

DATA EVALUATION RECORD

STUDY 17

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|--------------------------------------|------------|--------|
| CHEM 122990 | Mesotrione | §164-1 |
| CAS No. 104206-82-8 | | |
| FORMULATION--15--SOLUBLE CONCENTRATE | | |

STUDY ID 44505205

Graham, D. G., D. J. Elvira, and L. A. Wiebe. 1997. ZA1296: Residue levels after treatment of bare soil - Illinois, 1995-1996. Study No.: 1296-95-SD-01. Report No.: RR 96-016B. Unpublished study performed by ZENECA Inc., Richmond, CA; and submitted by ZENECA Inc., Wilmington, DE.

STUDY ID 44505126

Alferness, P. L. 1997. ZA1296: Liquid chromatographic determination with fluorescence detection of ZA1296, 4-methylsulfonyl-2-nitrobenzoic acid and 2-amino-4-methylsulfonyl-benzoic acid in soil (addendum to TMR0661B). Report No.: TMR0661B (ADD). Unpublished study performed by ZENECA Inc., Richmond, CA; and submitted by ZENECA Inc., Wilmington, DE.

STUDY ID 44505127

Nagra, B. S. and S. J. Crook. 1997. Independent laboratory confirmation of an analytical method for liquid chromatographic determination with fluorescence detection of ZA1296, 4-methylsulfonyl-2-nitrobenzoic acid and 2-amino-4-methylsulfonyl-benzoic acid in soil. Report No.: 97JH279. Unpublished study performed by ZENECA Ltd., Bracknell, Berkshire, UK; and submitted by ZENECA Inc., Wilmington, DE.

STUDY ID 44505210

Lalko, M. and S. Szuter. 1997. Independent laboratory method validation of 2-(4-methylsulfonyl-2-nitrobenzoyl)-1,3-cyclohexanedione (ZA1296), 4-methylsulfonyl-2-nitrobenzoic acid (MNBA) and 2-amino-4-methylsulfonyl-benzoic acid (AMBA) in soil by HPLC. McKenzie Laboratory Study No.: MK09-97. Report No.: RR 97-071B. Unpublished study performed by McKenzie Laboratories, Inc., Phoenix, AZ; and submitted by ZENECA Inc., Wilmington, DE.

DIRECT REVIEW TIME = 98 Hours

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CONCLUSIONS

Field Dissipation - Terrestrial

1. This study did not adequately account for the field dissipation of mesotrione on a bare ground plot of silty clay loam soil in Illinois. It does, however, provide *supplemental* aspects which are consistent with the laboratory findings of a relatively short residency time for mesotrione in soil.

Although parent mesotrione "disappeared" fairly rapidly, 1) no degradates, including MNBA and AMBA which were found in laboratory studies, were detected at any sampling interval, and 2) mesotrione was not observed to leach. Furthermore, because there was no water balance during the study (or even pan evaporation data), it could not be determined if and when conditions were favorable for leaching and whether potential leached amounts of parent or degradates could have escaped detection by leaching below the maximum depth sampled during the time between sampling intervals and/or by insufficiently low detection limits in the sampled soil profile. Thus, this study presents an unresolved account of the terrestrial field dissipation of mesotrione.

2. In addition to the fundamental problems cited above, this study does not meet Subdivision N Guidelines for the partial fulfillment of EPA data requirements on terrestrial field dissipation for reasons given in the Comments section of this report. In brief, some of these reasons are the following:
 - (i) application rates were not verified;
 - (ii) the reported disappearance half-life of parent mesotrione was calculated incorrectly on a soil sample wet-weight basis;
 - (iii) samples were excessively composited, precluding a determination of variability among replicates.
 - (iv) the soil extraction method was most likely inadequate;
 - (v) detection limits (not reported) and limits of quantitation (reported) were probably inadequate for tracking parent and degradates in the soil profile;
 - (vii) storage stability data may have been inadequate for parent and degradates.

In spite of the many shortcomings in this and two other similarly conducted terrestrial field dissipation studies (MRIDs 44505206 and 4450207), taking all the environmental fate and ecotoxicological studies as a whole, there would be little value added to satisfactory performance of definitive dissipation studies. Therefore, *EFED is not*

requiring additional terrestrial field dissipation studies at this time. However, the registrant should consider the critical elements cited above and in the Comments section of this document, as these would almost always prohibit the acceptability of future study submissions and elicit requirements for new studies.

