

US EPA ARCHIVE DOCUMENT

Degradation - Photodegradation on Soil

CONCLUSIONS

This study provides useful information on the photolytic degradation of diflufenzopyr on sandy loam soil. However, this study can not be used to fulfill the guideline requirements at this time because data (particularly material balance data) for the phenyl label study were reported from two separate studies conducted independently of each other. This study can be upgraded to acceptable if quantitative results from all sampling intervals are provided and acceptable under Subdivision N Guidelines.

ABSTRACT

The phototransformation of [phenyl-UL-¹⁴C]-labeled and [pyridinyl-4,6-¹⁴C]-labeled diflufenzopyr was studied on sandy loam soil. The treated samples were irradiated by continuous irradiation using a filtered xenon arc lamp with an average intensity of 514-517 W/m² (300-800 nm) which was comparable to spring sunlight at 40°N latitude (583 W/m²). Test vessels were connected to traps for the collection of CO₂ and organic volatiles. Samples were incubated for 15 days (phenyl label) and 18 days (pyridine label). Dark controls were incubated under similar conditions without light for up to 15-18 days. All samples were analyzed for total radioactivity using LSC and for parent compound (BAS 654 H) and its degradates by reverse-phase HPLC; compound identifications were confirmed by LC/MS and GC/MS.

[Phenyl-UL-¹⁴C]-labeled and [pyridinyl-4,6-¹⁴C]-labeled diflufenzopyr degraded with registrant-calculated half-lives of 11 days ($r^2 = 0.95$) and 8 days ($r^2 = 0.97$), respectively, on irradiated soil. [Phenyl-UL-¹⁴C]diflufenzopyr comprised 34.9% of the applied radioactivity in soil extracts after 15 days and [pyridinyl-4,6-¹⁴C]diflufenzopyr comprised 12.0-25.6% after 18 days. In the dark controls, [phenyl-UL-¹⁴C]-labeled and [pyridinyl-4,6-¹⁴C]-labeled diflufenzopyr degraded with half-lives of 28 days ($r^2 = 0.94$) and 12 days ($r^2 = 0.91$), respectively. [Phenyl-UL-¹⁴C]diflufenzopyr comprised 65.0% of the applied radioactivity in soil extracts after 15 days and [pyridinyl-4,6-¹⁴C]diflufenzopyr comprised 31.8% after 18 days.

Two major degradates, 2-acetyl nicotinic acid (M6; pyridine label) and 8-methyl-5-hydroxy-pyrido(2,3-d)-pyridazinone (M1; pyridine label), and five minor degradates, 3,5-difluorophenyl urea (M4; phenyl label), 3,5-difluoroaniline (M2; phenyl label), carbamoyl phthalazinone (M5; both labels), 8-hydroxymethyl-5(6H)-pyrido[2,3-d]pyridazinone (M10; pyridine label) and 8-methylpyrido(2,3-d)pyridazine-2,5(1H,6H)-dione (M9; pyridine label), were identified in irradiated and dark control soil extracts. Two additional compounds, M23 (both labels) and PH3 (phenyl label), were tentatively identified. In extracts from irradiated soil, M6 was detected at a maximum concentration of 38.7% (18 days) of the applied radioactivity, M1 at 10.3% (7 days), M2 at 6.2% (15 days) and M4 + PH3 at 6.5% (15 days). M5, M9, M10 and M23 were each detected at ≤5.1% of the applied. In extracts from dark control soil, M1 was detected at a maximum

28.9% (13 days) of the applied radioactivity and M6 at 9.6% (4 days); M2, M4 + PH3, M5, M9 and M23 were each detected at $\leq 3.0\%$ of the applied. In irradiated and dark control soil extracts, numerous (10-12) unidentified [^{14}C]compounds were each detected at $< 3.2\%$ of the applied.

At 15-18 days posttreatment, $^{14}\text{CO}_2$ totaled 2.0-6.9% of the applied radioactivity for irradiated soils and 1.0-2.4% for dark control soils. Unextractable [^{14}C]residues were 23.9-36.0% of the applied radioactivity at 15-18 days; humic acid, fulvic acid, and humin fractions comprised 0.4-0.8%, 7.6-15.2%, and 11.0-20.1% of the applied, respectively. For [phenyl-UL- ^{14}C]diflufenzopyr-treated irradiated soil, material balances were 99.2-104.2% of the applied from 0-10 days posttreatment and 90.2% of applied at 15 days. For the dark controls, material balances were 102.8-107.5% of the applied with no observed pattern of decline. For [pyridinyl-4,6- ^{14}C]diflufenzopyr-treated soils (irradiated and dark control), material balances were 100.8-106.7% of the applied from 0-13 days posttreatment and were 95.8-101.9% of applied at 18 days.

