

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

Data Requirement: PARA Data Code:
EPA DP Barcode: D303488
OECD Data Point:
EPA Guideline: 164-2

Test material: JAU6476

End Use Product name: JAU6476 480 SC
Formulation type: Soluble concentrate

Concentration of a.i.: 41.4%

Active ingredient

Common name: Prothioconazole.

Chemical name:

IUPAC: (RS)-2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione.

CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione.

CAS No: 178928-70-6.

Synonyms: JAU6476.

SMILES string: ClC1(C(Cc2ccccc2Cl)(CN2N=CNC2=S)O)CC1.

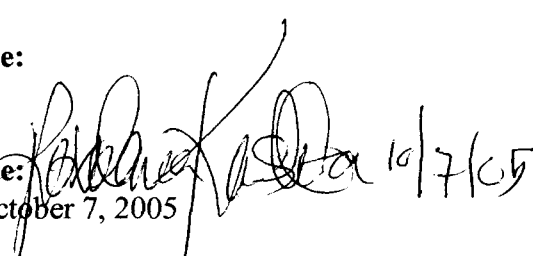
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Company Code:

Active Code:

Use Site Category:

EPA PC Code: 113961

CITATION: Wyatt, D.R. 2004. Aquatic field dissipation of JAU6476 in an Arkansas rice field, 2000. Unpublished study performed by A & L Great Lakes Laboratories, Inc., Fort Wayne, IN, Bayer CropScience, Stilwell, KS and Schoffner Farm Research, Newport, AR and submitted by Bayer CropScience, Research Triangle Park, NC. Submitting Laboratory Study No. J6022402. Bayer Report No. 200067. Experiment initiation July 11, 2000, and completion July 25, 2001 (field phase; p. 13). Final report issued March 17, 2004.



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Secondary Reviewer: John Ravenscroft
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Company Code:

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CITATION: Wyatt, D.R. 2004. Aquatic field dissipation of JAU6476 in an Arkansas rice field, 2000. Unpublished study performed by A & L Great Lakes Laboratories, Inc., Fort Wayne, IN, Bayer CropScience, Stilwell, KS and Schoffner Farm Research, Newport, AR and submitted by Bayer CropScience, Research Triangle Park, NC. Submitting Laboratory Study No. J6022402. Bayer Report No. 200067. Experiment initiation July 11, 2000, and completion July 25, 2001 (field phase; p. 13). Final report issued March 17, 2004.

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EXECUTIVE SUMMARY

Prothioconazole ((RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione; JAU6476; formulated as JAU6476 480SC, containing 41.1% prothioconazole) was applied twice (14 days apart) at target application rates of 220.7 g a.i./ha and 287.0 g a.i./ha, respectively, onto a flooded plot of loam soil (Foley Calhoun complex) planted with rice in Arkansas. Following application, water and soil/sediment samples were collected for analysis of prothioconazole and four transformation products: JAU6476-desthio (2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole); JAU6476-S-methyl (alpha-1(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol); JAU6476 thiazocine (6-(1-chlorocyclopropyl)-6,7-dihydro-triazole-5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol); and 1,2,4-triazole (1-H-1,2,4-triazole). Water samples were collected through 60 days after the second application, at which time the paddy water was allowed to evaporate from the plots, and sediment/soil samples were collected through 365 days after the second application.

Prothioconazole dissipated in the **paddy water** with a reviewer-calculated half-life value of 4.8 days ($r^2 = 0.96$) following the second application, using linear regression analysis.

Prothioconazole was detected in the **paddy water** at a mean concentration of 30.23 µg/L following the first application, decreased to 4.277 µg/L by 1 day, and was not detected by 13 days. Following the second application, prothioconazole was detected in the water at a mean concentration of 58.33 µg/L, decreased to 2.197 µg/L by 3 days, and was last detected at 0.227 µg/L at 7 days posttreatment (excluding a single replicate outlier at 28 days). The transformation product **JAU6476-desthio (2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole)** was initially detected in the water at a mean concentration of 64.3 µg/L immediately following the first application, increased to 97.8 µg/L by 1 day, and decreased to 12.5 µg/L by one day prior to the second application. Following the second application, JAU6476-desthio was detected at a maximum concentration of 109.8 µg/L at day 0, decreased to 66.7 µg/L by 7 days and 5.2 µg/L by 28 days, and was 0.8 µg/L at 60 days posttreatment. The transformation product **JAU6476-S-methyl (alpha-1(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol)** was initially detected in the water at a mean concentration of 0.233 µg/L immediately after the first application, was a maximum of 0.443 µg/L at 1 day after the first application, and was last detected above the LOQ at a mean concentration of 0.11 µg/L at 7 days following the first application. The transformation product **1,2,4-triazole (1-H-1,2,4-triazole)** was initially detected in the water above the LOQ at a mean concentration of 0.196 µg/L at 3 days after the first application, was a maximum of 0.421 µg/L at 7 days after the second application, and was last detected above the LOQ at a mean concentration of 0.223 µg/L at 28 days posttreatment. The transformation product JAU6476 thiazocine (6-(1-chlorocyclopropyl)-6,7-dihydro-triazole-5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol) was not detected above the LOQ at any sampling interval.

A half-life of prothioconazole in **sediment/soil** could not be determined due to too few detections. Prothioconazole was only detected in the 0- to 3-inch depth of the **sediment/soil** at a

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mean concentration above the LOQ once, at 11.1 µg/kg immediately following the second application. The transformation product **JAU6476-desthio** was initially detected in the sediment/soil at a mean concentration of 21.9 µg/kg immediately following the first application, increased to a maximum of 63.2 µg/kg by 3 days after the second application, and decreased to 32.2 µg/kg by 60 days and 20.3 µg/kg by 270 days, and was <LOQ at 365 days posttreatment. The reviewer-calculated half-life of JAU6476-desthio in sediment/soil following the second application was 122 days ($r^2 = 0.85$). The transformation product **JAU6476-S-methyl** was detected in the sediment/soil at levels below the LOQ throughout the study period. The transformation products **1,2,4-triazole** and **JAU6476 thiazocine** were either detected sporadically at levels below the LOQ or were not detected. Prothioconazole and its transformation products were not detected above the LOQ in soil below the 0-3 inch depth at any sampling intervals.

