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DATA EVALUATION RECORD

STUDY 1

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CONCLUSIONS

Degradation - Photodegradation in Water

1. The photodegradation in water study is partially acceptable. It can be upgraded if the following answers/information are submitted:

   (a) An explanation of why the dark-control photolysis half-life at pH 5 (34.4 days) is approximately 3 times the hydrolysis half-life (12.9) days at the same pH (pyridinyl study).

   (b) Why is the analytical purity of the test substance at time 0 between 86.3 - 95.8% (pyridinyl study)? The Agency recommends that the analytical purity of the test substance be between 90 - 110%.

   © Information on the half-lives of the persistent degradates M6 and M24 at pH's 5 and 7 and the persistent degradates M5, M26, and M27 at pH 9 (pyridinyl study). The studies were terminated close to the time that the half-life (unadjusted) of the parent was reached, making it difficult to assess the persistence of these degradates.

   (d) Information on the half-life and major degradates in the phenyl-labeled study as well as an explanation of why the phenyl-labeled study showed a much slower degradation rate than the pyridinyl labeled study.

2. EFED notes the following:

   (i) the incubation temperature was 22 ± 1°C rather than the recommended 25 ± 1°C;

   (ii) the photodegradation of phenyl ring-labeled diflufenzopyr was not studied at pH 5 and pH 9 as required for compounds which reversibly ionize at pH 5 to 9; however the pyridinyl ring-labeled parent was studied at these three pH's;

   (iii) the sterility of the test solutions was not confirmed by analysis during the incubation period although test solutions were autoclaved prior to the experiments.

   (iv) in this study, only a single container of buffer solution was treated for each pH/label combination and duplicate aliquots of solution were removed for analysis at each sampling interval. The data for the phenyl label study were variable, making it difficult to accurately assess the photodegradation of the parent compound in water, and did not agree with the (parent compound) data observed in the pH 7 pyridinyl label study.

4. Pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (SAN 835 H)

Nonradiolabeled plus pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (SAN 835 H), at a nominal concentration of 5 ppm, degraded with uncorrected half-lives of 6.9, 16.9, and 13.4 days respectively, in pH 5, 7 and 9 aqueous buffer solutions that were irradiated continuously with a xenon arc lamp while maintained at 22 ± 1 °C for up to 15.9 days. The dark-control half-lives were calculated to be 8.6, 41.8, and 30.4 days at pH's 5, 7, and 9, respectively. The adjusted net photolysis rates, which adjust for the light intensity in relationship to natural sunlight, were 12.6, 54.1, and 46.2 days at pH's 5, 7, and 9, respectively. All data (designated as percentages of the applied) represent percentages of the nominal application.

In the irradiated pH 5 buffer solution, the parent compound decreased from an initial 86.33% of the applied radioactivity to 54.18% by 141 hours posttreatment and was 18.78% at 381 hours (15.9 days). In contrast, 64.62% of applied radioactivity remained as parent following 381 hours of incubation in the dark control solution. The major degradate M6 was present in the irradiated solution at 29.86% of the applied radioactivity at 141 hours posttreatment and was a maximum of 57.97% at 381 hours. The major degradate M24 was 5.10% of the applied radioactivity at 141 hours posttreatment and was 10.05% at 381 hours. The persistence of these two degradates could not be determined because the study was terminated at 15.9 days. The major degradate M5 was present at 11.59% of applied radioactivity at 0 hours posttreatment, was a maximum of 15.19% at 69 hours posttreatment and decreased to 3.22% by 381 hours posttreatment. Three minor degradates (M23, M25 and M1) were detected in the irradiated solution at maximums of 9.61%, 2.99% and 2.25% of the applied radioactivity, respectively. In contrast, M1 was present as a major degradate in the dark control solution at 20.06% of the applied radioactivity at 381 hours posttreatment, while M5 was present as a major degradate at 23.2% of applied after 69 hours and decreasing thereafter. M23 and M24 were present as minor degradates. One degradate present in the irradiated solution, M25, was not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