MATERIALS AND METHODS

[Phenyl-UL- ^{14}C]diflufenzopyr

Samples (10 g, p. 72) of sieved (2 mm) sandy loam soil (69% sand, 22% silt, 9% clay, 1.5% organic matter, pH 7.2, CEC 884.7 meq/100 g; Table 2, p. 30), from Madison County, Illinois, were weighed into eight steel trays (irradiated samples; 8.5 x 4 x 1.1 cm, L x W x D) and four glass petri dishes (dark controls) and moistened to 75% of 0.33 bar (pp. 13, 15). The resulting soil layers (thickness ~ 2 mm) were surface-treated drop-wise with [phenyl-UL- ^{14}C]diflufenzopyr (BAS 654 H) [2(methyl-(((3,5-difluorophenylamine)-carbonyl)-hydrazone)-methyl)-3-pyridine carboxylic acid, radiochemical purity 96.2%, specific activity 255,137 dpm/ μg , Lot No. 980921, Inventory No. 278; pp. 11, 14, 29, 37, 75), in Trizma buffer (pH 7), at a nominal application rate of 1.05 ppm; actual applied dose was 1.18 ppm (pp. 15, 16). For time 0 samples, additional soil was weighed directly into duplicate centrifuge tubes and similarly treated. The steel trays were inserted into a larger jacketed steel tray, sealed with a quartz glass plate, and continuously irradiated using a xenon arc lamp equipped with a UV filter to eliminate radiation below 290 nm (Atlas Suntest CPS Plus system; pp. 12-13; Figure 6, p. 42). The light intensity (300-800 nm) of the xenon lamp was measured using a spectroradiometer (LI-COR LI-1800) at an average light intensity of 514 W/m^2 (300-800 nm) and determined to be comparable to natural sunlight intensity (583 W/m^2) in spring at 40°N latitude (pp. 12-13). Spectral distributions of the xenon lamp and natural sunlight (40°N latitude) were comparable (Figures 4-5, pp. 40-41). The irradiated samples were maintained at $22 \pm 1^\circ\text{C}$ by circulating coolant through the base of the jacketed steel tray; a temperature probe was inserted in an additional tray containing untreated soil for temperature monitoring. The jacketed steel tray was equipped with inlet/outlet ports to allow for the collection of volatiles; humidified, filtered (0.2 μm), CO_2 -free air was continuously drawn (flow rate not specified) through the chamber, then sequentially through traps containing ethylene glycol, 0.1 N sulfuric acid and 1 N sodium hydroxide. The treated dark control samples

were placed in a mini glass tower, then maintained in darkness at $22 \pm 1^\circ\text{C}$ in an incubator (p. 13). Irradiated and dark control samples were removed for analysis at 71, 188, 243, and 356 hours posttreatment (pp. 17, 124). Trapping solutions from the irradiated samples were changed at each sampling interval (p. 16). Prior to removal of the dark controls at each sampling interval, inlet/outlet ports on the glass tower were attached to a volatiles collection system; for approximately 1 hour, ambient, CO_2 -free air was purged (flow rate not specified) through the tower, then through the same sequence of trapping solutions as the irradiated samples (pp. 13, 16). During the study, the soil moisture content was maintained at 75% of 0.33 bar with the addition of water as needed. A microbial analysis of the sandy loam test soil was conducted one month prior to study initiation; results indicate that the soil was viable (3.82×10^6 CFU/g soil dry wt. bacteria, 1.14×10^4 CFU/g soil dry wt. fungi and 7.18×10^6 CFU/g soil dry wt. actinomycetes; Appendix 1, p. 68).