3. Mesotrione (ZA1296 4SC) broadcast applied twice (53-day interval), at nominal rates of 0.3 lb a.i./acre and 0.2 lb a.i./acre, disappeared with a registrant-calculated half-life of 9 days ($r^2 = 0.90$) following the second of two applications on a bare ground plot of silty clay loam soil in Illinois. However, the calculated half-life is subject to interpretation based on the limitations cited above and in the Comments section. Post-second application data (except day 0) represent single composite samples; replicate data were not obtained.

Following the *first application*, mesotrione was initially detected in the 0- to 6-inch depth at 0.096 mg/kg, decreased by approximately one-half to 0.047 mg/kg by 9 days posttreatment, and was last detected at 0.013 mg/kg at 24 days; the parent was not detected below the 0- to 6-inch depth. Following the *second application*, mesotrione was initially detected in the 0- to 6-inch depth at 0.070 mg/kg, decreased by approximately one-half to 0.034 mg/kg by 4 days posttreatment, and was last detected at 0.019 mg/kg at 15 days; the parent was not detected below the 0- to 6-inch depth. *The degradates AMBA and MNBA were not detected at any sampling interval or depth after either treatment.*

METHODOLOGY

Mesotrione (ZA1296 4SC) was broadcast applied twice (53-day interval) as a spray at nominal rates of 0.3 lb a.i./acre and 0.2 lb a.i./acre (total nominal application rate of 0.5 lb a.i./acre) onto one bare ground plot (120 x 75 ft with three 30 x 75 ft subplots, 0-2% slope, pp. 10, 12) of Drummer silty clay loam soil (12% sand, 51% silt, 37% clay, 3.6% organic matter, pH 6.3, CEC 24.3 meq/100 g soil; p. 11) near Champaign, Illinois. Applications were made using a tractor-mounted boom sprayer with nine nozzles (Appendix A, pp. 38, 39). After the first application, the pesticide was incorporated into the soil to a depth of ≤ 3 inches by rototilling. An untreated control plot (30 x 75 ft) was located 30 feet from the treated plot (Appendix A, p. 30). A three-year plot history indicated no prior use of mesotrione or related compounds (p. 12). The plot was treated once with atrazine (1.6 lb a.i./acre) and acetochlor (Surpass[®], 2.0 lb a.i./acre) one day prior to the first application and once with sethoxydion (Poast Plus[®], 0.19 lb a.i./acre) and copper oxychloride (COC[®] 1.0%) six weeks following the second application to maintain bare ground conditions (Appendix A, p. 40). The depth to the water table fluctuated seasonally and had a mean depth of six feet (p. 10). Precipitation was supplemented with irrigation; total water input (23.1 inches) was approximately 400% of the 30-year mean annual precipitation during the study period (Appendix A, p. 37). Environmental data were collected on-site (p. 11); pan evaporation data were not reported.

Soils samples from the treated and control plot were collected 1 day prior to treatment; at 0, 5, 9, 24, and 52 days following the first application (one day prior to the second application); and at 0, 4, 8, 15, 29, and 85 days following the second application (Appendix A, pp. 41-43). At each sampling interval, five soil cores were collected from transects extending diagonally across each treated subplot (15 soil cores total; Appendix A, p. 30; see Comment #5) and ten soil cores were collected from the control plot (p. 13). A three-phase sampling was performed using a tractor-mounted hydraulic probe with a butyrate liner to collect a 0- to 6-inch depth core (2-in i.d.), a 6- to 24-inch depth core (1.25-in i.d.) and a 24- to 42-inch depth core (1.25-in i.d.; Appendix A, pp. 31-34); soil cores collected immediately following the first application were only to a depth of 0- to 6-inches. Samples were shipped frozen to the analytical laboratory and stored frozen until processing (p. 14). Soil cores were sectioned into 6-inch increments and composited by depth and subplot; subsamples of each subplot composite were combined to make an aggregate composite for analysis (pp. 14-15; see Comment #4). Samples collected from the 36- to 42-inch depth were discarded. Field samples were stored frozen for 20-70 days except for two samples analyzed for mesotrione which were stored frozen for 323-351 days (p. 16; Appendix B, pp. 55-58).