In the irradiated pH 7 buffer solution, the parent compound decreased from an initial 95.79% of the applied radioactivity to 59.30% by 213 hours posttreatment and was 44.54% at 380 hours. In contrast, 61.80% of applied radioactivity remained as parent following 380 hours of incubation in the dark control solution. The major degradate M6 was present at 11.09% of applied radioactivity at 213 hours posttreatment and was 16.53% at 380 hours posttreatment. The major degradate M24 was present at 5.33% of the applied radioactivity at 69 hours posttreatment and was 11.53% at 380 hours. The persistence of these two degradates could not be determined because the experiment was terminated at 380 hours or 15.9 days. The major degradate M5 was present at a maximum of 10.80% of the applied radioactivity at 21 hours posttreatment, generally decreased to 3.73% of the applied radioactivity by 309 hours posttreatment, and was observed at 8.52% at 380 hours posttreatment. Five minor degradates (M27, M1, M25,

M23 and M26) were detected in the irradiated solution at maximums of 9.24%, 3.88%, 1.79%, 1.68% and 1.23% of the applied radioactivity, respectively. In contrast, M1 was present as a major degradate in the dark control solution at 30.82% of applied radioactivity at 380 hours posttreatment. In addition, M5, M6, M23 and M24 were present as minor degradates in the dark control solution. Two degradates present in the irradiated solution, M25 and M26, were not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

In the irradiated pH 9 buffer solution, the parent compound decreased from an initial 89.65% of the applied radioactivity to 55.95% by 213 hours posttreatment and was 37.61% at 381 hours. In contrast, 57.41% of applied radioactivity remained as parent following 381 hours of incubation in the dark control solution. The major degradate M27 was present at 11.40% of applied radioactivity at 141 hours posttreatment and was 15.11% at 381 hours posttreatment. The major degradate M26 was present at 9.72% of the applied radioactivity at 213 hours posttreatment and was 14.25% at 381 hours. The major degradate M5 was present at a maximum of 12.30% of the applied radioactivity at 0 hours posttreatment, and ranged from 7.59% to 11.69% from 21 to 381 hours posttreatment with the exception of 3.40% of the applied detected at 309 hours posttreatment. The persistence of these degradates could not be determined because the experiment was terminated at 381 hours or 15.9 days. Five minor degradates (M25, M6, M1, M24 and M23) were detected in the irradiated solution at maximums of 8.34%, 7.38%, 3.04%, 0.63% and 0.19% of the applied radioactivity, respectively. In contrast, M1 was present as a major degradate in the dark control solution at 30.82% of applied radioactivity at 381 hours posttreatment. In addition, M5 was present as a major degradate in the dark control solution, and M24 was present as a minor degradate. Four degradates present in the irradiated solution, M6, M25, M26, and M27, were not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

Uniformly phenyl ring-labeled [^{14}C]diflufenzopyr (SAN 835 H)

Nonradiolabeled plus uniformly phenyl ring-labeled [^{14}C]diflufenzopyr (SAN 835 H), at a nominal concentration of 5 ppm, degraded with an undetermined half-life in pH 7 aqueous buffer solution that was irradiated continuously with a xenon arc lamp while maintained at 22 ± 1 °C for up to 373 hours or 15.5 days. In contrast, the test compound degraded only slightly in the dark control solution, with 89.53% of the applied radioactivity remaining as parent at 373 hours posttreatment. However, in both the irradiated and dark control solutions, the variability of the data precluded an accurate assessment of the patterns of degradation of the test compound. Additionally, uniformly phenyl ring-labeled [^{14}C]diflufenzopyr exhibited vastly different degradation patterns (in both the irradiated and dark control solutions) from those observed for pyridinyl ring-labeled [4,6-^{14}C] diflufenzopyr in pH 7 aqueous buffer solution. In the irradiated solution, uniformly phenyl ring-labeled [^{14}C]diflufenzopyr was present at 96.62%-98.64% of the applied radioactivity

from 0 to 22 hours posttreatment, ranged from 81.78% to 91.24% of the applied radioactivity from 70 hours to 301 hours posttreatment and was 75.77% at 373 hours posttreatment. Radiolabeled $^{14}CO_2$ was present at 1.11% following 373 hours of incubation; [^{14}C]organic volatiles were negligible.

