sediment is characterized in Table I. Fortification level was at rate of 1.5 lb/acre (351 ug/3.1 in^2 water surface area). Sample vessels were maintained under positive air pressure at 25°C in the dark. Any volatilized organic compounds and/or $^{14}CO_2$ were collected in ethylene glycol and 0.1N NaOH traps, respectively.

Duplicate samples were taken at 0, 1, 2, 3, and 4 weeks after incubation. Samples were centrifuged 2X and the aqueous supernatant decanted after each centrifugation then combined. The soil pellet was extracted with aqueous 0.1N NaOH:methanol (50:50, v/v) 2x and extracts combined then reduced in volume.

Radioactivity in the volatiles traps, aqueous supernatant and soil extract was quantitated by liquid scintillation counting (LSC) of aliquots of each. Radioactivity in the soil pellet was determined by LSC of $^{14}CO_2$ released from combusted soil.

The radioactivity in the aqueous supernatant and soil extract was analyzed by thin-layer chromatography (TLC) of aqueous aliquots applied directly to TLC plates along with known Imazapyr standard. The plates were developed in a two-dimensional solvent system and a second confirmatory one-dimensional solvent system. The location of the radioactivity was by UV visualization of the known standard and then by autoradiography of the TLC plate. The radioactivity found on the TLC plate was quantitated by LSC of scrapings from the plate.

REPORTED RESULTS:

The authors report that material balance ranged from 99.5% to 102.7% of the applied radioactivity. No organic volatiles were found during the incubation period. $^{14}CO_2$ accounted for 0.65% to 1.12% of the applied radioactivity after 1 week and 4 weeks incubation, respectively.

During the course of the study, 96.3% to 99.7% of the applied radioactivity remained in the aqueous phase. Soil bound material accounted for approximately 1.5% to 2% of the radioactivity applied. Tables III and IV

Parent Imazapyr accounted for 97.6 to 99.9% of the applied radioactivity after 4 weeks incubation. Table V

Based on the results of the study, the authors concluded that no degradation of Imazapyr was observed.

DISCUSSION:

EFGWB concludes that the aerobic aquatic study is scientifically sound and satisfies the data requirement for an aerobic aquatic metabolism study. The results of the study indicate that Imazapyr did not degrade when exposed to aquatic conditions in water or sediment maintained in the laboratory. After 4 weeks incubation, 97.6% to 99.9% of the applied radioactivity was recovered from water and sediment as parent Imazapyr.

Based on the results of the study, EFGWB concludes that Imazapyr will be stable to degradation under aerobic aquatic conditions in the environment.

DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Tollackson, L. G. 1988. Aerobic Soil Metabolism of ^{13}C- and ^{14}C-AC 243,997 in Sandy Loam Soil at 1.5 ppm Concentration at 25° C. Laboratory Report No. 34927. ABC Laboratories for American Cyanamid Company. MRID No. 41023201

TYPE OF STUDY: Aerobic soil metabolism

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED

Signature: Clinton Fletcher
Date: 7-10-89

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED

Signature: Paul J. Mastradone
Date:

CONCLUSIONS:

EFGWB concludes that this study is scientifically sound and (with the previously submitted study) satisfies the data requirement for an aerobic soil metabolism study. This study also satisfies the condition for registration of ARSENAL for the forestry use.

The results of the study indicated that Imazapyr is essentially stable to degradation in soil maintained in the laboratory under aerobic conditions. After 12 months incubation in soil under aerobic conditions, 87.6% of the applied radioactivity was recovered as parent Imazapyr. The half-life was calculated to be 5.9 years.

Based on the results of the study, EFGWB concludes that Imazapyr will be stable to microbial degradation in the soil environment. Rotational crops and non-target organisms will be exposed to parent Imazapyr in the environment.