Soil samples were analyzed for parent mesotrione (ZA1296) and the degradates 4-(methylsulfonyl)-2-nitrobenzoic acid (MNBA) and, 2-amino-4-(methylsulfonyl)-benzoic acid (AMBA). Subsamples (10 g) were extracted by shaking with 0.05 M ammonium hydroxide and centrifuged (p. 15; Appendix c, pp. 60-68). An aliquot of the extract was transferred to a centrifuge tube and the pH was adjusted to 3.5-4.0 with formic acid. The extract was shaken, centrifuged, and syringe filtered. The extract was analyzed for AMBA by reverse-phase HPLC (Phenomenex Prodigy C₁₈ column) using a mobile phase of (A) 6 mM ammonium acetate:formic acid (100:0.30, v:v):(B) acetonitrile:water (95:5, v:v); OR by reverse-phase HPLC (Keystone Prism RP column) using a mobile phase of (A) 50 mM ammonium acetate:formic acid (100:0.30):(B) acetonitrile:water (95:5, v:v) OR by reverse-phase HPLC (Phenomenex Ultracarb C₁₈ column) using a mobile phase of (A) water:formic acid (100:0.1):(B) acetonitrile:formic acid (95:5) with fluorescence (424 nm) detection. The mobile phase gradient for all systems was 100:0 to 30:70 to 5:95 to 0:100 (A:B, v:v; Attachment 1, p. 65). The limit of quantitation was 0.01 mg/kg (pp. 18, 19); the limit of detection was not reported. Individual fractions of the parent and degradate MNBA were collected. The parent and MNBA were converted to AMBA prior to HPLC analysis. To convert the parent to AMBA, the eluent was evaporated under nitrogen and reconstituted in 6% H₂O₂. Aliquots of catalase enzyme were added to the eluent until peroxide was no longer detected in the eluent; peroxide test strips were used to measure peroxide. Aliquots of 2 N HCl plus 60 mg/mL of SnCl₂ were added to the eluent. The solution was heated, cooled to room temperature, diluted with distilled water and applied to a C₁₈ solid phase extraction (SPE) column. The column was eluted with 0.2% formic acid in acetonitrile. The eluent was evaporated to dryness and reconstituted with 0.2% formic acid in water prior to analysis by HPLC as described previously. Chromatographs were compared to those of reference standards. To convert MNBA to

AMBA, the eluent fraction containing MNBA was diluted with distilled water, 2 N HCl plus 60 mg/mL SnCl₂ was added to the eluent fraction, and the eluent was heated then cooled; the eluent was diluted with an aliquot of distilled water. The eluent was cleaned by SPE and analyzed by HPLC as described previously. A confirmatory method of analysis was not performed.

The application rate was not confirmed using monitoring pads or a similar method. The concentration of the parent in soil immediately following the first and second applications (0.096 mg/kg and 0.070 mg/kg) was 62% and 84% of the expected, respectively, based on the nominal application rates (p. 18; Figures 1, 2; p. 25).

Mean concurrent recoveries (\pm C.V.) from control soil samples fortified with mesotrione (0.01-0.2 ppm), MNBA (0.01-0.05 ppm), and AMBA (0.01 ppm) were $91.5 \pm 10.7\%$, $95.7 \pm 9.4\%$, and $98.1 \pm 4.7\%$, respectively (p. 16; Table I, p. 21).

In a frozen storage stability study, soil samples were fortified separately at 0.1 mg/kg with mesotrione, MNBA, and AMBA and placed in frozen storage for up to 12 months (Table II, p. 22; see Comment #7). Reported recoveries are reviewer-calculated means of two replicates (see Comment #8). Mesotrione appeared to be relatively stable in frozen storage, but data were variable, precluding a definitive conclusion of stability; mean corrected recoveries of mesotrione were initially (day 0) 109.5%, were 153% following 1 month, and were 80-87% following 3 to 12 months of storage. The degradate MNBA may have been unstable in frozen storage following 6 months; mean corrected recoveries of MNBA were 87-91.5% following 0 to 6 months and were 77% following 12 months of storage. The degradate AMBA was not stable in frozen storage following 3 months; mean corrected recoveries of AMBA were 90.5-91.5% from 0 to 1 month, decreased to 82.5% following 3 months and 76% following 6 months, and were 64.5% following 12 months of storage.

Method Validation MRID 44505126

Soil samples (unidentified soil; soil characterization data not reported) were fortified with mesotrione, MNBA, or AMBA at 0.005-0.02 mg/kg, then extracted as described previously for the field study. Samples were analyzed by HPLC (Phenomenex Prodigy C₁₈ column) with a mobile phase gradient of (A) 9 mM ammonium acetate plus 0.25% formic acid in water:(B) acetonitrile:water (95:5, v:v; A:B, 93:7 to 55:45 to 10:90, v:v, for separation; 95:5 to 85:15 to 60:40 to 10:90, v:v; for analytical determination; p. 25). Mean recoveries (\pm C.V.) of mesotrione, MNBA, and AMBA were $92 \pm 9.7\%$, $98 \pm 8.1\%$, and $94 \pm 8.2\%$, respectively (Table I, pp. 43, 44).