METHODOLOGY

Nonradiolabeled plus pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (SAN 835 H; 2-(methyl-(((3,5-difluorophenylamine)-carbonyl)-hydrazone-methyl)-3-pyridine carboxylic acid; radiochemical purity 98.1%, specific activity 53 mCi/mmole), dissolved in acetonitrile, was added at a nominal concentration of 5 ppm to pH 5 (biphthalate), pH 7 (phosphate), and pH 9 (borate) sterile 0.1 M aqueous buffer solutions (p. 15). An additional test system was prepared using nonradiolabeled plus uniformly phenyl ring-labeled [^{14}C]diflufenzopyr (radiochemical purity 98.0%, specific activity 56 mCi/mmole) in pH 7 sterile aqueous buffer solution. An aliquot of each treated buffer solution was placed in amber glass containers which were wrapped with aluminum foil and maintained at 22 ± 1 °C to serve as dark controls. The remainder of each treated buffer solution was transferred to a glass photolysis dish equipped with a water cooling jacket to maintain the temperature at 22 ± 1 °C. The test vessel had outlets which were connected to a series of volatile traps containing silica gel, ethylene glycol and sodium hydroxide; air was drawn through the traps by means of a vacuum pump (Figure 1, p. 37). The photolysis dish was covered with a quartz glass plate and continuously irradiated for approximately 16 days with a 2500 watt xenon arc lamp; borosilicate glass was used to filter out light below 290 nm. The light intensity between 300 nm and 800 nm was measured at the initiation and termination of the incubation period. A comparison of the irradiance for the artificial light used to natural sunlight was presented in Figure 3 (p. 39). The average light intensity for the pyridinyl radiolabel was 8.55×10^2 W/m^2 at pH 5, 7.54×10^2 W/m^2 at pH 7, 8.87×10^2 W/m^2 at pH 9; and for the phenyl radiolabel was 8.42×10^2 W/m^2 at pH 7 (p. 15). The reported natural sunlight intensity in spring at 40°N latitude was 5.83×10^2 W/m^2 (p. 15). Aliquots of the irradiated and dark control test solutions were removed for analysis at 0, 21, 69, 141, 213, 309 and 380 or 381 hours posttreatment (pyridinyl label); and 0, 22, 70, 142, 214, 301, and 373 hours posttreatment (phenyl label).

At each sampling interval, duplicate aliquots of each solution were analyzed for total radioactivity by LSC (p. 15). Aliquots of irradiated and dark control solutions were each separated into aqueous and organic phases using a solid phase extraction column (SPE; C18) eluted with acetonitrile. The aqueous fractions were freeze dried, re-dissolved in methanol and analyzed by LSC. Extracts with greater than 10% of the applied radioactivity were analyzed by either one or two-dimensional TLC using silica gel plates (with fluorescent indicator) developed with numerous solvent systems (p. 16). Areas of radioactivity on the plates were located and quantified using radioimaging scanning. The organic fractions were rotary evaporated and analyzed by TLC as described previously.

Organic extracts were spotted alone or co-chromatographed with reference standards which were visualized by UV detection. To confirm compound identities, additional analysis was performed using reverse-phase HPLC (Phenomenex C18 column) with a mobile phase of acetonitrile:water with 1% acetic acid (50:50, v:v) and radioactive flow detection; samples were co-chromatographed with reference standards detected by UV.

DATA SUMMARY

Pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (SAN 835 H)

Nonradiolabeled plus pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (radiochemical purity 98.1%), at a nominal concentration of 5 ppm, degraded with an uncorrected half-life of 165 hours or 6.9 days (r^2 = 0.99, Figure 4, p. 40; Table 13, p. 36) in pH 5 aqueous buffer solution that was irradiated continuously with a xenon arc lamp while maintained at 22 ± 1°C for up to 381 hours or 15.9 days. The dark-control corrected half-life was 206 hours (8.6 days), while the adjusted net photolysis half-life was 302 hours (12.6 days). In contrast, in the dark control the parent compound degraded with a half-life of 825 hours or 34.4 days (r^2 = 0.94, Figure 4, p. 40; Table 13, p. 36). In the irradiated samples, the parent compound decreased from an initial 86.33% of the applied radioactivity to 54.18% by 141 hours posttreatment, and was 18.78% at 381 hours (Table 5, p. 28). In the dark control solution, the parent was initially present at 86.33% of the applied radioactivity and decreased to 64.62% by 381 hours posttreatment (Table 6, p. 29). The major degradate

