

US EPA ARCHIVE DOCUMENT

4-17-97

DATA EVALUATION RECORD 2

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CHEM 123000	Isoxaflutole	§164-1
CAS No. 141112-29-0		
FORMULATION--06--WETTABLE POWDER (WP)		

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STUDY ID 43904838

Chancey, E. L. 1995. A terrestrial soil dissipation study with isoxaflutole (RPA 201772). Protocol No. US93701R, File No. 44947, Study No. US93701. Unpublished study performed and submitted by Rhône-Poulenc Ag Company, Environmental Chemistry Division, Research Triangle Park, NC.

STUDY ID 43904840

Plaisance, R.S. 1995. Isoxaflutole - Validation of method of analysis for isoxaflutole and its metabolites in/on agricultural soil. Laboratory Project No. EC-95-299. Unpublished study performed and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC.

STUDY ID 43904841

Schuster, L.L. 1995. Method confirmation for RPA 201772 and its metabolites RPA 202248, RPA 203328, and RPA 205834 in soil. Rhône-Poulenc Project No. EC95-305, ABC/Pan-Ag Study No. 95468 Amended Report. Unpublished study performed by ABC Laboratories, Pan-Ag Division, Madera, CA and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC.

STUDY ID 44092101

Chancey, E. L. 1996. Supplemental data in support of the study titled "A terrestrial soil dissipation study with isoxaflutole (RPA 201772), Study No. 96707940, File No. 4511. Unpublished study performed and submitted by Rhône-Poulenc Ag Company, Environmental Chemistry Department, Research Triangle Park, NC.

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DIRECT REVIEW TIME = 108 Hours

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CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study is scientifically valid and provides useful estimates of the persistence of isoxaflutole and its metabolites under field conditions in Nebraska, Washington, North Carolina, and California.
2. This study does not meet Subdivision N Guidelines for the fulfillment of EPA data requirements on terrestrial field dissipation because no estimates of water balance could be determined. No pan evaporation data was provided in the studies.
3. Isoxaflutole rapidly dissipated ( $t_{1/2}$ 's=1.4-3 days) in field dissipation studies in Nebraska, Washington, California, and North Carolina in plots planted to corn. The half-lives for RPA 202248 were 133 days in CA and 11-17 days for NE, WA, and NC. The large discrepancy in reported half-lives may be attributed to the low moisture conditions at the CA site. The maximum depth of leaching was 12 inches in the CA study. RPA 202248 did appear to leach in the field dissipation studies in NE and NC. RPA 203328 was present as the terminal residue in the environment at all the sites, and was more persistent than RPA 202248. The maximum depth of leaching of 203328 ranged from 12-18 inches at the NC, WA, and CA sites. Since the amount of evapotranspiration was not reported, a complete field study water balance could not be determined, and the maximum depth of leaching is unknown. However, the fact that residues of RPA 202248 and RPA 203328 were mobile in the field dissipation study indicates that aged residues of isoxaflutole are likely to reach shallow ground water under some environmental conditions.
4. The analytical method for determination of isoxaflutole and its metabolites in or on agricultural soil used for the field dissipation study was successfully validated by the registrant and by an independent laboratory.

## METHODOLOGY

Isoxaflutole (EXP31130A 77% a.i. WP) was broadcast applied as a pre-emergence spray at a nominal rate of 0.22 lb ai/A onto sandy loam, silt loam, loamy sand, and loam soils in four field plots, one each located in Nebraska, Washington, North Carolina, and California, in 1994. Experimental plots were planted to corn with a variety appropriate for the test location 0 to 5 days prior to treatment with isoxaflutole. Corn plants died due to phytotoxicity in the North Carolina and California test plots (K. Shearer, Rhone-Poulenc to J. Breithaupt, EPA, letter dated 8/96). Filter paper plaques (four per subplot) were placed randomly on the soil surface of the spray area in an attempt to verify application rates at each site. Filter papers were collected within minutes of isoxaflutole application and stored frozen for 14 to 15 months prior to analysis. The registrant stated that the mean recoveries of isoxaflutole residues from filter paper were low (32.4-67.8% of the nominal application rate) because of an apparent instability of the residues on the filter paper (pages 29, 30). The registrant also attempted to determine the actual application rate by quantifying both pre- and post-application volume of the treatment formulation in the applicator. The registrant-calculated application rates based on this determination were 0.213-0.227 lb ai/A (97.0-103.2%) of the nominal rate (MRID 43904838, p. 21).