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Independent Method Validation MRID 44505127

Samples of sieved (2 mm) sandy loam soil (from the U. K.; soil characterization data not reported) were fortified with mesotrione, AMBA or MNBA at 0.005 or 0.05 mg/kg, then extracted and analyzed as described previously in MRID 44505126 (pp. 6, 7). Mean recoveries (\pm C.V.) of mesotrione, MNBA and AMBA were $90 \pm 10\%$, $112 \pm 7\%$ (2 of 10 samples $>120\%$ recovery), and $89 \pm 9\%$, respectively (Tables 1-5, pp. 10-12).

Independent Method Validation MRID 44505210

Soil samples (unidentified soil; soil characterization data not reported) were fortified with mesotrione, MNBA or AMBA at 0.005 or 0.05 ppm, then extracted and analyzed as described previously in MRID 44505126 except using a Phenomenex Prodigy ODS-2 column (pp. 12, 13; Table II, p. 14). Mean recoveries (\pm standard deviation) of mesotrione were $108 \pm 8.8\%$ and $76 \pm 8.6\%$ (1 of 5 samples $<70\%$ recovery) for the 0.005 ppm and 0.05 ppm fortifications, respectively (Table III, p. 22). Mean recoveries (combined for both fortifications) of MNBA, and AMBA were $78 \pm 5.9\%$ and $82 \pm 5.9\%$, respectively (Tables IV-V, pp. 23, 25).

DATA SUMMARY

Mesotrione (ZA1296 4SC), broadcast applied twice (53-day interval) at nominal rates of 0.3 lb a.i./acre and 0.2 lb a.i./acre, dissipated with a registrant-calculated half-life of 9 days ($r^2 = 0.90$) following the second of two applications on a bare ground plot of silty clay loam soil in Illinois (Figure 2, p. 25). However, the interpretation and utility of this half-life is limited by numerous study deficiencies, including calculations based on a variable wet-weight basis (p. 17). Post-second application data (except day 0) represent single composite samples; replicate data were not obtained (see Comment #4).

Following the first application, mesotrione was initially detected in the 0- to 6-inch depth at 0.096 mg/kg, decreased to 0.047 mg/kg by 9 days posttreatment, and was last detected at 0.013 mg/kg at 24 days posttreatment (p. 8; Table III, p. 23); mesotrione was not detected below the 0- to 6-inch depth. The degradates AMBA and MNBA were not detected at any sampling interval or depth following the first application.

Following the second application, mesotrione was initially detected in the 0- to 6-inch depth at 0.070 mg/kg, decreased 0.034 mg/kg by 4 days and 0.028 by 8 days posttreatment, and was last detected at 0.019 mg/kg at 15 days posttreatment (p. 8; Table III, p. 24); mesotrione was not detected below the 0- to 6-inch depth. The degradates AMBA and MNBA were not detected at any sampling interval or depth following the second application.

COMMENTS

1. The study failed to adequately demonstrate the field dissipation of the test compound. Although the parent dissipated fairly rapidly, the degradates MNBA and AMBA were not detected at any sampling intervals and the parent was not observed to leach. MNBA was a major degradate (>10% of the applied radioactivity) detected at a maximum of 0.049 ppm in an aerobic soil (sandy loam) metabolism study (MRID 44505208); AMBA was a minor degradate. The reviewer noted that in an aerobic soil metabolism study of cyclohexanedione ring-labeled [2-¹⁴C]mesotrione (MRID 44373530), evolved ¹⁴CO₂ accounted for 2.1% of the applied radioactivity at 1 day, 38.9% by 15 days, and 82.6% at 180 days posttreatment.

It is further noted, however, that the analytical methods utilized in several of the submitted aerobic soil metabolism studies (e.g.: MRID 44373531) were considered to be inadequate for the determination of the parent and degradates, as unextracted residues were high and parts of the analytical method, as reported, were of questionable accuracy. (Also see Comment #13). It is likely that similar methodology problems hinder the interpretation of the dissipation of the parent in the current study; especially since there was but one extraction step and only with 0.05M NH₄OH in this study, whereas in numerous lab studies it was demonstrated with aged samples that more extraction steps combined with the use of organic solvents significantly increased yields of parent and degradates. The issue of adequacy of extraction will be discussed further in Comment #13 and in the EFED fate assessment of the new chemical review document for mesotrione.