2-acetylnicotinic acid (M6)

was initially present (0 hours) in irradiated samples at 1.16% of applied radioactivity, increased to 29.86% by 141 hours posttreatment and was 57.97% at 381 hours posttreatment. The major degradate

6-((3,5-difluorophenyl-carbamoyl)-8-methyl)-pyrido (2,3-d)-5-pyridazinone (M5)

was initially present (0 hours) at 11.59% of applied radioactivity, decreased to 7.06% by 21 hours, then increased to a maximum of 15.19% by 69 hours posttreatment and was 3.22% of the applied at 381 hours posttreatment. The major degradate

M24 (name not specified; structure presented in Table 3, p. 25)

was initially present at 0.50% of applied radioactivity, increased to 5.10% by 141 hours posttreatment and was 10.05% at 381 hours posttreatment. The minor degradate M23 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 9.53-9.61% at 213-309 hours posttreatment and was 8.99% at 381 hours posttreatment. The minor degradate 8-methyl-5(6H)-pyrido[2,3-d]pyridazinone (M1) ranged from 0.74%

to 2.25% of applied radioactivity from 0 hours to 381 hours posttreatment. In contrast, M1 was present as a major degradate in the dark control solution at 20.06% of applied radioactivity at 381 hours posttreatment. In addition, M5 and M6 were present as major degradates in the dark control solution, and M23 and M24 were present as minor degradates. One degradate present in the irradiated solution, M25, was not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

Material balances for the irradiated solutions ranged from 101.16% to 105.34% of applied radioactivity.

Nonradiolabeled plus pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (radiochemical purity 98.1%), at a nominal concentration of 5 ppm, degraded with an uncorrected half-life of 405 hours (16.9 days) ($r^2 = 0.93$, Figure 5, p. 41; Table 13, p. 36) in pH 7 aqueous buffer solution that was irradiated continuously with a xenon arc lamp while maintained at 22 ± 1°C for up to 380 hours or 15.9 days. The dark-control corrected half-life was 1004 hours (41.8 days), while the adjusted net photolysis rate was 1299 hours (54.1 days). In contrast, in the dark control the parent compound degraded with a registrant-calculated half-life of 679 hours or 28.3 days ($r^2 = 0.89$, Figure 5, p. 41; Table 13, p. 36). The parent compound in the irradiated solution decreased from an initial 95.79% of the applied radioactivity to 59.30% by 213 hours posttreatment and was 44.54% at 380 hours (Table 7, p. 30). The parent in the dark control solution was initially present at 95.79% of the applied radioactivity, decreased to 76.34% by 69 hours posttreatment and was 61.80% at 380 hours posttreatment (Table 8, p. 31). The major degradate

2-acetylnicotinic acid (M6)

was initially present in irradiated samples at 1.10% of applied radioactivity at 21 hours posttreatment, increased to 11.09% by 213 hours posttreatment and was 16.53% at 381 hours posttreatment. The major degradate

M24 (name not specified; structure presented in Table 3, p. 25)

was initially present (0 hours) at 0.21% of applied radioactivity, increased to 5.33% by 69 hours posttreatment and was 11.53% at 380 hours posttreatment (Table 7, p. 30). The major degradate