Study Acceptability: This study is classified **supplemental** and does not satisfy the USEPA Subdivision N Guideline §164-2 for aquatic field dissipation because prothioconazole was not stable in frozen storage, and the laboratory storage stability study was inadequate to demonstrate stability of any of the analytes during storage because samples were not analyzed at time 0, and sampling intervals were inadequate to determine stability of the analytes over time.

MATERIALS AND METHODS

The aquatic field dissipation of prothioconazole ((RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione; JAU6476), formulated as JAU6476 480SC (containing 41.1% prothioconazole), was conducted on a flooded plot (375 x 24 ft; Figure 5, p. 67) planted to rice in Jackson County, Arkansas (pp. 13-14; Figures 2-3, pp. 64-65). The soil at the test site was a Foley Calhoun complex and was classified as a loam from 0-18 inches (0-6 inches: 37.2% sand, 44.0% silt, 18.8% clay, pH 5.3, 0.99% organic matter, CEC 6.01 meq/100 g, bulk density 1.42 g/cm³; Table 3, p. 36). The treated plot was divided into five equal-sized sections for sampling, and each section was further divided into 25 rows with three subsections (p. 15). A control plot (75 x 24 ft) was located 100 ft from the treated plot and planted with rice. A five-year plot history indicated that Propanil, Facet, Basagran, Reflex, Assure, Atrazine, Dual, Treflan, and Prowl were recently applied to the test plot (Table 2, p. 35). The test area was disked, landplaned, and cultivated approximately 2-3 months prior to treatment, and the plot was flooded approximately 1 month prior to treatment (Table 6, p. 39). Characteristics of the paddy water were as follows: total suspended solids 64 mg/L, pH 8.0, hardness 136 mg CaCO₃/L, total dissolved solids 196 mg/L, total organic carbon 8.83 mg/L (Table 4, p. 37). The test plot was maintained under 2-4 inches of water until 60 days posttreatment of the second application, when the flood water was allowed to evaporate (p. 28; Table 5, p. 38). Details regarding the rice crop (variety, date of planting, harvest, etc.) were not provided.

Meteorological data were recorded on-site (p. 16). After the 60-day sampling interval when the plot was allowed to dry, total precipitation for the remainder of the study period was 39.9 inches

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or 94% of the 30-year average for the same time period; air and soil temperatures were typical for the site (p. 28; Table 7, p. 40).

Prothioconazole was broadcast twice, on July 11, 2000 and July 25, 2000, at target application rates of 220.7 g a.i./ha (3.15 oz a.i./A) and 287.0 g a.i./ha (4.1 oz a.i./A), respectively, onto the flooded plot (p. 14). The target application rate was 110% of the proposed label rate for the first application and 146% of the label for the second application. The application was made using a boom equipped with 13 flat fan nozzles spaced 20 inches apart and 16 inches above the water. Meteorological conditions during each application were as follows: wind speed 0-2 mph, air temperature 68-80°F, relative humidity 82-88% (p. 14). The test site was maintained weed-free during the study period with three applications of Roundup Ultra® (1.5-2 pt/A; Table 6, p. 39).

The application rate was verified for both applications using solvent saturation pads and water pans (pp. 14-15). Two solvent saturation pads (13.7 x 22 cm) were floated on foam pads in each of the five sections of the test plot immediately prior to each application (10 pads total for each application). Following each application, the two pads from each section of the plot were collected and placed together in a plastic bag (one bag for each section). The pads were extracted three times by shaking for 30 minutes, once with 100 mL of 0.01% L-cysteine hydrochloride and 100 mL of acetonitrile and twice with 160 mL of acetonitrile:water (1:1, v:v; pp. 17-18 and Appendix 3, pp. 139-141). The extracts were combined and brought to volume with acetonitrile:water (1:1, v:v), and an aliquot was filtered (0.45- μ m Acrodisc filter) and analyzed for prothioconazole and JAU6476-desthio by HPLC-UV (Phenomenex Luna C-18(2) column, 150 mm x 2.0 mm, 5- μ m; mobile phase of 0.1% phosphoric acid:acetonitrile, 55:45, v:v).

Metal pans (231 cm²) containing approximately 225 mL of control water were also floated in each section of the test plot prior to each application (5 pans total for each application; p. 15). Water from each pan was collected and poured into a plastic bag after each application. Samples of water (2 mL) from the water pans were diluted to 100 mL with acetonitrile:50-60 mg/L cysteine hydrochloride in water (2:8), filtered (0.45- μ m nylon Acrodisc®), and analyzed for prothioconazole and JAU6476-desthio by HPLC-UV (Betasil C₁₈ column, 100 x 2 mm, 5- μ m) using a mobile phase of A: 0.1% formic acid in water, B: 0.1% formic acid in acetonitrile, A:B, 80:20 to 10:90 to 80:20 (v:v; pp. 18-19; Appendix 4, pp. 145-149).

Water samples were collected from the treated plot one day prior to the first application, at each application, at 1, 3, 7, and 13 days after the first application, and at 3, 7, 14, 28 and 60 days following the second application (p. 15; Table 6, p. 39). Three 500-mL water samples were collected at each sampling interval by combining five 100-mL aliquots (one from each of the five sections of the treated plot; p. 16). Water samples were stored frozen for 723-795 days prior to analysis (Table 11, pp. 44-47).

Sediment samples were collected from the treated plot one day prior to the first application, at each application, at 1, 3, 7, and 13 days after the first application, and at 3, 7, 14, 28, and 60 days following the second application (p. 15; Table 6, p. 39). Soil samples were collected at 90, 120, 184, 270, and 365 days after the second application. For each sampling event, one row from each of the five sections of the treated plot was randomly selected and one core was collected

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from each of the three subsections from each row. Each subsection was only sampled once during the study and only one acceptable core was taken from each subsection. Sediment samples were collected to a depth of 6 inches using a 2¼-inch diameter liner. Soil cores were taken in two segments, 0-6 inches and 6-12 inches, using a 2-stage hand soil probe; 0-6 inch depth cores were taken with a 2¼-inch diameter soil probe and 6-12 inch depth cores were taken with a 1½-inch diameter soil probe (p. 16). Sediment/soil cores were stored frozen at the field facility before being shipped frozen to the processing laboratory. Cores were sectioned into 3-inch segments and combined to produce three composite samples (by combining one core from each of the five sections of the treated plot) per segment and sampling event. Composite samples were homogenized by mixing with dry ice and then run through a hammermill equipped with a 2-mm sieve. The milled soil was mixed in a bucket mixer and transferred to a freezer for dry ice sublimation. The samples were split into analytical and long-term samples and placed back into frozen storage until analysis. Sediment/soil samples were stored frozen for 429-807 days prior to analysis (Tables 12-16, pp. 48-57).