Four soil core samples were collected at random from each subplot at each sampling interval. At the 0 to 4 days posttreatment sampling intervals, soil cores were collected only for the 0- to 15-cm soil depth using a copper pipe (no i.d. given). At subsequent sampling intervals, soil cores were collected to a depth of 90 cm using a bucket auger (no i.d. given). Soil cores were composited by subplot and depth (15-cm increments) and stored frozen until they were analyzed.

### York, Nebraska

Isoxaflutole (EXP31130A 77% a.i. WP) was broadcast applied as pre-emergence spray at a nominal rate of 0.22 lb ai/A onto a test plot (90 x 120 feet with four designated subplots of 45 x 60 feet, <1% slope) of Hasting silt loam soil (20.5% sand, 62.0% silt, 17.5% clay, 2.6% organic matter, pH 5.8, CEC 18.0 meq/100 g) that was planted to corn (NK N3808) one day prior to treatment. Soil conditions were dry at the time of application. The registrant-calculated application rate of 0.227 lb ai/A was 103.2% of the nominal application rate based on the pre-and post-application volumes of treatment formulation in the applicator (MRID 43904838, p.21). However, mean recovery of isoxaflutole from filter paper plaques was only 32.4%  $\pm$  4.6 of the target amount of 626  $\mu$ g isoxaflutole/plaque sample (MRID 43904838, pages 29, 30). The plot was irrigated as needed with on-site well water using an overhead gun; total water input was 106.8% of the 10-year historical precipitation average. A two-year plot history indicated no prior use of isoxaflutole.

The test plot was treated twice during the in-life phase of the test with glyphosphate (ROUNDUP) at a rate of 1-1.5 qt/A to control weeds. The depth to the water table was 85.9 feet. Pan evaporation data were not available. Soil cores were collected randomly at 0, 1, 2, 3, 6, 14, 28, 62, 125, and 154 days posttreatment.

#### Ephrata, Washington

Isoxaflutole (EXP31130A 77% a.i. WP) was broadcast applied as pre-emergence spray at a nominal rate of 0.22 lb ai/A onto a test plot (120 x 306 feet with four designated subplots of 50 x 144 feet separated by 10-ft buffer strips, 1% slope) of Timmerman sandy loam soil (66.5% sand, 28.5% silt, 5.0% clay, 1.2% organic matter, pH 7.1, CEC 11.7 meq/100 g) that was planted to corn (Pioneer Hybrid 3645) five days prior to treatment. Soil conditions were wet at the time of application. The registrant-calculated application rate of 0.226 lb ai/A was 102.7% of the nominal application rate based on the pre-and post application volumes of treatment formulation in the applicator (MRID 43904838, p.21). However, mean recovery of isoxaflutole from filter paper plaques was only 32.7%  $\pm$  2.5 of the target amount of 626  $\mu$ g isoxaflutole/plaque sample (MRID 43904838, pp. 29, 30). The plot was irrigated every four to five days from 3 June through 3 October 1994, and from 2 April through 16 July 1995, with on-site well water using overhead sprinklers; total water input was 475.5% of the 10-year historical precipitation average. A two-year plot history indicated no prior use of isoxaflutole, but 2,4-D was used in 1993 at a rate of 2.5 lb ai/A (2,4-D interferes with the analysis of RPA 203328). The test plot was treated twice with glyphosate (ROUNDUP) at a rate of 1.0 lb ai/A and once with paraquat (GRAMOXONE) at 1.2 lb ai/A during the in-life phase of the test to control weeds. The depth to the water table was 70 feet. Soil cores were collected randomly at 0, 1, 2, 4, 7, 14, 30, 59, 122, and 248 days posttreatment.