Soil samples were extracted by shaking twice with ethyl acetate:acetone (2:1, v:v) followed by three times with Trizma buffer (pH 7):acetone (3:1, v:v) and centrifuged (p. 18; Figure 8, p. 44). Respective extracts were combined and triplicate aliquots (100 μL) analyzed for total radioactivity by LSC. An aliquot (15 mL) of the ethyl acetate:acetone extract was concentrated under a stream of nitrogen and an aliquot (30 mL) of the buffer:acetone extract was concentrated by rotary evaporation (temperature not specified). Each concentrated extract was reconstituted in DMSO (100 μL) and aliquots were analyzed for total radioactivity by LSC and for specific compounds by reverse-phase HPLC using the following conditions:

Column	YMC ODS AQ, 250 mm x 4.6 mm i.d., 5 μm particle size
Mobile phase	A = water:acetonitrile:TFA (98:2:0, v:v:v) B = acetonitrile
Gradient	initial; isocratic A:B (2:98, v:v) 0-15 minutes; linear to A:B (40:60) 15-24 minutes linear to A:B (80:20) 24-28 minutes isocratic A:B (80:20) 28:30 minutes linear to A:B (2:98)
Flow rate	1 mL/minute
Detection	UV; wavelength not specified Radioactivity; Packard Flo-One
Reference standards Diflufenzopyr (BAS 654 H)	Retention time (pp. 37-39) 23.4-24.1 minutes

Samples were co-chromatographed with unlabeled reference standards of parent diflufenzopyr plus eight possible degradates (p. 19; Table 1, p. 29).

Unextractable [^{14}C]residues remaining in the extracted soil samples were quantified by LSC following combustion (p. 18). To characterize unextractable [^{14}C]residues in the soil

(final sampling interval only), extracted soil samples were further extracted twice with 0.1 N sodium hydroxide with shaking for ~24 hours for the first extraction and 45 minutes for the second; extracts were separated from soil by centrifugation (p. 21; Figure 24, p. 60). Sodium hydroxide extracts were combined and acidified to pH 1 with concentrated hydrochloric acid. The resulting precipitate (humic acid) was removed by centrifugation, re-dissolved in 0.5 N sodium hydroxide and analyzed by LSC. The remaining extract (fulvic acid) was partitioned with ethyl acetate; resulting organic and aqueous phases were analyzed by LSC. The remaining organic phase was concentrated under nitrogen, then the residue was re-dissolved in DMSO:acetone (1:9, v:v) and analyzed by HPLC as described above. [¹⁴C]Residues remaining in the extracted soil (humin) were quantified by LSC following combustion.

Aliquots (1 mL) of each trapping solution were analyzed for total radioactivity by LSC (p. 17). To quantify ¹⁴CO₂, an aliquot (~6 mL) of the sodium hydroxide trapping solution was reacted with 5 N sulphuric acid, then released ¹⁴CO₂ was trapped in Harvey cocktail solution and analyzed by LSC; the remaining neutralized NaOH and H₂SO₄ solutions were also analyzed by LSC (p. 17; Figure 7, p. 43).

Five additional samples (9.44 ± 0.09 g dry weight, p. 73) of sandy loam soil were treated with [phenyl-UL-¹⁴C]diflufenzopyr (described above, radiochemical purity 97.9%; pp. 14, 38) at 1.4 ppm (two time zero and three irradiated samples) because of low mass balance at the final sampling interval of the initial study (~88% of applied radioactivity, p. 13); and five soil samples were treated with [phenyl-UL-¹⁴C]diflufenzopyr plus unlabeled diflufenzopyr (purity 98.8%, Lot No. RS-835-101096; pp. 14, 38) at 19 ppm as high dose samples (all irradiated) for further degradate identification; no dark controls were prepared (p. 16). The treated soil samples were irradiated as described above. The 14 ppm-treated samples were removed for analysis after 353 hours of irradiation and the 19 ppm-treated samples were removed for analysis after 99, 166 and 353 hours of irradiation (p. 17). Soil samples were extracted and analyzed as described above. For degradate identification, fractions containing isolated [¹⁴C]compounds were collected following HPLC (described above) of the ethyl acetate:acetone and Trizma buffer:acetone extracts; respective fractions were combined, further processed if necessary (phase partitioning, acidification), concentrated, and co-chromatographed with corresponding unlabeled reference standards (pp. 19-20). The identifications of [¹⁴C]compounds were confirmed by LC/MS or GC/MS (pp. 26-27).