MATERIALS AND METHODS:

Princeton sandy loam soil (characterized in Table II) sieved through 9 mesh screen was fortified with a ^{14}C-Imazapyr (44.07 uCi/mg, 98.2% pure)/^{13}C-Imazapyr solution (146 ug/ml, 5.27×10^4 DPM/ug) to a soil concentration of 1.5 ppm. Soil moisture was approximately 75% of field capacity. The individually treated sample tubes were maintained under positive air pressure in a sealed resin-pot at 25° C in the dark. The vessel was connected to a series of traps (ethylene glycol, 1N sulfuric acid, and 1 N potassium hydroxide) to trap any volatiles (organics and/or CO_2) formed during the course of the study.

At days 0, 30, 60, 123, 182, 273, and 365 of incubation, individual soil tubes were removed for analysis. Volatiles trapping solutions were also collected on the same days (except day 0). Soil samples were frozen between the time of collection and analysis.

Soil was extracted 3X with 0.5N (initially) or 1 N NaOH. The extraction solution was acidified to pH 2 then extracted with methylene chloride. The methylene chloride was reduced in volume and aliquots were applied to thin-layer chromatography (TLC) plates for characterization of extracted radioactivity.

The TLC characterization of the radioactivity used a one dimensional system (R_f Imazapyr =0.3) and a second one-dimensional system for comparison and confirmation (R_f Imazapyr = 0.14). Radioactivity on the TLC plates was located by Radioactive-TLC scanning and quantitated by comparison of signal generated peak area.

Material balance (recovery) for the applied radioactivity was determined by taking aliquots of aqueous fractions and extractions for liquid scintillation counting (LSC) of radioactivity. Unextracted radioactivity in soil and in extracted humic acid fraction were quantitated by LSC of $^{14}CO_2$ from combustion of soil or humic acid fraction.

REPORTED RESULTS:

The authors report that the material balance (recovery of applied dose) averaged 101% with a range of 107.3% at day 0 to 91.5% at day 365.

The authors report that following 365 day aerobic soil incubation, a total of 87.6% of the applied radioactivity remained as parent Imazapyr. The apparent half-life was calculated to be 5.9 years. Tables IV and Figures 3 and 4

Unextractable residues averaged 4.3% of the applied radioactivity during the study and accounted for 5.3% of the applied radioactivity at 365 days of incubation. Cumulative $^{14}CO_2$ volatile residues accounted for up to 7.0% of the applied radioactivity after 365 days incubation. Table V

Five minor unidentified degradation products were noted at intermittent periods during the study and accounted for 0.1% to 1.3% of the applied radioactivity. However, these products did not correspond to any known reference standard compounds (described in Figure 2).

The authors stated that no storage stability samples were maintained for the period of time the samples were stored prior to analysis. However, the day 0 samples, upon extraction and analysis, indicated a recovery of 99.2% as parent Imazapyr.

DISCUSSION:

EFGWB concludes that this study is scientifically sound and satisfies the data requirement for an aerobic soil metabolism study.

This study confirms the results of the previously reviewed aerobic soil metabolism study. The results of the study indicated that Imazapyr is essentially stable to microbial degradation in soil maintained in the laboratory

under aerobic conditions. The half-life was estimated to be 5.9 years. (Note: The previously reported half-life for carboxyl-^{14}C-Imazapyr under aerobic soil metabolism was calculated to be 17 months.)

Based on the results of the study, EFGWB concludes that Imazapyr will be essentially stable to microbial degradation in the soil environment.

EFGWB notes that the extraction procedure used here (namely, caustic extraction with 1N NaOH) is a method commonly used to extract residues bound to soil particles (via extraction of humic and fulvic acid organic matter fractions from the soil). It is not recommended as the initial method for extraction of residues in the aerobic soil metabolism study. Artifacts may be formed from such caustic extraction. However, the data suggests that residues of Imazapyr which bind to soil bind is parent material and is released as un-degraded parent material (and not as extraction artifacts) even after caustic soil extraction. The previous aerobic soil metabolism study did not indicate that binding to soil was a mechanism for dissipation of Imazapyr in the soil environment.

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Pages 10 through 13 are not included in this copy.

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_____ Description of the product manufacturing process.

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_____ Identity of the source of product ingredients.

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_____ A draft product label.

_____ The product confidential statement of formula.

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