#### Clayton, North Carolina

Isoxaflutole (EXP31130A 77% a.i. WP) was broadcast applied as pre-emergence spray at a nominal rate of 0.22 lb ai/A onto a test plot (79 x 198 feet with four designated subplots of 49 x 79 feet, 2% slope, 0% slope in direction of the rows) of Norfolk sandy loam soil [characterized as a loamy sand in the surface 15 cm (MRID 43904838, p. 18); 86.5% sand, 10.0% silt, 3.5% clay, 0.6% organic matter, pH 5.9, CEC 2.7 meq/100 g] that was planted to corn (DeKalb DK743) just prior to treatment; corn plants died after an unspecified post plant time interval due to phytotoxicity. Soil conditions were moist at the time of application. The registrant-calculated application rate of 0.213 lb ai/A was 97% of the nominal application rate based on the pre-and post-application volumes of treatment formulation in the applicator (MRID 43904838, p. 21). However, mean recovery of isoxaflutole from filter paper plaques was only 33.3%  $\pm$  4.1 of the target amount of 626  $\mu$ g isoxaflutole/plaque sample (pages 29, 30). Although the plot was not irrigated, total water input as precipitation was 122.6% of the 9-year historical average. A two-year

plot history indicated no prior use of isoxaflutole. There was no recorded use of maintenance chemicals for weed control. The depth to the water table was not reported. Daily air and soil temperature data and pan evaporation data were not available. Soil cores were collected randomly at 0, 1, 2, 3, 6, 13, 30, 64, 126, and 251 days posttreatment.

#### San Juan Batista, California

Isoxaflutole (EXP31130A 77% a.i. WP) was broadcast applied as pre-emergence spray at a nominal rate of 0.22 lb ai/A onto a test plot (39 x 262 feet with four designated subplots of 39 x 66 feet, <1% slope) of Sorrento silt loam soil [characterized as a loam in the surface 15 cm (MRID 43904838, page 18); 45.0% sand, 37.0% silt, 18.0% clay, 0.8% organic matter, pH 8.0, CEC 17.6 meq/100 g] that was planted to corn (Pioneer Hybrid 3503) five days prior to treatment; corn plants died after an unspecified post-plant time interval due to phytotoxicity. Soil conditions were dry at the time of application. The registrant-calculated application rate was 102.3% of the nominal application rate based on the pre-and post application volumes of treatment formulation in the applicator (MRID 43904838, page 21). However, mean recovery of isoxaflutole from filter paper plaques used to verify the application rate was only 67.8%  $\pm$  4.6 of the target amount of 626  $\mu$ g isoxaflutole/plaque sample (MRID 43904838, pp. 29, 30). The higher recovery at the California site relative to the other test locations may have resulted from the use of spray nozzles normally used for band applications. Use of the band nozzles applied more chemical over the row where the filter paper plaques were placed. The plot was irrigated on an average of once per week during the dry season with on-site well water using overhead sprinklers; total water input was 267.6% of the 10-year average (MRID 44092101, p. 13). A two-year plot history indicated no prior use of isoxaflutole. The test plot was treated with three applications of PROTOCOL (5%) at 6.5 oz/gal to control weeds. The depth to the water table was 65 feet. Daily air temperature data were not collected. Soil cores were collected randomly at 0, 1, 2, 3, 6, 14, 28, 54, 112, 239, 356, 414, 461, 496, 532, and 566 days posttreatment.

The quality of the irrigation water from sites using wells (Nebraska, Washington, and California) was characterized and the data were presented on page 17 of MRID 43904838.

Soil samples were analyzed for isoxaflutole, RPA 202248, RPA 203328, and RPA 205834 by HPLC following extraction by shaking with 1:1 (v:v) acidified water (pH 2.1-2.4 with H<sub>3</sub>PO<sub>4</sub>) and acetonitrile. Residues in the extract were separated by sequential use of a C8 solid phase extraction (SPE) cartridge and a Diol 20 SPE cartridge and evaporated to dryness. Dried residues were resolubilized in 80:20 (v:v) acidified water:acetonitrile and analyzed by HPLC using a C18 column with UV (270 nm for isoxaflutole and RPA 203328; 300 nm for RPA 202248 and RPA 205834) or photodiode array (PDA) detection. The mobile phase consisted of water (pH 2.1-2.4

with H<sub>3</sub>PO<sub>4</sub>) (Solvent A) and acetonitrile (Solvent B). The solvent gradient programs used for the analysis of each analyte are described on pages 347-350. The limit of quantitation (LOQ) was 0.01 ppm and a minimum detection limit (MDL) of 0.005 ppm was used for all analytes. Actual MDLs were 0.005 ppm for isoxaflutole, 0.004 ppm for RPA 202248 and RPA 205834, and 0.006 ppm for RPA 203328.