6-((3,5-difluorophenyl-carbamoyl)-8-methyl)-pyrido (2,3-d)-5-pyridazinone (M5)

was initially present (0 hours) at 6.25% of applied radioactivity, increased to a maximum of 10.80% by 21 hours posttreatment, decreased to 3.73% of applied radioactivity by 309 hours posttreatment, and then increased to 8.52% by 380 hours posttreatment. The minor degradate M27 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 9.24% of applied radioactivity at 309 hours and was 5.05% at 380 hours

posttreatment. The minor degradate 8-methyl-5(6H)-pyrido[2,3-d]pyridazinone (M1) was present at a maximum of 3.88% of applied radioactivity at 21 hours posttreatment and decreased to 1.12% by 380 hours posttreatment. The minor degradate M25 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 1.79% of applied radioactivity at 380 hours posttreatment. The minor degradate M26 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 1.23% of applied radioactivity at 309 hours posttreatment. The minor degradate M23 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 1.68% of applied radioactivity at 380 hours posttreatment. In contrast, in the dark control solution M1 was present as a major degradate at 30.82% of applied radioactivity at 380 hours posttreatment. In addition M5, M6, M23 and M24 were present as minor degradates in the dark control solution. Two degradates present in the irradiated solution, M25 and M26, were not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

Material balances for the irradiated solutions ranged from 99.98% to 107.46% of applied radioactivity (Table 7, p. 30).

Nonradiolabeled plus pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr (radiochemical purity 98.1%), at a nominal concentration of 5 ppm, degraded with an uncorrected half-life of 322 hours or 13.4 days ($r^2 = 0.98$, Figure 6, p. 42; Table 13, p. 36) in pH 9 aqueous buffer solution that was irradiated continuously with a xenon arc lamp while maintained at 22 ± 1 °C for up to 381 hours or 15.9 days. The dark-control corrected half-life was 729 hours or 30.4 days, while the adjusted net photolysis rate was 1110 hours or 46.2 days. In contrast, in the dark control solution the parent compound degraded with a half-life of 578 hours or 24.1 days ($r^2 = 0.93$, Figure 6, p. 42; Table 13, p. 36). The parent compound in the irradiated solution decreased from an initial 89.65% of the applied radioactivity to 55.95% by 213 hours posttreatment and was 37.61% at 381 hours (Table 9, p. 32). The parent in the dark control solution was initially present at 89.65% of the applied radioactivity, decreased to 72.20% by 141 hours posttreatment and was 57.41% at 381 hours posttreatment (Table 10, p. 33). The major degradate

M27 (name not specified; structure presented in Table 3, p. 25)

was present in irradiated samples at 7.49% of applied radioactivity at 69 hours posttreatment, increased to 11.40% by 141 hours posttreatment and was a maximum of 15.11% at 381 hours posttreatment (Table 9, p. 32). The major degradate

M26 (name not specified; structure presented in Table 3, p. 25)

was present at 0.47% of applied radioactivity at 69 hours posttreatment, increased to 9.72% by 213 hours posttreatment and was a maximum of 14.25% at 381 hours posttreatment (Table 9, p. 32). The major degradate

6-((3,5-difluorophenyl-carbamoyl)-8-methyl)-pyrido (2,3-d)-5-pyridazinone (M5)

was initially present at 12.30% at 0 hours posttreatment, and was present at 7.59%-11.69% from 21 to 381 hours posttreatment with the exception of 3.40% at 309 hours posttreatment. The minor degradate M25 (name not specified; structure presented in Table 3, p. 25) was a maximum of 8.34% of the applied radioactivity at 381 hours posttreatment. The minor degradate 2-acetylnicotinic acid (M6) was present initially at 1.04% of applied radioactivity, increased to 3.61% by 69 hours posttreatment and a maximum of 7.38% by 141 hours, and was 7.05% at 381 hours posttreatment. The minor degradate 8-methyl-5(6H)-pyrido[2,3-d]pyridazinone (M1) was present at a maximum of 3.04% of the applied radioactivity at 21 hours posttreatment. The minor degradate M24 (name not specified; structure presented in Table 3, p. 25) was present at a maximum of 0.63% of applied radioactivity at 69 hours posttreatment. The minor degradate M23 (name not specified; structure presented in Table 3, p. 25) was present at 0.19% of applied radioactivity at 381 hours posttreatment and was not detected at any other sampling interval. In contrast, M1 was present as a major degradate in the dark control solution at 30.82% of applied radioactivity at 381 hours posttreatment. In addition, M5 was present as a major degradate in the dark control solution, and M24 was present as a minor degradate. Four degradates present in the irradiated solution, M6, M25, M26 and M27, were not detected in the dark control solution. Radiolabeled [^{14}C]volatiles were negligible.