[Pyridinyl-4,6-¹⁴C]diflufenzopyr

Samples (10 g, p. 99) of sandy loam soil were treated with [pyridinyl-4,6-¹⁴C]diflufenzopyr [radiochemical purity, 97.1%, 243,782 dpm/μg, Lot No. 980921, Inventory No. 279; pp. 11, 14, 39, 101) at 1.11 ppm and incubated under irradiated and dark control conditions as described above, except the intensity of the xenon lamp averaged 517 W/m² (pp. 12, 15). Irradiated and dark control samples were removed for analysis at 0, 96, 168, 309 and 428 hours posttreatment; soil samples and trapping solutions were analyzed by LSC and HPLC as described above (pp. 17, 18, 21, 125). Eight additional soil samples were treated with [pyridinyl-4,6-¹⁴C]diflufenzopyr plus

unlabeled diflufenzopyr (described above) at 24 ppm and as high dose samples for degradate identification. High dose samples were removed for analysis after 95, 258, 455 and 882 hours of irradiation (no dark controls); soil samples were analyzed by LSC, HPLC, LC/MS and GC/MS as described above (pp. 17, 20, 21).

RESULTS/DISCUSSION

[Phenyl-UL-¹⁴C]-labeled and [pyridinyl-4,6-¹⁴C]-labeled diflufenzopyr (BAS 654 H), at 1.1-1.4 ppm, degraded with registrant-calculated half-lives of 11 days ($r^2 = 0.95$) and 8 days ($r^2 = 0.97$), respectively, on sandy loam soil that was continuously irradiated using a filtered xenon arc lamp (average intensity 514-517 W/m² at 300-800 nm) at 22 ± 1°C and 75% of 0.33 bar moisture for 15-18 days (pp. 10-13; Table 7, p. 35; Appendix 7, pp. 154 and 156). The intensity of the xenon lamp was compared to spring sunlight at 40°N latitude (583 W/m²; Figures 4-5, pp. 40-41). In the dark control samples, [phenyl-UL-¹⁴C]-labeled and [pyridinyl-4,6-¹⁴C]-labeled diflufenzopyr degraded with half-lives of 28 days ($r^2 = 0.94$) and 12 days ($r^2 = 0.91$), respectively (Appendix 7, pp. 153 and 155).

[Phenyl-UL-¹⁴C]diflufenzopyr

In extracts from *irradiated soil*, [¹⁴C]diflufenzopyr averaged 94.3% of the applied at time 0, 68.1% at 70 hours (3 days) posttreatment, 59.8% at 188 hours (8 days), 52.4% at 243 hours (10 days), and 34.9% at 354 hours (15 days; Table 4, p. 32). The degradate M2 was detected at a maximum 6.2% of the applied at 15 days posttreatment, M4 + PH3 was 6.5% at 15 days, M23 was 3.7% at 8 days, and M5 was 3.4% at 3 days. Five unidentified [¹⁴C]compounds (PH1, PH2, PH4 and PH5 plus one) with HPLC retention times >16.0 minutes were each detected at ≤1.9% of the applied. Five additional unidentified [¹⁴C]compounds with HPLC retention times <16.0 minutes were each detected at ≤1.5% of the applied. At 15 days posttreatment, ¹⁴CO₂ totaled 6.9% of the applied radioactivity (Table 8, p. 36). Unextractable [¹⁴C]residues increased to 30.1% of the applied radioactivity at 15 days; humic acid, fulvic acid, and humin fractions comprised 0.6%, 8.8%, and 19.7% of the applied, respectively (Appendix 2, p. 88). Parent diflufenzopyr and M5 were detected in fulvic acid fraction extracts (p. 28; Figure 25, p. 61). Material balances ranged from 99.2-104.2% of the applied from time 0 to 10 days posttreatment, then were 90.2% of applied at 15 days posttreatment (Appendix 2, pp. 80-86).

In extracts from *dark control soil*, [¹⁴C]diflufenzopyr averaged 94.3% of the applied at time 0, 82.1% at 71 hours (3 days) posttreatment, 72.0% at 188 hours (8 days), 68.8% at 243 hours (10 days), and 65.1% at 356 hours (15 days, Table 4, p. 32). Degradates M4 + PH3, M2, M5 and M23 were each detected at ≤3.0% of the applied. Nine unidentified [¹⁴C]compounds (four RT >16.0 minutes, five RT <16.0 minutes) were each detected at ≤0.75% of the applied. Volatilized [¹⁴C]compounds totaled 1.0% of the applied at 15 days posttreatment (Table 8, p. 36). Unextractable [¹⁴C]residues increased to 36% of the applied radioactivity at 15 days; humic acid, fulvic acid, and humin fractions comprised for 0.8%, 15.2%, and 20.1% of the applied, respectively (Appendix 2, p. 94). Parent diflufenzopyr and M5 were detected in fulvic acid fraction extracts (Figure 25, p. 61).