Average method recovery efficiencies from soil samples fortified with isoxaflutole and its three metabolites at 0.01 ppm and 0.05 ppm, respectively, were 82.3 and 86.8% for isoxaflutole, 82.7 and 85.1% for RPA 202248, 87.1% and 87.1% for RPA 203328, and 89.7 and 93.8% for RPA 205834 (MRID 43904838, p. 31). Mean concurrent procedural recoveries from untreated soils (collected from each site) fortified with isoxaflutole and its metabolites at 0.01-0.1 ppm (0.01-0.2 ppm for California soil samples) were 88.2-92.4% for isoxaflutole, 80.3-89.7% for RPA 202248, 72.0-94.4% for RPA 203328, and 89.2-93.8% for RPA 205834 (MRID 43904838, p. 31). Experimental sample data were corrected for the procedural recoveries.

Additional procedural recoveries presented with the supplemental information in MRID 44092101 (p. 15) were qualitatively similar to the recovery data described above.

In a frozen storage stability study, untreated bulk soil samples were collected from each test location and two subsamples were fortified separately with 0.1 ppm each of technical isoxaflutole and each of its three metabolites, and then analyzed after 0, 1, 2, 4, 6, 8, 10, 12, and 14 months of frozen (-20 °C) storage; subsamples were analyzed only for the analyte used to fortify the subsample. Mean recoveries (mean of two subsamples per analyte averaged across all sites) after 0, 10, and 14 months of storage are presented below in Table 1 (means were calculated by the reviewer using data reported by the registrant). Individual recoveries from each subsample for the respective analytes are presented in MRID 43904838, p.49 (10 months of storage) and pp. 2183-2203 (0- through 10-month sampling intervals); and MRID 44092101, p. 18 (14 months of storage) and pp. 219-301 (12 and 14 months of storage).

Table 1. Average recoveries of isoxaflutole and its metabolites from fortified soils after 10 and 14 months of frozen storage.

Analyte	% Mean Recoveries	
	10-Month (range) <sup>1,2</sup>	14-Month (range) <sup>1,3</sup>
Isoxaflutole	91.2 (89.2-98.4%)	93.2 (90.5-96.4)
RPA 202248	93.6 (70.1-104.5%)	89.7 (67.8-99.2) <sup>4</sup>
RPA 203328	106.7 (91.1-140.5%)	102.7 (99.1-109)
RPA 205834	114.7 (113-116.5%)	119 (117-120)

<sup>1</sup>Mean of two subsamples per analyte averaged across all sites.

<sup>2</sup>Data source: MRID 43904838.

<sup>3</sup>Data source: MRID 44092101.

<sup>4</sup>Mean recovery (67.8%) for RPA 202248 reported for soil collected from NC; mean recoveries of RPA 202248 collected from CA, NE, and WA were >94%.

The maximum duration of frozen storage between sampling and analysis was 481 days for the Nebraska samples, 489 days for the Washington samples, 460 days for the North Carolina samples, and 459 days for the California samples (MRID 43904838, p. 38).

#### Validation of the Analytical Method (MRID 43904840)

A separate study (Rhône-Poulenc Study No. EC-95-299) was conducted by the registrant to validate the analytical method used for the field dissipation study. Untreated soil samples were collected from each field test site (Nebraska, Washington, North Carolina, and California) and subsamples (50 g) were fortified with a standard mixture containing isoxaflutole, RPA 202248, RPA 203328, and RPA 205834. Fortified soils were extracted with 1:1 (v:v) acetonitrile:water (acidified with trifluoroacetic acid) by shaking. Extraction efficiency was not evaluated in this study, but the registrant summarized data obtained from a previous aerobic metabolism study (MRID 43588006) demonstrating that mean procedural recoveries of radiolabeled isoxaflutole residues were 96% and 98%, respectively, from sandy loam and clay soils (pages 25, 26). Residues in the extracts were separated and analyzed, as previously described in the terrestrial field dissipation study, by reverse-phase HPLC using either C18 or phenyl columns with UV or PDA single wavelength detection. Isoxaflutole standards used in the study degraded 20% after approximately 5 months of frozen storage; degradation of RPA 202248, RPA 203328, and RPA 205834 was <10% during the same storage interval.