Water, soil and sediment samples were analyzed for prothioconazole and the transformation products JAU6476-desthio (2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole); JAU6476-S-methyl (alpha-1(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol); JAU6476 thiazocine (6-(1-Chlorocyclopropyl)-6,7-dihydro-triazole-5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol); and 1,2,4-triazole (1-H-1,2,4-triazole; p. 20; Figure 1, pp. 60-62).

Complete chemical names for prothioconazole and its transformation products.

Applicant's Code Name	Chemical Name	Molecular Weight
Prothioconazole (JAU6476)	2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione	344.3
JAU6476-desthio	2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole	312.2
JAU6476-S-methyl	Alpha-1(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol	358.0
JAU6476 thiazocine	6-(1-Chlorocyclopropyl)-6,7-dihydro-triazole-5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol	307.8
1,2,4-triazole	1-H-1,2,4-triazole	69.1

Chemical names and molecular weights were obtained from Figure 1, pp. 60-62 in the study report.

Analytical method for prothioconazole, JAU6476-desthio, JAU6476-S-methyl, and JAU6476 thiazocine in water. Water samples (50 mL) were fortified with a mixed internal standard of prothioconazole, JAU6476-desthio, JAU6476-S-methyl, and JAU6476 thiazocine, and passed through a C₁₈ SPE cartridge (p. 23; Appendix 7, 168-171). Residues were eluted from the cartridge with acetonitrile:water (9:1) and analyzed by HPLC (Luna C18 column, 100 x 4.6 mm, 5 µ) using MS/MS detection. The mobile phase conditions for the separation consisted of mobile phase A (0.1% formic acid in water) and B (0.1% formic acid in acetonitrile) under the following

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gradient conditions: A:B, 55:45 to 5:95 to 55:45. Retention times were 3.5 minutes for JAU6476 thiazocine, 4.8 minutes for JAU6476-desthio, 5.4 minutes for prothioconazole, and 6.7 minutes for JAU6476-S-methyl. The LOQ was 0.3 µg/L for each analyte in water (p. 26).

Analytical method for 1,2,4-triazole in water. Water samples (50 mL) were fortified with a triazole internal standard, and the sample was derivatized with dansyl chloride to form a dansyl triazole derivative (p. 25; Appendix 8, 175-177). The extracts were partitioned twice with ethyl acetate and the extracts were combined, concentrated to dryness, and redissolved in water:acetonitrile (1:1, v:v). Extracts were analyzed by HPLC (Luna C18 column, 100 x 4.6 mm, 5 µ) using MS/MS detection. The mobile phase conditions for the separation consisted of mobile phase A (0.1% formic acid in water) and B (0.1% formic acid in acetonitrile) under the following gradient conditions: A:B, 50:50 to 30:70 to 10:90 to 50:50. The approximate retention time of dansyl 1,2,4-triazole was 5.4 minutes. The LOQ was 0.1 µg/L for 1,2,4-triazole in water (p. 26).

Analytical method for prothioconazole, JAU6476-desthio, JAU6476-S-methyl, and JAU6476 thiazocine in soil/sediment. Soil/sediment samples (15 g) were extracted by shaking for one hour with acetonitrile:water:cysteine hydrochloride (800:200:0.5, v:v:w) and the slurry was centrifuged for 10 minutes (p. 20; Appendix 5, pp. 153-156). Following extraction, a mixed internal standard of prothioconazole, JAU6476-desthio, JAU6476-S-methyl, and JAU6476 thiazocine was added to an aliquot of the extract, and a 700-µL aliquot was diluted with 300 µL of water. The extracts were analyzed by LC/MS/MS as previously described for the water samples. The LOQ was 10 µg/kg for each analyte in soil (p. 26).

Analytical method for 1,2,4-triazole in soil/sediment. Soil samples (15 g) were sonicated for one hour at 65°C with acetonitrile:water (6:4, v:v), and sediment samples were sonicated with 1.0% sodium hydroxide:acetonitrile (6:4, v:v); the slurry was centrifuged for 10 minutes (p. 22; Appendix 6, pp. 160-164). Following extraction, a triazole internal standard was added to a 1-mL aliquot of the extract, and 4 mL of 10 mM dansyl chloride and 4 mL of 0.25 M sodium bicarbonate were added to form a dansyl triazole derivative. After sonication for 30 minutes, 1 mL of 0.5 M ammonium hydroxide was added and the derivative was partitioned with 6 mL of ethyl acetate. The ethyl acetate layer was dried through anhydrous sodium sulfate, evaporated to dryness and reconstituted in 1 mL of water:acetonitrile (1:1, v:v), then filtered through a 0.45-µm nylon Acrodisc. The extracts were analyzed by LC/MS/MS as previously described for the water samples. The LOQ was 10 µg/kg for 1,2,4-triazole in soil (p. 26).

To determine the efficiency of the analytical methods, samples of water were fortified with prothioconazole and the transformation products JAU6476-desthio, JAU6476-S-methyl, and JAU6476 thiazocine at 0.3 µg/L and 3 µg/L, and with 1,2,4-triazole at 0.1 µg/L and 1 µg/L (p. 26). Soil samples were fortified with each analyte at 10 µg/kg and 100 µg/kg.

Mean (± SD) method validation recoveries of prothioconazole and its transformation products from water and soil.