Material balances for the irradiated solutions ranged from 102.37% to 107.42% of applied radioactivity (Table 9, p. 32).

Uniformly phenyl ring-labeled [^{14}C]diflufenzopyr (SAN 835 H)

Nonradiolabeled plus uniformly phenyl ring-labeled [^{14}C]diflufenzopyr (radiochemical purity 98.0%), at a nominal concentration of 5 ppm, degraded with an undetermined half-life in pH 7 aqueous buffer solution that was irradiated continuously with a xenon arc lamp while maintained at 22 ± 1 °C for up to 373 hours. The parent compound was present in irradiated samples at 96.62%-98.64% of the applied radioactivity from 0 to 22 hours posttreatment, ranged from 81.78% to 91.24% of the applied radioactivity from 70 hours to 301 hours posttreatment and was 75.77% at 373 hours (15.5 days) posttreatment (Table 11, p. 34). In contrast, in the dark control solution the parent was present at 89.53%-96.62% of the applied from 0 hours to 373 hours posttreatment (Table 12, p. 35). In the irradiated solution, the minor degradate 6-((3,5-difluorophenyl-carbamoyl)-8-methyl)-pyrido (2,3-d)-5-pyridazinone (M5) ranged from 5.11% to 8.25% of the applied radioactivity from 0 hours to 373 hours posttreatment; in the dark control, M5 was present at 4.36%-7.48% of the applied radioactivity. Radiolabeled $^{14}CO_2$ was present at 1.11% following 373 hours of incubation; [^{14}C]organic volatiles were negligible.

Material balances in the irradiated solutions ranged from 97.00% to 104.53% of applied radioactivity (Table 11, p. 34).

COMMENTS

1. In the pyridinyl-labeled study at pH 5, the dark control half-life is 3 times the hydrolysis half-life at the same pH.

2. The data were variable for the phenyl ring-labeled parent compound in irradiated and dark control pH 7 aqueous buffer solutions. In the irradiated solution, the parent compound was present at 96.62%-98.64% of the applied at 0-22 hours posttreatment, decreased to 83.67% by 142 hours, then increased to 90.14% by 214 hours and decreased to 75.77% by 373 hours. In the dark control solution, the parent compound was present at 96.62%-97.26% of the applied radioactivity at 0-70 hours posttreatment, decreased to 91.57%-91.90% by 142-214 hours, then increased to 96.97% by 301 hours, and was 89.53% at 373 hours. Additionally, the aqueous photolysis studies of pyridinyl ring-labeled [4,6-^{14}C]diflufenzopyr and uniformly phenyl ring-labeled [^{14}C]diflufenzopyr at pH 7 should provide similar results regarding the degradation rate of the parent compound (for both the irradiated and dark control solutions); however, the data presented in Tables 7, 8, 11 and 12 indicated different degradation rates for the two radiolabels. In the pyridinyl label study, only 44.54% and 61.80% of the applied radioactivity remained as parent compound in the irradiated and dark control solutions, respectively, at the end of the incubation period (380 hours; Tables 7, 8; pp. 30, 31). The study author needs to explain the discrepancy between the degradation rates observed for the two different labeled studies at pH 7.

3. A single test vessel was used for the duration of each study from which duplicate sample aliquots were removed for analysis at each sampling interval. The use of a single treated solution is generally not considered to be good laboratory practice. EFED recommends that, at a minimum, duplicate sampling (removed from individual, duplicate test vessels at each sampling interval) be used for the determination of a half-life.

4. The incubation temperature was 22 ± 1 °C rather than at 25 ± 1 °C. Subdivision N Guidelines require that the experimental temperature be held at 25 ± 1 °C.

5. The photodegradation of phenyl ring-labeled diflufenzopyr was studied only at pH 7. Additional studies at pH 5 and 9 should be conducted with compounds which reversibly ionize between pH 5 and 9. Studies with pyridinyl ring-labeled parent, though, were studied at all three pH's.

6. It could not be determined whether the solutions used in the study were sterile. Tests to confirm the sterility of the treated and dark control solutions throughout the incubation

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