To determine the Method Detection Limit (MDL) and the Limit of Quantitation (LOQ), eight samples were fortified at the estimated MDL for each analyte (3 ppb for isoxaflutole, RPA 202248, and RPA 205834; 6 ppb for RPA 203328) and analyzed as previously described; half of the samples were analyzed on each of two different days. The MDL for each analyte was determined by summing the mean apparent residues in four non-fortified soil samples and 3x the sample standard deviation for each analyte in the fortified samples. The MDL was defined by the registrant as the minimum concentration of an analyte that can be measured and reported with 99% confidence that the analyte concentration is >0. The LOQ of each analyte was determined by summing the apparent residues in four non-fortified soil samples and 10x the sample standard deviation for each analyte in the fortified samples. The LOQ was defined by the registrant as the analyte level in soil above which quantitative data are obtained with a specified degree of confidence. A summary of the results for the registrant-calculated MDLs and LOQs is presented in below Table 2 (MRID 43904840, page 31).

Table 2. Summary of the registrant-calculated Minimum Detection Limits (MDL) and Limits of Quantitation (LOQ) for isoxaflutole and its metabolites in soil (MRID 43904840, page 31).

Analyte	MDL, ppb	LOQ, ppb
Isoxaflutole	5.425	13.974
RPA 205834	4.186	8.908
RPA 202248	3.912	12.723
RPA 203328	6.052	18.932

The accuracy and precision of the method were determined by analyzing five soil samples fortified with each analyte at 10 ppb (the established LOQ) and five soil samples fortified with each analyte at 50 ppb (5x LOQ); half of the samples were analyzed on each of two different days. Two non-fortified soil samples were also analyzed. Mean percent recoveries for all analytes were 77-89% for soils fortified at 10 ppb and 86-106% for soils fortified at 50 ppb (MRID 43904840, p. 32). The mean recoveries were within the registrant-defined target recovery range of 70% to 120%. Representative chromatograms were submitted demonstrating that detector response for all analytes was linear for samples fortified at 24-96 ppb (low range) and 96-300 ppb (high range) with  $r^2 > 0.99$  (MRID 43904840, pp. 175, 180, 181, 192, 198, 203).

The specificity of the method was evaluated by analyzing 129 pesticide formulations registered for use on corn or listed for tolerances in or on corn in 40 CFR 180 (dated July 1, 1994) and which may be present in soils used for corn production (MRID 43904840, pp. 148-171). Carbaryl (SEVIN), fluometuron (COTORAN), and 2,4-D (WEEDONE) interfered with the detection of RPA 202248 when they were analyzed as external standards, but only 2,4-D interfered with RPA 202248 following extraction from fortified soil (MRID 43904840, p. 151).

The analytical method of determination for isoxaflutole and its metabolites in or on agricultural soil used for the field dissipation study was successfully validated.

Method confirmation was by HPLC MS/MS using a YMS ODS-AQ column with a mobile phase of 70:30 (v:v) acetonitrile:0.5% formic acid/0.4% triethylamine (v/v) in water. Analytes were detected and confirmed by mass spectrometry with the MS in the multiple reaction monitoring mode (MRM) (MRID 43904840, pp. 22-25).