Material balances ranged from 102.8-107.5% of the applied during the study with no observed pattern of decline (Appendix 2, pp. 80-81, 89-92).

[Pyridinyl-4,6-¹⁴C]diflufenzopyr

In extracts from *irradiated soil*, diflufenzopyr averaged 92.1% of the applied at time 0, 70.5% at 95.9 hours (4 days) posttreatment, 54.7% at 168 hours (7 days), 37.9% at 309 hours (13 days), and 18.8% at 428 hours (18 days; Table 5, p. 33). The degradates M6 and M23 were detected at maximum concentrations of 38.7% and 5.1% of the applied, respectively, at 18 days posttreatment. The cocentration of M1, detected at a maximum of 10.3% of the applied at 7 days, decreased to 5.1% at 15 days. M5, M9 and M10 were each detected at ≤1.9% of the applied. Eight unidentified [¹⁴C]compounds with HPLC retention times >15.0 minutes (including PY1 and PY2) were each detected at ≤3.1% of the applied. Four additional unidentified [¹⁴C]compounds with HPLC retention times <15.0 minutes were each detected at ≤1.5% of the applied. ¹⁴CO₂ totaled 2.0% of the applied at 18 days posttreatment (Table 8, p. 36). Unextractable [¹⁴C]residues increased to 23.1-24.6% of the applied; in one replicate humic acid, fulvic acid, and humin fractions comprised for 0.4%, 9.9%, and 11.0% of the applied, respectively (Appendix 3, pp. 109-111). Parent diflufenzopyr, M1, M5 and M6 were detected in fulvic acid fraction extracts (p. 28; Figure 27, p. 63). Material balances were 100.8-106.4% of the applied from time 0 to 13 days posttreatment, and were 97.9-101.9% of applied at 18 days posttreatment (Appendix 3, pp. 103-110).

In extracts from *dark control soil*, diflufenzopyr averaged 92.1% of the applied at time 0, 62.9% at 95.9 hours (4 days) posttreatment, 44.5% at 168 hours (7 days), ~~37.6% at 309~~ 31.82% at 428.3 hours (18 days; Table 5, p. 33). M1 increased to a maximum 28.9% of the applied at 13 days posttreatment and was 26.3% at 18 days (Table 5, p. 33). M6 increased to 9.6% of the applied at 4 days, then decreased to 4.0% at 18 days. M5, M23 and M9 were each detected at ≤2.5% of the applied. Ten unidentified [¹⁴C]compounds (eight RT >15.0 minutes, two RT <15.0 minutes) were each detected at ≤1.0% of the applied. Volatilized [¹⁴C]compounds totaled 2.4% of the applied at 18 days posttreatment (Table 8, p. 36). Unextractable [¹⁴C]residues increased to 28.8% of applied at 13 days posttreatment and were 27.3% at 18 days; humic acid, fulvic acid, and humin fractions comprised 0.4%, 7.6%, and 18.3% of the applied, respectively, at 18 days (Appendix 3, pp. 103-104, 113-117). Parent diflufenzopyr, M1, M5 and M6 were detected in fulvic acid fraction extracts (Figure 26, p. 62). Material balances were 100.8-106.7% of the applied from time 0 to 13 days posttreatment and were 95.8% of applied at 18 days posttreatment (Appendix 3, pp. 103-104, 113-116).

COMMENTS

1. Due to low material balance at the last sampling interval (~88% of applied radioactivity, p. 13) in the phenyl label study, a second phenyl label study was conducted at the same application rate. However, complete results were not reported for either study. Data on the four samples analyzed at 356 hours in the initial study were not provided for review.

Instead, data from the second phenyl label study was substituted. All quantitative results from the degradation rate experiments need to be reported for review. This study can be upgraded to fulfill the guideline requirement if complete data sets are provided and are acceptable under Subdivision N Guidelines.