2. The reported half-life was determined with data which were reported on a wet-weight basis (p. 17) and which were obtained from soil samples which were excessively composited prior to analysis (also see Comment #4). Because the moisture in the soil samples would not likely be constant over time, the resulting concentration data may not be validly compared over time, as a dilution or concentration effect may occur. Therefore, the data should be reported on a dry-weight basis (corrected for moisture content). The study authors stated that "measured moisture contents of 0-6-inch samples ranged from 18 to 22%" (p. 17). With these relatively small *differences* in soil moisture, the reviewer notes that failure to correct for moisture has only a minor effect on apparent final results.
3. Water balance data (or even pan evaporation data) were not provided. Such data are necessary to assess whether daily fluctuations in soil moisture were sufficient to facilitate leaching of the test substance. For interpretative purposes, these daily data should be plotted on the same graph as chemical dissipation data. Although total water input during the study period (23.1 inches) was approximately 400% of the 30-year mean annual precipitation, antecedent soil moisture conditions, soil hydraulic properties,

evapotranspiration, and the timing of water input (water input distribution) govern leaching potential.

4. Soil samples were excessively composited prior to analysis, precluding a determination of variability between replicates. At each sampling interval, five soil cores were collected from each of the three treated subplots (total of 15 cores) to a depth of 42 inches. Soil cores were sectioned into 6-inch increments and composited by depth and subplot (three composites per depth). At 0 and 5 days following the first application and immediately following the second application, each of the three composites was analyzed for the parent and degradates. For all other sampling intervals, the three composites were combined into a larger single composite for analysis (p. 14; Table III, p. 23). Subdivision N Guidelines require that a minimum of 15 soil cores with a minimum of three composites be analyzed in order to provide a measure of the statistical variability of the treated plots. Irrespective of Guidelines requirements/recommendations, it is scientifically appropriate to determine the size of the surface area to be sampled in relation to the number of samples and replications which are necessary to capture the inherent sample variability in all studies.
5. Samples were not collected randomly. Soil cores were collected from transects extending diagonally across the subplots in a systematic fashion (p. 30). The study authors stated that this sampling plan was designed to minimize variability between subplots at each sampling interval (p. 13). Although Subdivision N Guidelines require that soil cores be collected randomly in order to accurately represent variability in the test plots and to minimize variability among the data points, this reviewer agrees with the study authors, and believes that the judicious use of such transects tends to eliminate application artifacts and more efficiently captures sample variability.
6. The application rate was not verified by monitoring pads or, preferably, by collection of a sufficiently large number of large area surface soil samples (see also related Comment 5 above). Recoveries of the parent from soil were 62% and 84% of the expected immediately following the first and second application, respectively (p. 18; Appendix B, p. 47).
7. Frozen storage stability data may not have been adequate. It was unclear whether the soil samples utilized were from the test site; the reviewer noted that storage stability data were identical to data reported for terrestrial field dissipation studies conducted in Mississippi, and North Carolina (MRID's 44505206 and 44505207, respectively). Subdivision N Guidelines require that storage stability studies be conducted with samples from the test site which have been fortified separately with the parent compound and its degradates and stored for a duration equal to the longest interval for which the test compounds were stored. Clarification by the registrant is appropriate.

8. The study authors reported frozen storage stability data in Table II (p. 22); however, data were not corrected for concurrent recoveries. Therefore, the reviewer calculated corrected storage stability data by dividing individual storage stability recoveries by their respective concurrent recoveries. The reviewer reported mean corrected recoveries (reviewer-calculated) in the Data Summary section of this DER.
9. The total application rate utilized (0.5 lb a.i./acre) was stated to be the highest recommended label rate for multiple applications. This value compares with the currently proposed maximum total rate of 0.43 lb a.i./acre.
10. Limits of quantitation were reported, but detection limits were not. Both limits of detection and quantitation should be reported to allow the reviewer to evaluate the adequacy of the method for the determination of the test compound and its degradates at potentially very low concentrations deeper in the soil profile and at later sampling times.
11. The study authors stated that additional terrestrial field dissipation studies were conducted on bare ground plots in Mississippi and North Carolina (MRID's 44505206 and 44505207; p. 8).
12. The reviewer noted that the treated subplots were true replicate subplots separated by 15-ft buffer zones (Appendix A, p. 30).
13. Method validation data were presented in MRID's 44505126, 44505127, and 44505210; results indicated that the method was adequate for the determination of *freshly spiked* mesotrione, MNBA, and AMBA in soil. The reviewer notes, however, that in an extraction efficiency study (MRID 44505125) in which field samples were extracted one to three times, recoveries of the parent and AMBA were only 87% and 86%, respectively, of the amounts recovered from the soils following three extractions; recoveries of MNBA following one extraction were 101%. Additionally, method validation data included in the extraction efficiency study indicated that the analytical method utilizing three extractions still only resulted in a recovery of 82% of the applied from samples fortified with the parent; recoveries of MNBA and AMBA from separately fortified samples were 76% and 95% of the applied. In the current study, only a single extraction was utilized.