#### Independent Laboratory Validation (MRID 43904841)

An independent laboratory validation of the analytical method used for the dissipation study was conducted by ABC Laboratories, Pan Ag Division (ABC/Pan-Ag Study No. 95468). Untreated soil samples collected from the Nebraska and California test sites were prepared as follows: five samples were fortified with each metabolite at their respective MDLs (0.005 ppm for isoxaflutole, 0.004 ppm for RPA 202248 and RPA 205834, and 0.006 ppm for RPA 203328), five samples were fortified with each analyte at 0.01 ppm (the LOQ), and five samples were fortified with each analyte at 0.1 ppm (10x LOQ); a reagent blank and a control were also included with each sample set. Reference standards of isoxaflutole, RPA 202248, RPA 203328, and RPA 205834 were obtained from the registrant and stored at  $4^{\circ}\text{C} \pm 5^{\circ}\text{C}$  when not in use. Two sample sets (trials) using Nebraska soil and three sample sets using California soil were analyzed. During the first trial with Nebraska soil, recoveries of RPA 202248 and RPA 203328 were either variable or low (<70%) when fortified at the LOQ and for RPA 202248 fortified at 10X the LOQ (MRID 43904841, p. 27). In the first trial using California soil, recoveries of RPA 202248 and RPA 203328 were either variable or low (<70%) for all fortification levels (page 28). A second trial with California soil was terminated when it was observed that recoveries of RPA 203328 remained unacceptably low (32.9-66.1%) (MRID 43904841, p. 22).

ABC/Pan Ag Labs made adjustments to the method by changing the pH and elution volumes for the C8 solid phase extraction step and by replacing a C8 column on the HPLC with a reverse-phase C18 column (as specified in the original method) (MRID 43904841, p. 22). Following the method modifications, mean recoveries from Nebraska soil samples at all three fortification levels were within the target range of approximately 70-120%, except for that of RPA 203328 (mean recovery 188%) from

soil fortified at the MDL (0.006 ppm) (MRID 43904841, page 32). The high recovery of RPA 203328 was attributed to the presence of an interference. Recoveries from California soil samples at all three fortification levels were within the registrant-defined target range of approximately 70-120%, except for the mean recovery of RPA 202248 (125%) from soil fortified at the MDL (0.004 ppm).

## DATA SUMMARY

Isoxaflutole (EXP31130A 77% a.i. WP), applied at a nominal rate of 0.22 lb ai/A, dissipated in the surface 15 cm of sandy loam, loam, loamy sand, and silt loam soils in Nebraska, Washington, California, and North Carolina, with registrant-calculated half-lives of 1.4 to 3.0 days in plots planted to corn. Parent isoxaflutole was not detected below the 0- to 15-cm soil depth at any test location. The isoxaflutole metabolites

2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl)propane-1,3-dione (RPA 202248), and

2-methylsulfonyl-4-trifluoromethylbenzoic acid (RPA 203328),

identified in an aerobic soil metabolism study (MRID 43588006), were detected at all four test locations and were primarily in the 0- to 15-cm soil depth. A third metabolite (identified by the registrant in an unspecified anaerobic soil study), 2-aminomethylene-1-cyclopropyl-3-(2-methylsulphonyl-4-trifluoromethylphenyl)propan-1,3-dione (RPA 205834) was not detected at any of the four test locations.

York, Nebraska: Isoxaflutole dissipated with a registrant-calculated half-life of 1.53 days in the 0- to 15-cm depth of a Hasting silt loam soil planted to corn (page 41). Isoxaflutole residues declined from a mean concentration of 0.168 ppm at 0 days posttreatment to <0.01 ppm by 6 days posttreatment and were not detectable by 14 days posttreatment (MRID 43904838, p. 34).

In the 0- to 15-cm soil depth, RPA 202248 increased to maximum soil concentration of 0.070 ppm by 6 days posttreatment and dissipated with a registrant-calculated half-life of 8.4 days (MRID 43904838, p. 42). By 28 days posttreatment, RPA 202248 declined to 0.015 ppm and was not detectable by 62 days posttreatment. There was a single observation of RPA 202248 at <0.01 ppm in the 15- to 30-cm soil depth at 6 days posttreatment.

In the 0- to 15-cm soil depth, RPA 203328 reached a maximum soil concentration of 0.067 ppm by 28 days posttreatment then declined to 0.01 ppm by 62 days posttreatment and was not detectable by 125 days posttreatment. One of four samples

showed residues >MDL of 0.005 ppm in the 15- to 30-cm soil depth at 62 and 125 days posttreatment.

Isoxaflutole and its metabolites were not detected below 30 cm.

Ephrata, Washington: Isoxaflutole dissipated with a registrant-calculated half-life of 2.21 days in the 0- to 15-cm depth of a Timmerman sandy loam soil planted to corn (MRID 43904838, p. 43). Isoxaflutole residues declined from a mean concentration of 0.088 ppm at 0 days posttreatment to <0.01 ppm by 7 days posttreatment (MRID 43904838, p. 35).