2. Duplicate samples were not prepared and analyzed at all sampling intervals for irradiated soil. Single samples were analyzed at all intervals for the dark controls (Appendix 4, pp. 124, 125). The use of single test samples is generally not considered good laboratory practice; at a minimum, duplicate samples should be used at all sampling intervals.
3. Reportedly ten soil samples were treated for the second phenyl label experiment. Five samples were treated at 1.4 ppm (two time 0 controls, three irradiated samples) and five treated at 19 ppm (high dose irradiated samples); however, only nine soil weights were recorded (Appendix 2, p. 73).
4. The study author reported that degradate M23 was positively identified (p. 11); the information provided indicate that only a tentative identification was achieved. Chromatograms from HPLC (Figures 12 and 19, pp. 48 and 55, respectively) and MS (pp. 131-132, 138-140) analyses of isolated M23 were provided. M23 isolated from phenyl label- and pyridine label-treated soil extracts co-chromatographed during HPLC indicating that M23 was the same compound produced from both labels; however, M23 was not compared to any reference standard. A chemical structure for M23 was provided based on the MS analysis (pp. 26-27); a chemical name was not provided.
5. A chemical structure for degradate ~~PH3~~ was also proposed based on MS analysis (pp. 26-27); a chemical name was not provided. The study author noted that degradate PY2 had an HPLC retention time similar to PH3 and may possibly be the same compound (p. 11). In phenyl label-treated soil extracts, PH3 co-chromatographed with M4 (retention time ~18.6-21.0 minutes; Table 4, p. 32). In pyridine label-treated soil extracts, PY2 eluted over ~18.6-21.0 minutes (Table 5, p. 33).
6. Soil samples were extracted within one day of sampling and extracts analyzed within 4 days of extraction; storage conditions during that time were not reported (Appendix 4, pp. 124-125). High dose samples were stored frozen (temperature unspecified) for unspecified length of time prior to extraction and analysis (p. 17).
7. Almost all volatilized radioactivity was recovered in the sodium hydroxide trapping solutions (Appendix 2, pp. 82-86, 89-92; Appendix 3, pp. 105-110, 113-116). The study author reported that essentially all of the volatilized radioactivity was identified as $^{14}\text{CO}_2$; however, supporting results were not provided.
8. The study author reported that the average light intensity of the xenon lamp was measured at 514 and 517 Watts/m² for the phenyl ring- and pyridine ring-labeled studies, respectively (p. 12). The study author did not specify over what interval the light intensities were averaged. In addition, the actual ranges of measured light intensity should be provided for review.

9. The distance from the light source to the soil surface was not reported. Also not specified was the distance from the light source at which intensity measurements were taken.
10. The HPLC column used for sample analysis was reported as a Columbus C18 (250 mm x 4.6 mm, 5 μ m) under section III. Materials, E. Equipment (p. 12), but as a YMC ODS AQ (250 mm x 4.6 mm, 5 μ m) under section V. Analytical Methods, B. Quantitation and Identification of Radioactive Residues in Soil (p. 18).
11. The wavelength used to detect unlabeled compounds during HPLC analysis was not specified.
12. Limits of detection and quantitation for the analytical methods (LSC, HPLC, LC/MS, GC/MS) used in this study were not reported.
13. The study author calculated the degradation half-life of [phenyl-UL-¹⁴C]diflufenzopyr in the dark control soil samples using intervals of 0, 70.71, 187.96, 242.76 and 353.45 hours (Appendix 7, p. 153), when the final sampling interval was actually 356.13 hours (Table 4, p. 32; Appendix 4, p. 124). Using 356.13 hours as the final sampling interval yields a degradation half-life of 671.64 hours (28.0 days, $r^2 = 0.969$).
14. A proposed scheme for the degradation of diflufenzopyr on irradiated soil is presented in Figure 28 (p. 64).
15. The study author stated that the nominal application rate of 1.05 ppm selected for this study corresponded to the maximum recommended field rate of 0.14 lb a.i/A (p. 15).
16. Good Laboratory Practice (GLP) Compliance and Quality Assurance Statements were provided with the study.

ATTACHMENT 1
Data Critical to the Study Interpretation

THE FOLLOWING ATTACHMENT IS NOT AVAILABLE ELECTRONICALLY
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Page ___ is not included in this copy.

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The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product inert impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
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- The product confidential statement of formula.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

ATTACHMENT 2
Excel Worksheet