It is important in all environmental fate studies to determine whether extraction and analysis methods reasonably and efficiently distinguish between potentially bioavailable parent compound (and related degradates/metabolites) and those residues which become irreversibly and truly bound to the soil matrix and, therefore, unavailable to the biota. In numerous studies for mesotrione, variably high concentrations of unextracted soil residues, ostensibly intractably or permanently bound to soil, prompted the reviewer to compare the different soil extraction procedures used in various studies. A comparison of the soil extraction procedures indicates that some of them were less successful than others; therefore, these would have an effect on the interpretation of apparent half-lives

and availability of parent and/or degradates. As is stated in Comment #1, the issue of the adequacy of extraction will be discussed in greater detail in the EFED fate assessment of the new chemical review document for mesotrione.

Report Title

ZA1296: Residue Levels After Treatment of Bare Soil - Illinois, 1995-1996

Data Requirement

Guideline §164-1

Authors

D. G. Graham, D.J. Elvira, and L. A. Wiebe

Study Completion Date

June 26, 1997

Performing Laboratory

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Study Number

1296-95-SD-01
(Trial 04-IL-95-835)

Report Number

RR 96-016B

Page 1 of 81

12

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Report Title

ZA1296: Liquid Chromatographic Determination with Fluorescence Detection
of ZA1296, 4-methylsulfonyl-2-nitrobenzoic Acid and
2-amino-4-methylsulfonyl-benzoic Acid in Soil
(addendum to TMR0661B)
Guideline Requirement

160 Series

Author

P. L. Alferness

Study Completion Date

December 4, 1997

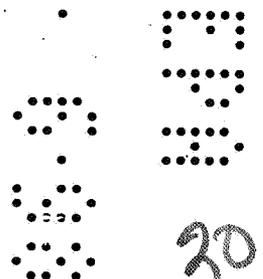
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TMR0661B (ADD)

1 of 75 Pages



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VOLUME 74 445051-27

Study Title

ZA1296 :
Independent Laboratory Confirmation of an Analytical Method for Liquid Chromatographic
Determination with Fluorescence Detection of ZA1296, 4-methylsulfonyl-2-nitrobenzoic acid and
2-amino-4-methylsulfonyl-benzoic acid in Soil.

Data Requirement

Guideline Ref. OPPTS 860.1340
160 Series

Authors

B S Nagra and S J Crook

Study Completed On

19 November 1997

Performing Laboratory

ZENECA AGROCHEMICALS (ZENECA LIMITED)

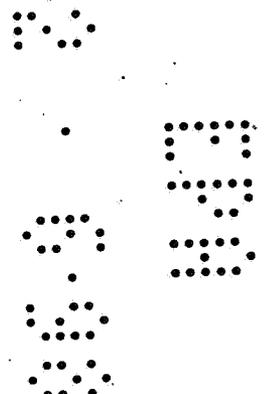
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Study Title

Independent Laboratory Method Validation of 2-(4-methylsulfonyl-2-nitrobenzoyl)-1,3-cyclohexanedione (ZA1296), 4-methylsulfonyl-2-nitrobenzoic Acid (MNBA) and 2-amino-4-methylsulfonyl-benzoic Acid (AMBA) in soil by HPLC.

Guideline Requirement

160 Series Supplemental

McKenzie Laboratories' Study Number

MK09-97

Study Director

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Analytical Completion Date

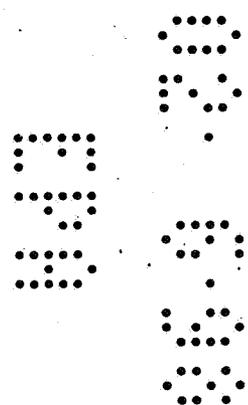
22 October 1997

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Report Number

RR-97-071B



M# 44505205, -126, -127 & -210

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Pages 36 through 40 are not included in this copy.

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.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

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.