In the 0- to 15-cm depth, RPA 202248 increased to a maximum soil concentration of 0.066 ppm by 7 days posttreatment and dissipated with a registrant-calculated half-life of 13.1 days (MRID 43904838, p. 44). By 30 days posttreatment, RPA 202248 declined to 0.02 ppm and was not detectable by 59 days posttreatment.

In the 0- to 15-cm depth, RPA 203328 reached a maximum soil concentration of 0.04 ppm by 30 days posttreatment, declined to <0.01 ppm by 59 days posttreatment, and was not detectable by 122 days posttreatment. In the 15- to 30-cm depth and the 30- to 45-cm depth, RPA 203328 was detected at 0.022 ppm and <0.01 ppm, respectively, at 59 days posttreatment. By 122 days posttreatment, RPA 203328 was <0.01 ppm in the 15- to 30-cm and 30- to 45-cm depths, respectively, and was not detectable by 248 days posttreatment.

Isoxaflutole and its metabolites were not detected below 45 cm.

Clayton, North Carolina: Isoxaflutole dissipated with a registrant-calculated half-life of 3.0 days in the 0- to 15-cm depth of a Norfolk sandy loam soil (characterized by the registrant as a loamy sand) planted to corn (MRID 43904838, p. 45). Isoxaflutole residues declined from a mean concentration of 0.078 ppm at 0 days posttreatment to 0.019 ppm by 6 days posttreatment and was not detectable by 13 days posttreatment (page 36).

In the 0- to 15-cm depth, RPA 202248 increased to maximum soil concentration of 0.042 ppm by 2 days posttreatment and dissipated with a registrant-calculated half-life of 16.3 days (MRID 43904838, p. 46). By 30 days posttreatment, RPA 202248 declined to 0.012 ppm and was not detectable by 64 days posttreatment.

In the 0- to 15-cm soil depth, RPA 203328 reached a maximum soil concentration of 0.027 ppm by 13 days posttreatment, declined to <0.01 ppm by 30 days posttreatment, and was not detectable by 64 days posttreatment. In the 15- to 30-cm soil depth, RPA 203328 was detected at 0.015 ppm at 30 days posttreatment and at <0.01 ppm at 64 days posttreatment. By 126 days posttreatment, only one of four

samples in the 15- to 30-cm soil depth showed residues  $>0.006$  ppm; RPA 203328 was not detectable by 251 days posttreatment.

Isoxaflutole and its metabolites were not detected below 30 cm.

San Juan Batista, California: Isoxaflutole dissipated with a registrant-calculated half-life of 1.4 days in the 0- to 15-cm depth of a Sorrento silt loam soil (characterized by the registrant as a loam) planted to corn (MRID 43904838, p. 47). Isoxaflutole residues declined from a mean concentration of 0.201 ppm at 0 days posttreatment to 0.099 ppm by 3 days posttreatment and were not detectable by 6 days posttreatment (MRID 43904838, p. 37).

In the 0- to 15-cm depth, RPA 202248 increased to a maximum soil concentration of 0.155 ppm by 28 days posttreatment and dissipated with a registrant-calculated half-life of 124.5 days (MRID 43904838, p. 48); by 496 days posttreatment, RPA 202248 declined to 0.011 ppm. Supplemental data (MRID 44092101, p. 17) showed that RPA 202248 was  $<0.010$  ppm by 532 days posttreatment and that only one of four samples had residues  $>0.004$  ppm by 566 days posttreatment. In the 15- to 30-cm soil depth, RPA 202248 levels were variable between 6 and 356 days posttreatment (range: not detectable to 0.037 ppm) with a maximum concentration of 0.037 ppm detected at 28 days posttreatment. Concentration of RPA 202248 in the 15- to 30-inch soil depth declined to  $<0.01$  ppm by 239 days posttreatment and was not detectable by 414 days posttreatment.