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Analyte	Percent Recovery			
	Water		Soil	
	0.3 µg/L	3 µg/L	10 µg/kg	100 µg/kg
Prothioconazole (JAU6476)	96 ± 17	99 ± 3.9	88 ± 4.2	93 ± 2.7
JAU6476-desthio	107 ± 4.6	99 ± 2.2	113 ± 3.6	105 ± 2.5
JAU6476-S-methyl	104 ± 1.1	99 ± 1.1	118 ± 1.5	107 ± 2.8
JAU6476 thiazocine	103 ± 4.8	99 ± 1.3	115 ± 2.8	107 ± 3.3
	0.1 µg/L	1 µg/L		
1,2,4-triazole	115 ± 4.0	102 ± 1.2	104 ± 4.8	98 ± 0.9

Means were obtained from Tables 9-10, pp. 42-43 of the study report.

To determine the frozen storage stability of prothioconazole and its transformation products in soil and water, soil samples were fortified with prothioconazole and JAU6476 thiazocine at 100 ppb, and with JAU6476-desthio, JAU6476-S-methyl, and 1,2,4-triazole at 50 ppb, and water samples were fortified with each analyte at 20 µg/kg (p. 27; Table 18, p. 59). Soil samples were analyzed for prothioconazole and JAU6476 thiazocine following 652 days of storage, for JAU6476-desthio and JAU6476-S-methyl following 813 days, and for 1,2,4-triazole following 1161 days. Water samples were analyzed for JAU6476 thiazocine following 652 days of storage and for all analytes following 807-822 days of storage. Samples were not analyzed at day 0 to determine initial recoveries.

RESULTS AND DISCUSSION

Prothioconazole ((RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione; JAU6476; formulated as JAU6476 480SC, containing 41.1% prothioconazole), applied twice (14 days apart) at target application rates of 220.7 g a.i./ha and 287.0 g a.i./ha, respectively, onto a flooded plot of loam soil (Foley Calhoun complex) planted with rice, dissipated in the paddy water with a reviewer-calculated half-life value of 4.8 days ($r^2 = 0.96$); a half-life of prothioconazole in sediment/soil could not be determined due to too few detections. The half-life in water is based on detections following the second application, and was calculated using linear regression analysis performed on a plot of ln-transformed prothioconazole concentrations vs. time and the equation $t_{1/2} = -\ln 2 / k$, where k is the rate constant.

Mean recoveries of prothioconazole from the saturation pads were 69% and 110% of the label rate (2.86 oz a.i./A) for the first and second applications, respectively, and corresponding recoveries from the water pans were 58% and 95% of the label rate, respectively (p. 28; Table 8, p. 41).

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Prothioconazole was detected in the **paddy water** at a mean concentration of 30.23 µg/L following the first application, decreased to 4.277 µg/L by 1 day, and was not detected by 13 days (Table 11, p. 44). Following the second application, prothioconazole was detected in the water at a mean concentration of 58.33 µg/L, decreased to 2.197 µg/L by 3 days, and was last detected at 0.227 µg/L at 7 days posttreatment (excluding a single replicate outlier at 28 days; Table 11, p. 46). The transformation product **JAU6476-desthio (2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole)** was initially detected in the water at a mean concentration of 64.3 µg/L immediately following the first application, increased to 97.8 µg/L by 1 day, and decreased to 12.5 µg/L by one day prior to the second application. Following the second application, JAU6476-desthio was detected at a maximum concentration of 109.8 µg/L at day 0, decreased to 66.7 µg/L by 7 days and 5.2 µg/L by 28 days, and was 0.8 µg/L at 60 days posttreatment. The transformation product **JAU6476-S-methyl (alpha-1(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol)** was initially detected in the water at a mean concentration of 0.233 µg/L immediately after the first application, was a maximum of 0.443 µg/L at 1 day after the first application, and was last detected above the LOQ at a mean concentration of 0.11 µg/L at 7 days following the first application. The transformation product **1,2,4-triazole (1-H-1,2,4-triazole)** was initially detected in the water above the LOQ at a mean concentration of 0.196 µg/L at 3 days after the first application, was a maximum of 0.421 µg/L at 7 days after the second application, and was last detected above the LOQ at a mean concentration of 0.223 µg/L at 28 days posttreatment. The transformation product **JAU6476 thiazocine (5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol,6-(1-chlorocyclopropyl)-6,7-dihydro-triazole)** was not detected above the LOQ at any sampling interval.

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Mean concentration of prothioconazole residues expressed as µg/L soil, in paddy water.

	Days posttreatment of the last application										
	App 1 (-14)	(-13)	(-11)	(-7)	(-1)	App 2 (0)	3	7	14	28	60
Prothioconazole	31.24	4.00	1.22	<MDL	<MDL	57.33	2.34	(0.21)	<MDL	<MDL	<MDL
	32.37	4.45	1.31	<MDL	<MDL	59.72	2.36	(0.17)	<MDL	<MDL	<MDL
	27.08	4.38	[lost]	<MDL	<MDL	57.94	1.89	0.30	<MDL	0.75	<MDL
JAU6476-desthio	66.36	95.27	90.59	40.81	12.67	111.74	101.37	68.55	28.42	5.18	0.80
	66.24	97.52	85.96	40.62	12.14	109.89	98.42	67.95	27.67	5.25	0.82
	60.40	100.56	[lost]	42.39	12.68	107.73	97.48	63.73	25.19	5.19	0.83
JAU6476-S-methyl	0.24	0.44	0.43	0.11	(0.03)	(0.15)	(0.24)	(0.12)	(0.02)	<MDL	<MDL
	0.24	0.43	0.35	0.11	(0.03)	(0.15)	(0.23)	(0.13)	(0.02)	<MDL	<MDL
	0.22	0.46	[lost]	0.11	(0.03)	(0.15)	(0.23)	(0.12)	(0.03)	<MDL	<MDL
JAU6476 thiazocine	<MDL	(0.05)	(0.05)	<MDL	<MDL	<MDL	(0.06)	<MDL	<MDL	<MDL	<MDL
	<MDL	(0.05)	<MDL	<MDL	<MDL	<MDL	(0.05)	<MDL	<MDL	<MDL	<MDL
	<MDL	(0.06)	[lost]	<MDL	<MDL	<MDL	(0.05)	<MDL	<MDL	<MDL	<MDL
1,2,4-triazole	(0.04)	(0.09)	0.19	0.18	0.15	0.15	0.27	0.40	0.22	0.22	(0.04)
	(0.02)	(0.10)	0.21	0.19	0.16	0.15	0.31	0.39	0.23	0.22	(0.04)
	(0.03)	0.10	[lost]	0.19	0.16	0.16	0.27	0.47	0.23	0.24	(0.03)

Data were obtained from Table 11, pp. 44-47 of the study report. Values in parenthesis are below the LOQ and above the Method Detection Limit.

MDL: Prothioconazole: 0.16 µg/L, JAU6476-desthio: 0.04 µg/L, JAU6476-S-methyl: 0.01 µg/L, JAU6476 thiazocine: 0.05 µg/L, 1,2,4-triazole: 0.01µg/L.

LOQ: Prothioconazole, JAU6476-desthio, JA6476-S-methyl, and JAU6476 thiazocine: 0.3 µg/L, 1,2,4-triazole: 0.1 µg/L.

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

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Prothioconazole was only detected in the 0- to 3-inch depth of the **sediment/soil** at a mean concentration above the LOQ once, at 11.1 µg/kg immediately following the second application (Table 12, pp. 48-49). The transformation product **JAU6476-desthio** was initially detected in the sediment/soil at a mean concentration of 21.9 µg/kg immediately following the first application, increased to a maximum of 63.2 µg/kg by 3 days after the second application, then decreased to 32.2 µg/kg by 60 days and 20.3 µg/kg by 270 days, and was <LOQ at 365 days posttreatment (Table 12, pp. 50-51). The reviewer-calculated half-life of JAU6476-desthio in sediment/soil following the second application was 122 days ($r^2 = 0.85$). The transformation product **JAU6476-S-methyl** was detected in the sediment/soil at levels below the LOQ throughout the study period. Transformation products **1,2,4-triazole** and **JAU6476 thiazocine** were either detected sporadically at levels below the LOQ or were not detected (Tables 14-16, pp. 52-57). Prothioconazole and its transformation products were not detected above the LOQ below the 0-3 inch depth at any sampling intervals.

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

Mean concentration of prothioconazole residues expressed as µg/kg soil, in sediment/soil.

	Depth (in)	Days posttreatment of the last application															
		App 1 (-14)	(-13)	(-11)	(-7)	(-1)	App 2 (0)	3	7	14	28	60	90	120	184	270	365
Prothioconazole	0-3	(7.8) (7.5) 11.7	<MDL (1.3) (1.5)	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	(8.9) 11.5 12.8	<MDL (1.8) <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
	3-6	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	(1.7) <MDL (2.1)	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
JAU6476-desthio	0-3	21.3 17.8 26.6	30.8 30.3 33.7	39.2 37.8 36.3	28.3 29.8 35.7	24.9 23.1 25.7	41.9 47.3 49.2	63.4 61.9 64.3	47.7 59.4 63.8	52.1 65.9 48.5	31.3 32.6 40.0	29.7 32.3 34.6	20.9 24.3 26.6	23.1 26.3 23.2	18.9 22.7 17.5	20.1 17.6 23.3	(4.1) (4.1) (5.1)
	3-6	(1.4) (1.5) (1.4)	(2.8) (2.5) (1.7)	(2.5) (2.3) (3.0)	(4.8) (3.1) (2.4)	(1.8) (1.8) (2.1)	(5.4) (5.2) (4.5)	(6.3) (3.0) (3.0)	(8.1) (5.1) (4.3)	(4.3) (3.0) (4.1)	(2.5) (1.7) (1.7)	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
JAU6476-S-methyl	0-3	(0.9) (0.8) (1.0)	<MDL <MDL (0.6)	(0.7) (0.9) (0.9)	(0.7) (0.7) (0.9)	(0.6) (0.5) (0.80)	(1.0) (1.4) (1.0)	(1.4) (1.5) (1.3)	(1.1) (1.6) (1.9)	(1.3) (2.3) (1.4)	(1.2) (1.1) (1.4)	(1.3) (1.6) (1.4)	(0.9) (0.8) (1.0)	(0.8) (0.9) (0.8)	(0.7) (0.7) (0.6)	(0.8) (0.6) (0.8)	<MDL <MDL <MDL
	3-6	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
JAU6476 thiazocine	0-3	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
	3-6	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL
1,2,4-triazole	0-3	<MDL (1.5) <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL (2.6) (2.0)	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL (1.8) (1.5)	<MDL (1.6) (1.5)	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	(3.9) (2.6) (2.3)	(2.9) (2.8) <MDL
	3-6	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL	<MDL <MDL <MDL

Data were obtained from Tables 12-16, pp. 48-57 of the study report. Values in parenthesis are below the LOQ and above the Method Detection Limit.
 MDL: Prothioconazole: 1.3 ug/kg, JAU6476-desthio: 1.1 ug/kg, JAU6476-S-methyl: 0.5 ug/kg, JAU6476 thiazocine: 0.9 ug/kg, 1,2,4-triazole: 1.5 ug/kg.
 LOQ: Prothioconazole, JAU6476-desthio, JA6476-S-methyl JAU6476 thiazocine, and 1,2,4-triazole: 10 ug/kg.

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The laboratory storage stability study was inadequate to demonstrate stability of any of the analytes during storage because samples were not analyzed at time 0 to determine initial recoveries, and were analyzed only at one time point (Table 18, p. 59). Recovery of prothioconazole from soil was 9.90% following 652 days and recovery from water was 26.00% following 807 days. Recovery of JAU6476-desthio from soil was 85.00% following 813 days and recovery from water was 88.00% following 807 days. Recovery of JAU6476-S-methyl from soil was 87.20% following 813 days and recovery from water was 73.00% following 807 days, Recovery of JAU6476 thiazocine from soil was 90.60% following 652 days and recovery from water was 89.50% following 652 days. Recovery of 1,2,4-triazole from soil was 46.00% following 1161 days and recovery from water was 73.00% following 822 days.

STUDY DEFICIENCIES

1. The laboratory storage stability study was inadequate to demonstrate stability of any of the analytes during storage because samples were not analyzed at time 0 to determine initial recoveries, and sampling intervals were inadequate to determine stability of the analytes over time. Laboratory storage stability samples were only analyzed at one time point, between 652 and 1161 days. Laboratory storage stability samples should be analyzed at time 0 and up to at least the maximum storage interval for test samples, with a sufficient number of intervals in between, to allow the reviewer to determine stability over time.