In the 0- to 15-cm depth, RPA 203328 concentrations increased to a maximum of 0.06 ppm by 54 days posttreatment and were variable but declined to  $<0.010$  ppm by 566 days posttreatment (MRID 44092101, p. 17). In the 15- to 30-cm soil depth, RPA 203328 levels were variable between 239 and 532 days posttreatment (range:  $<0.010$  ppm to 0.014 ppm) with the maximum concentration of 0.014 ppm detected at 239 days posttreatment; the concentration of RPA 203328 in the 15- to 30-cm soil depth declined to  $<0.01$  ppm by 496 days posttreatment and was not detectable by 566 days posttreatment. In the 30- to 45-cm soil depth, RPA 203328 was detected at a maximum concentration of 0.011 ppm by 356 days posttreatment and was not detectable by 566 days posttreatment.

Isoxaflutole and its metabolites were not detected below 45 cm, except for sporadic detections that were  $>$ MDL in one of four samples at 28, 239, 414, 496, 532, and 566 days posttreatment (MRID 44092101, p. 17).

COMMENTS

1. The registrant did not provide pan evaporation data for determination of water balance. Since pan evaporation data was not reported, a complete field study water balance could not be determined, and the maximum depth of leaching is unknown. However, the fact that residues of RPA 202248 and RPA 203328 were mobile in the field dissipation study indicates that aged residues of isoxaflutole are likely to reach shallow ground water under some environmental conditions.
2. The use of filter paper plaques to confirm the actual field application rate of isoxaflutole was invalid because of an apparent instability of isoxaflutole residues in or on filter paper in frozen storage. Analyses of the filter paper plaques were conducted 14 to 15 months posttreatment and residue recoveries from the plaques were 32.4%, 32.7%, and 33.3%, respectively, for the Nebraska, Washington, and North Carolina test sites, and 67.8% for the California test site. Although residue recovery from the plaques at the California test site was higher relative to the other sites, field application of isoxaflutole was non-uniform due to the use of banding nozzles on the spray applicator. The banding nozzles applied a greater amount of treatment formulation over the row containing the filter paper plaques and, therefore, the filter papers may have absorbed more residues in California than at the other three test sites. The registrant did attempt to calculate the actual application rate (MRID 43904838, p. 21) by quantifying both pre- and post-application volume of the treatment formulation in the applicator. Using this method, calculated application rates were 97-103.2% of the nominal application rate of 0.22 lb ai/A.
3. A half-life was not calculated for the dissipation of RPA 203328 in the California test plots, although sufficient data were available. The registrant stated that the data indicate that the half-life of this metabolite is equal to or greater than the half-life of RPA 202248 in California.
4. Approximately half of the soil samples collected from each site were stored frozen for time intervals (approximately 15 to 16 months) prior to analysis that exceeded the duration of the frozen storage stability study (approximately 14 months). However, except for North Carolina soil fortified with RPA 202248, it is not likely that there was appreciable residue degradation in samples stored 15 to 16 months.  
  
Recoveries of isoxaflutole and its metabolites were > 89% after 14 months of frozen storage, except for RPA 202248 from soil (Norfolk sandy loam) collected from North Carolina (67.8%). It is noted that recoveries of RPA 202248 were > 93% after 14 months of frozen storage in soils collected from sites in the other three states (CA, NE, and WA).
5. The maximum proposed label application rates for isoxaflutole on corn are 0.094 lb ai/A on sandy soils and 0.1875 lb ai/A on medium to heavy soils (K.S. Shearer,

Rhone-Poulenc to J. Breithaupt, EPA; letter dated 4/96). In this study, the nominal application rate was 0.22 lb ai/A (approximately 2.3x and 1.17x the proposed maximum use rate for sandy and medium to heavy soils, respectively).

6. Dates of corn harvest in Nebraska and Washington were not reported and data for residues in corn plants were not submitted.
7. There are many minor discrepancies and/or data transcription errors between the summarized description of the field study in Volume 1 and the detailed study descriptions and raw data in Volumes 2 through 4.
8. This Data Evaluation Record contains supplementary information submitted in MRID 44065801(dated 1996) that was incorporated into the original Data Evaluation Record for MRIDs 43904838, 43904840, and 43904841(each dated 1995). The following new information was included in MRID 44065801: (i) analysis of samples from CA collected at 532 days and 566 days posttreatment; (ii) storage stability data for isoxaflutole and its metabolites stored frozen for 12 and 14 months; and (iii) supplemental data pertaining to analytical method procedural recoveries.