Of particular concern, prothioconazole was not shown to be stable in soil or water samples stored frozen for any length of time, with a recovery of 9.90% in soil following 652 days of storage and a recovery of 26.00% in water following 807 days of storage (Table 18, p. 59). It is necessary to demonstrate the stability of prothioconazole under typical storage conditions to ensure that the degradation of the parent occurred in the field and not during storage of the test samples. If the parent compound degraded during storage of the samples, then the calculated half-life value will not correctly reflect dissipation in the field. However, the study author stated that in an experiment to test the binding of ¹⁴C-labeled prothioconazole to soil, control soil was fortified and immediately analyzed for the parent, and that the time zero recovery indicated that 28% of the applied radioactivity was bound to the soil (pp. 27 and 32). The author stated that in a similar study described in another study report, only 41% of prothioconazole could be recovered one hour after fortification (p. 32). In a similar study conducted with [¹⁴C] 1,2,4-triazole, 31% of the applied radioactivity was bound to soil following 28 days in frozen storage, indicating that poor recoveries from the laboratory frozen storage stability study were due to adsorption and not degradation.

REVIEWER'S COMMENTS

1. The registrant-calculated DT₅₀ values for prothioconazole in paddy water were 0.7 days and 0.87 days, respectively, for the first and second application (Figures 23-24, pp. 113-114); a half-life was not calculated for prothioconazole in sediment/soil. The registrant-calculated DT₅₀ values for JAU6476-desthio in paddy water were 4.7 days and 8.1 days, respectively, for

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- the first and second application, and the registrant-calculated DT_{50} value for sediment/soil was 59 days following the second application (Figure 25, p. 115). Half-life calculations were performed using linear regression and GraphPad Prism software (p. 31).
2. The target application rate for the second application was increased from 220.7 g a.i./ha (3.15 oz a.i./A) to 287.0 g a.i./ha (4.1 oz a.i./A) because recoveries from the application monitors indicated that the first application was not achieved; recoveries from the saturation pads and water pans were 69% and 58% of the label rate, respectively, following the first application (p. 28; Table 8, p. 41). The target application rate for the second application was 146% of the label rate (110% for the first application). Recoveries from application monitors indicated 95-110% of the label rate was achieved for the second application.
 3. Recoveries from duplicate water samples that were fortified with prothioconazole and transformation products at 1.5 $\mu\text{g/L}$ and analyzed concurrently with the test samples were 104-105% for prothioconazole, 93-95% for JAU6476-desthio, 96-97% for JAU6476-S-methyl, 100% for JAU6476 thiazocine, and 105-112% for 1,2,4-triazole (p. 30). Recoveries from duplicate soil samples that were fortified with prothioconazole and transformation products at 50 $\mu\text{g/kg}$ and analyzed concurrently with the test samples were 87-93% for prothioconazole, 93-109% for JAU6476-desthio, 101-106% for JAU6476-S-methyl, 102-108% for JAU6476 thiazocine, and 84-102% for 1,2,4-triazole.
 4. The study author stated that field spikes were prepared for the parent and transformation products in soil (p. 16). However, recoveries were not reported and results were not discussed.
 5. Tank mix samples were collected before and after both applications, but were not analyzed for the first application because no method was available (pp. 15 and 28). Recoveries of the parent from the application two tank mix ranged from 100.86-118.7% of theoretical (Table 8, p. 41).
 6. The reviewer notes that two additional aquatic field dissipation studies were conducted on rice cropped plots in California (MRID 46246522) and Arkansas (MRID 46246524).
 7. Signed and dated Good Laboratory Practice, Quality Assurance, Certification of Authenticity, and Data Confidentiality statements were provided with the study (pp. 2-5).

ATTACHMENT Structures of Parent and Transformation Products

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

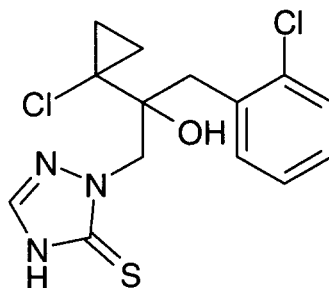
Prothioconazole [JAU6476]

IUPAC name: (RS)-2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione.

CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione.

CAS No: 178928-70-6.

SMILES string: ClC1(C(Cc2ccccc2Cl)(CN2N=CNC2=S)O)CC1.



Data Evaluation Report on the aquatic field dissipation of prothioconazole

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EPA MRID Number 46246523

Identified Compounds

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PMRA Submission Number N/A

EPA MRID Number 46246523

Prothioconazole [JAU6476]

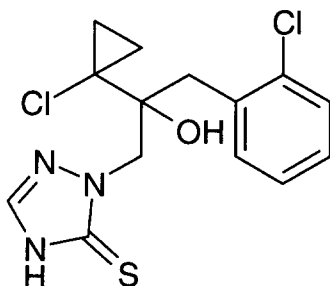
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CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione.

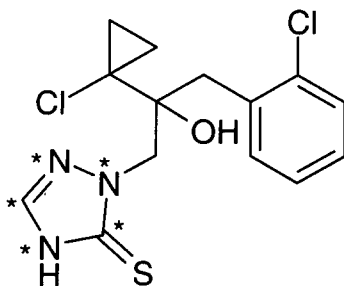
CAS No: 178928-70-6.

SMILES string: ClC1(C(Cc2ccccc2Cl)(CN2N=CNC2=S)O)CC1.

Unlabeled



[Triazole-1,2,4-¹⁵N,3,5-¹³C]JAU6476



*Position of radiolabel.

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

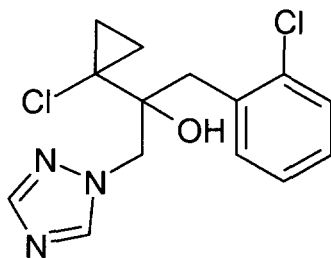
JAU6476-desthio [SXX0665]

IUPAC name: Not reported.

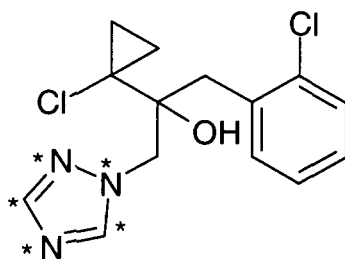
CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole.

CAS No.: Not reported.

Unlabeled



[1,2,4-¹⁵N₃,3,5-¹³C₂]JAU6476-desthio



*Position of radiolabel.

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PMRA Submission Number N/A

EPA MRID Number 46246523

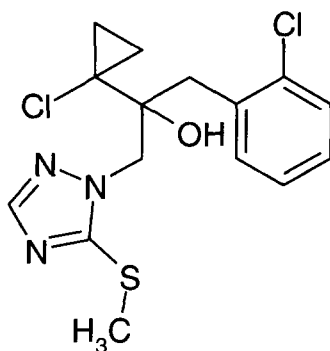
JAU6476-S-methyl or S-methyl-JAU6476 [KTS9473; WAK7681]

IUPAC name: Not reported.

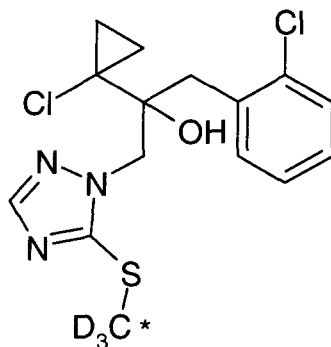
CAS name: alpha-1(1-Chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-3-(methylthio)-1H-1,2,4-triazole-1-ethanol.

CAS No.: Not reported.

Unlabeled



[Methyl-d₃-¹³C]JAU6476-S-methyl or [Methyl-d₃-¹³C]S-methyl-JAU6476



*Position of radiolabel; D = deuterium; ²H.

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

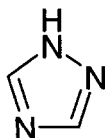
1,2,4-triazole or 1-H-1,2,4-triazole

IUPAC name: Not reported.

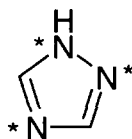
CAS name: 1-H-1,2,4-triazole.

CAS No.: Not reported.

Unlabeled



[1,2,4-¹⁵N₃]1,2,4-triazole or [1,2,4-¹⁵N₃]1-H-1,2,4-triazole



*Position of radiolabel.

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

Unidentified reference compounds

Data Evaluation Report on the aquatic field dissipation of prothioconazole

PMRA Submission Number N/A

EPA MRID Number 46246523

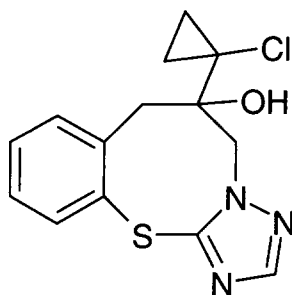
JAU6476-thiazocine

IUPAC name: Not reported.

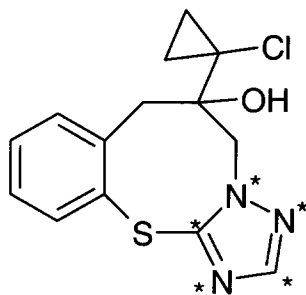
CAS name: 6-(1-Chlorocyclopropyl)-6,7-dihydro-triazole-5H-[1,2,4]triazolo[5,1-b][1,3]benzothiazon-6-ol.

CAS No.: Not reported.

Unlabeled



[Thiazocine-¹⁵N₃-¹³C₂]JAU6476-thiazocine



*Position of radiolabel.

Chemical Name Prothioconazole
 PC Code 113961
 MRID 46246523
 Guideline No. 164-2

Water

Half-life in water (days) = 4.8

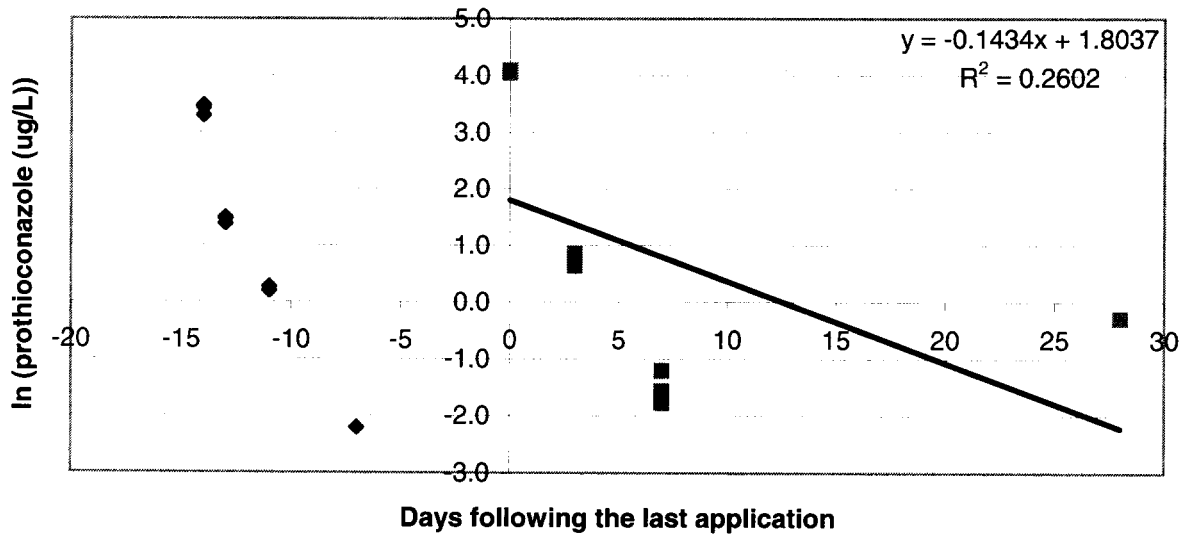
Days posttreatment of the last application	Prothioconazole (µg/L)	Ln (Prothioconazole)
-14	31.24	3.442
-14	32.37	3.477
-14	27.08	3.299
-13	4.00	1.386
-13	4.45	1.493
-13	4.38	1.477
-11	1.22	0.199
-11	1.31	0.270
-7	<MDL	
-7	0.11	-2.207
-7	0.11	-2.207
-1	<MDL	
-1	<MDL	
-1	<MDL	
0	57.33	4.049
0	59.72	4.090
0	57.94	4.059
3	2.34	0.850
3	2.36	0.859
3	1.89	0.637
7	0.21	-1.561
7	0.17	-1.772
7	0.30	-1.204
14	<MDL	
14	<MDL	
14	<MDL	
28	<MDL	
28	<MDL	
28	0.75	-0.288

Data obtained from Table 11, pp. 44 and 46 of the study report.

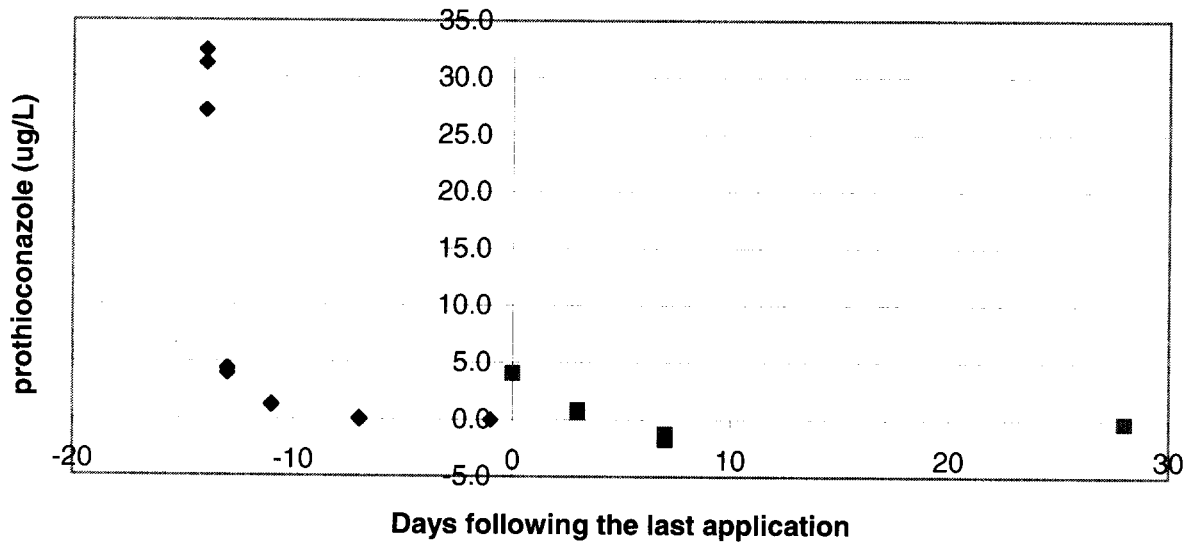
Chemical Name
PC Code
MRID
Guideline No.

Prothioconazole
113961
46246523
164-2

Dissipation of prothioconazole in water following two applications in Arkansas



Dissipation of prothioconazole in water following two applications in Arkansas



Chemical Name Prothioconazole
 PC Code 113961
 MRID 46246523
 Guideline No. 164-2

Arkansas field site (JAU6476-desthio)

Half-life in sediment (days) = 121.6 * 0- to 7.5-cm soil depth

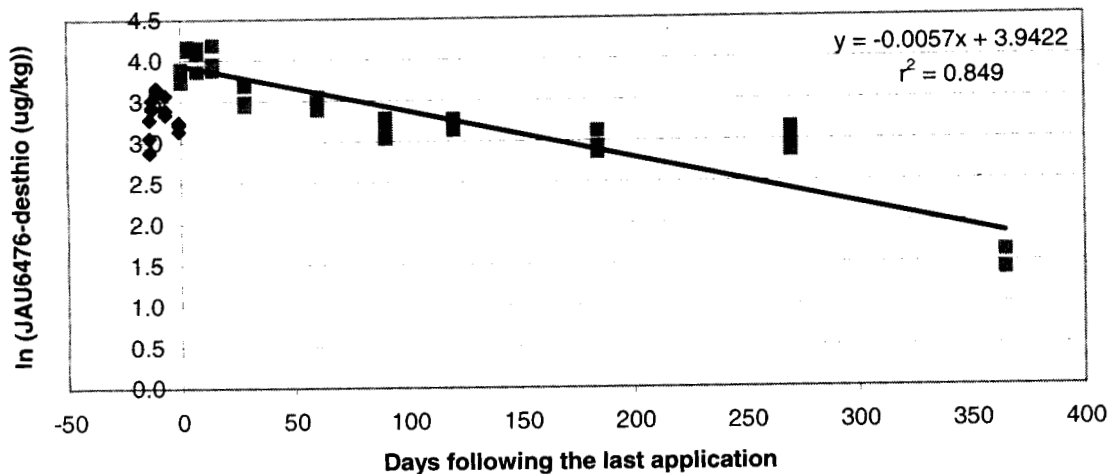
Days posttreatment of the last application	JAU6476-desthio ($\mu\text{g}/\text{kg}$)	Ln (JAU6476-desthio)
-14	21.3	3.059
-14	17.8	2.879
-14	26.6	3.281
-13	30.8	3.428
-13	30.3	3.411
-13	33.7	3.517
-11	39.2	3.669
-11	37.8	3.632
-11	36.3	3.592
-7	28.3	3.343
-7	29.8	3.395
-7	35.7	3.575
-1	24.9	3.215
-1	23.1	3.140
-1	25.7	3.246
0	41.9	3.735
0	47.3	3.857
0	49.2	3.896
3	63.4	4.149
3	61.9	4.126
3	64.3	4.164
7	47.7	3.865
7	59.4	4.084
7	63.8	4.156
14	52.1	3.953
14	65.9	4.188
14	48.5	3.882
28	31.3	3.444
28	32.6	3.484
28	40.0	3.689
60	29.7	3.391
60	32.3	3.475
60	34.6	3.544
90	20.9	3.040
90	24.3	3.190
90	26.6	3.281
120	23.1	3.140
120	26.3	3.270
120	23.2	3.144
184	18.9	2.939
184	22.7	3.122
184	17.5	2.862
270	20.1	3.001
270	17.6	2.868
270	23.3	3.148
365	4.1	1.411
365	4.1	1.411
365	5.1	1.629

Data obtained from Table 13, pp. 50-51 of the study report.

Chemical Name
PC Code
MRID
Guideline No.

Prothioconazole
113961
46246523
164-2

Dissipation of JAU6476-desthio in sediment/soil following two applications in Arkansas (0- to 7.5-cm soil depth)



Dissipation of JAU6476-desthio in sediment/soil following two applications in Arkansas (0- to 7.5-cm soil depth)

